PUBLIC

COUNCIL OF THE EUROPEAN UNION

Brussels, 21 September 2011 (OR. en)

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NOTE

from:	General Secretariat
to:	Delegations
Subject:	Treaty concerning the Accession of the Republic of Croatia

Delegations are informed that documents AC 31/11 and AC 30/11, which are attached to this note as annexes I and II respectively, have been released to the public today pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

It should be noted that these documents contain the draft text of the Accession Treaty with Croatia as negotiated in English and approved by Coreper on 14 September 2011.

These documents are still subject to legal-linguistic revision.

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ANNEX I

COUNCIL OF THE EUROPEAN UNION

GENERAL SECRETARIAT

Brussels, 13 September 2011

AC 31/11

LIMITE

FINAL EUROPEAN UNION AND CANDIDATE COUNTRY AGREED TEXT ON THE ACCESSION TREATY

Subject:	Accession Treaty: Treaty concerning the accession of the Republic of Croatia

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TREATY

BETWEEN

THE KINGDOM OF BELGIUM, THE REPUBLIC OF BULGARIA, THE CZECH REPUBLIC, THE KINGDOM OF DENMARK, THE FEDERAL REPUBLIC OF GERMANY, THE REPUBLIC OF ESTONIA, IRELAND, THE HELLENIC REPUBLIC, THE KINGDOM OF SPAIN, THE FRENCH REPUBLIC, THE ITALIAN REPUBLIC, THE REPUBLIC OF CYPRUS, THE REPUBLIC OF LATVIA, THE REPUBLIC OF LITHUANIA, THE GRAND DUCHY OF LUXEMBOURG, THE REPUBLIC OF HUNGARY, THE REPUBLIC OF MALTA, THE KINGDOM OF THE NETHERLANDS, THE REPUBLIC OF AUSTRIA, THE REPUBLIC OF POLAND, THE PORTUGUESE REPUBLIC, ROMANIA, THE REPUBLIC OF SLOVENIA, THE SLOVAK REPUBLIC, THE REPUBLIC OF FINLAND, THE KINGDOM OF SWEDEN, THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

(MEMBER STATES OF THE EUROPEAN UNION)

AND

THE REPUBLIC OF CROATIA,

CONCERNING THE ACCESSION OF THE REPUBLIC OF CROATIA TO THE EUROPEAN UNION

HIS MAJESTY THE KING OF THE BELGIANS,

THE PRESIDENT OF THE REPUBLIC OF BULGARIA,

THE PRESIDENT OF THE CZECH REPUBLIC,

HER MAJESTY THE QUEEN OF DENMARK,

THE PRESIDENT OF THE FEDERAL REPUBLIC OF GERMANY,

THE PRESIDENT OF THE REPUBLIC OF ESTONIA,

THE PRESIDENT OF IRELAND,

THE PRESIDENT OF THE HELLENIC REPUBLIC,

HIS MAJESTY THE KING OF SPAIN,

THE PRESIDENT OF THE FRENCH REPUBLIC,

[INSERT ENTRY FOR CROATIA,]

THE PRESIDENT OF THE ITALIAN REPUBLIC,

THE PRESIDENT OF THE REPUBLIC OF CYPRUS,

THE PRESIDENT OF THE REPUBLIC OF LATVIA,

THE PRESIDENT OF THE REPUBLIC OF LITHUANIA,

HIS ROYAL HIGHNESS THE GRAND DUKE OF LUXEMBOURG,

THE PRESIDENT OF THE REPUBLIC OF HUNGARY,

THE PRESIDENT OF MALTA,

HER MAJESTY THE QUEEN OF THE NETHERLANDS,

THE FEDERAL PRESIDENT OF THE REPUBLIC OF AUSTRIA,

THE PRESIDENT OF THE REPUBLIC OF POLAND,

THE PRESIDENT OF THE PORTUGUESE REPUBLIC,

THE PRESIDENT OF ROMANIA,

THE PRESIDENT OF THE REPUBLIC OF SLOVENIA,

THE PRESIDENT OF THE SLOVAK REPUBLIC,

THE PRESIDENT OF THE REPUBLIC OF FINLAND,

THE GOVERNMENT OF THE KINGDOM OF SWEDEN,

HER MAJESTY THE QUEEN OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

UNITED in their desire to pursue the attainment of the objectives of the European Union,

DETERMINED to continue the process of creating an ever closer union among the peoples of Europe on the foundations already laid,

CONSIDERING that Article 49 of the Treaty on European Union affords European States the opportunity of becoming members of the Union,

CONSIDERING that the Republic of Croatia has applied to become a member of the Union,

CONSIDERING that the Council, after having obtained the opinion of the Commission and the consent of the European Parliament, has declared itself in favour of the admission of the Republic of Croatia,

HAVE AGREED on the conditions of admission and the adjustments to be made to the Treaty on European Union, the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community, and to this end have designated as their Plenipotentiaries:

HIS MAJESTY THE KING OF THE BELGIANS,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF BULGARIA,

[List signatories]

THE PRESIDENT OF THE CZECH REPUBLIC,

[List signatories]

HER MAJESTY THE QUEEN OF DENMARK,

[List signatories]

THE PRESIDENT OF THE FEDERAL REPUBLIC OF GERMANY,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF ESTONIA,

[List signatories]

THE PRESIDENT OF IRELAND,

[List signatories]

THE PRESIDENT OF THE HELLENIC REPUBLIC,

[List signatories]

HIS MAJESTY THE KING OF SPAIN,

[List signatories]

THE PRESIDENT OF THE FRENCH REPUBLIC,

[List signatories]

[INSERT ENTRY FOR CROATIA,]

[List signatories]

THE PRESIDENT OF THE ITALIAN REPUBLIC,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF CYPRUS,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF LATVIA,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF LITHUANIA,

[List signatories]

HIS ROYAL HIGHNESS THE GRAND DUKE OF LUXEMBOURG,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF HUNGARY,

[List signatories]

THE PRESIDENT OF MALTA,

[List signatories]

HER MAJESTY THE QUEEN OF THE NETHERLANDS,

[List signatories]

THE FEDERAL PRESIDENT OF THE REPUBLIC OF AUSTRIA,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF POLAND,

[List signatories]

THE PRESIDENT OF THE PORTUGUESE REPUBLIC,

[List signatories]

THE PRESIDENT OF ROMANIA,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF SLOVENIA,

[List signatories]

THE PRESIDENT OF THE SLOVAK REPUBLIC,

[List signatories]

THE PRESIDENT OF THE REPUBLIC OF FINLAND,

[List signatories]

THE GOVERNMENT OF THE KINGDOM OF SWEDEN,

[List signatories]

HER MAJESTY THE QUEEN OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

[List signatories]

WHO, having exchanged their full powers found in good and due form,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

1. The Republic of Croatia hereby becomes a member of the European Union and of the European Atomic Energy Community.

2. The Republic of Croatia becomes a Party to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community as amended or supplemented.

3. The conditions of admission and the adjustments to the Treaties referred to in paragraph 2, entailed by such admission, are set out in the Act annexed to this Treaty. The provisions of that Act shall form an integral part of this Treaty.

ARTICLE 2

The provisions concerning the rights and obligations of the Member States and the powers and jurisdiction of the institutions of the Union as set out in the Treaties to which the Republic of Croatia becomes a Party by virtue of Article 1(2) shall apply in respect of this Treaty.

ARTICLE 3

1. This Treaty shall be ratified by the High Contracting Parties in accordance with their respective constitutional requirements. The instruments of ratification shall be deposited with the Government of the Italian Republic by 30 June 2013.

2. By ratifying this Treaty, the Republic of Croatia is also deemed to have ratified or approved any amendments to the Treaties referred to in Article 1(2) open for ratification or approval by the Member States pursuant to Article 48 of the Treaty on European Union at the moment of ratification of this Treaty by Croatia, as well as any acts of the institutions, adopted on or before that same moment and which only enter into force after having been approved by the Member States in accordance with their respective constitutional requirements.

3. This Treaty shall enter into force on 1 July 2013 provided that all the instruments of ratification have been deposited before that date.

4. Notwithstanding paragraph 3, the institutions of the Union may adopt before accession the measures referred to in Articles 3(7), 6(2), second subparagraph, 6(3), second subparagraph, 6(6), second and third subparagraphs, 6(7), second subparagraph, 6(8), third subparagraph, 17, 29(1), 30(5), 31(5), 35(3) and (4), 38, 39, 41, 42, 43, 44, 49, 50, 51, and Annexes IV to VI of the Act referred to in Article 1(3).

These measures shall enter into force only subject to and on the date of the entry into force of this Treaty.

5. Notwithstanding paragraph 3, Article 36 of the Act referred to in Article 1(3) applies upon signature of this Treaty.

ARTICLE 4

This Treaty, drawn up in a single original in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, the texts in each of these languages being equally authentic, shall be deposited in the archives of the Government of the Italian Republic, which will remit a certified copy to each of the Governments of the other Signatory States.

В ПОТВЪРЖДЕНИЕ НА КОЕТО, долуподписаните упълномощени представители подписаха настоящия договор.

EN FE DE LO CUAL, los plenipotenciarios abajo firmantes suscriben el presente Tratado.

NA DŮKAZ ČEHOŽ připojili níže podepsaní zplnomocnění zástupci k této smlouvě své podpisy.

TIL BEKRÆFTELSE HERAF har undertegnede befuldmægtigede underskrevet denne traktat.

ZU URKUND DESSEN haben die unterzeichneten Bevollmächtigten ihre Unterschriften unter diesen Vertrag gesetzt.

SELLE KINNITUSEKS on nimetatud täievolilised esindajad käesolevale lepingule alla kirjutanud.

ΣΕ ΠΙΣΤΩΣΗ ΤΩΝ ΑΝΩΤΕΡΩ, οι κάτωθι υπογεγραμμένοι πληρεξούσιοι υπέγραψαν την παρούσα Συνθήκη.

IN WITNESS WHEREOF the undersigned Plenipotentiaries have signed this Treaty.

EN FOI DE QUOI, les plénipotentiaires soussignés ont apposé leurs signatures au bas du présent traité.

DÁ FHIANÚ SIN, chuir na Lánchumhachtaigh thíos-sínithe a lámh leis an gConradh seo.

U POTVRDU TOGA niže potpisani opunomoćenici potpisali su ovaj Ugovor.

IN FEDE DI CHE, i plenipotenziari sottoscritti hanno apposto le loro firme in calce al presente trattato.

TO APLIECINOT, Pilnvarotie ir parakstījuši šo Līgumu.

TAI PALIUDYDAMI šią Sutartį pasirašė toliau nurodyti įgaliotieji atstovai.

FENTIEK HITELÉÜL az alulírott meghatalmazottak aláírták ezt a szerződést.

B'XIEHDA TA' DAN il-Plenipotenzjarji sottoskritti iffirmaw dan it-Trattat.

TEN BLIJKE WAARVAN de ondergetekende gevolmachtigden hun handtekening onder dit Verdrag hebben gesteld.

W DOWÓD CZEGO niżej podpisani pełnomocnicy złożyli swoje podpisy pod niniejszym Traktatem.

EM FÉ DO QUE, os plenipotenciários abaixo-assinados apuseram as suas assinaturas no final do presente Tratado.

DREPT CARE subsemnaţii plenipotenţiari au semnat prezentul tratat.

NA DÔKAZ TOHO splnomocnení zástupcovia podpísali túto zmluvu.

V POTRDITEV TEGA so spodaj podpisani pooblaščenci podpisali to pogodbo.

TÄMÄN VAKUUDEKSI ALLA MAINITUT täysivaltaiset edustajat ovat allekirjoittaneet tämän sopimuksen.

SOM BEKRÄFTELSE PÅ DETTA har undertecknade befullmäktigade ombud undertecknat detta fördrag.

[To be inserted in all the official languages: 'Done at…on the…in the year.']

Pour Sa Majesté le Roi des Belges
Voor Zijne Majesteit de Koning der Belgen
Für Seine Majestät den König der Belgier

Cette signature engage également la Communauté française, la Communauté flamande, la Communauté germanophone, la Région wallonne, la Région flamande et la Région de Bruxelles-Capitale.

Deze handtekening verbindt eveneens de Vlaamse Gemeenschap, de Franse Gemeenschap, de Duitstalige Gemeenschap, het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest.

Diese Unterschrift bindet zugleich die Deutschsprachige Gemeinschaft, die Flämische Gemeinschaft, die Französische Gemeinschaft, die Wallonische Region, die Flämische Region und die Region Brüssel-Hauptstadt.

За Република България

Za prezidenta České republiky

For Hendes Majestæt Danmarks Dronning

Für den Präsidenten der Bundesrepublik Deutschland

Eesti Vabariigi Presidendi nimel

Thar ceann Uachtarán na hÉireann

For the President of Ireland

Για τον Πρόεδρο της Ελληνικής Δημοκρατίας

Por Su Majestad el Rey de España

Pour le Président de la République française

['Insert entry for Croatia']

Per il Presidente della Repubblica italiana

Για τον Πρόεδρο της Κυπριακής Δημοκρατίας

Latvijas Republikas Valsts prezidenta vārdā

Lietuvos Respublikos Prezidento vardu

Pour Son Altesse Royale le Grand-Duc de Luxembourg

A Magyar Köztársaság Elnöke részéről

Għall-President ta' Malta

Voor Hare Majesteit de Koningin der Nederlanden

Für den Bundespräsidenten der Republik Österreich

Za Prezydenta Rzeczypospolitej Polskiej

Pelo Presidente da República Portuguesa

Pentru Preşedintele României

Za predsednika Republike Slovenije

Za prezidenta Slovenskej republiky

Suomen Tasavallan Presidentin puolesta

För Republiken Finlands President

För Konungariket Sveriges regering

For Her Majesty the Queen of the United Kingdom of Great Britain and Northern Ireland

ACT

concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community

PART ONE

PRINCIPLES

ARTICLE 1

For the purposes of this Act:

– the expression 'original Treaties' means:

  (a) the Treaty on European Union ('TEU') and the Treaty on the Functioning of the European Union ('TFEU'), as amended or supplemented by treaties or other acts which entered into force before the accession of the Republic of Croatia,

  (b) the Treaty establishing the European Atomic Energy Community ('EAEC Treaty'), as amended or supplemented by treaties or other acts which entered into force before this accession;

– the expression 'present Member States' means the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, Romania, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland;

– the expression 'the Union' means the European Union founded on the TEU and on the TFEU and/or, as the case may be, the European Atomic Energy Community;

– the expression 'the institutions' means the institutions established by the TEU.

ARTICLE 2

From the date of accession, the provisions of the original Treaties and the acts adopted by the institutions before accession shall be binding on Croatia and shall apply in Croatia under the conditions laid down in those Treaties and in this Act.

Where amendments to the original Treaties have been agreed by the representatives of the governments of the Member States pursuant to Article 48(4) TEU after the ratification of the Accession Treaty by Croatia and where those amendments have not entered into force by the date of accession, Croatia shall ratify those amendments in accordance with its constitutional requirements.

ARTICLE 3

1. Croatia accedes to the decisions and agreements of the Heads of State or Government of the Member States meeting within the European Council.

2. Croatia accedes to the decisions and agreements adopted by the Representatives of the Governments of the Member States meeting within the Council.

3. Croatia is in the same situation as the present Member States in respect of declarations or resolutions of, or other positions taken up by, the European Council or the Council and in respect of those concerning the Union adopted by common agreement of the Member States. Croatia will accordingly observe the principles and guidelines deriving from those declarations, resolutions or other positions and will take such measures as may be necessary to ensure their implementation.

4. Croatia accedes to the conventions and protocols listed in Annex I. Those conventions and protocols shall enter into force in relation to Croatia on the date determined by the Council in the decisions referred to in paragraph 5.

5. The Council, acting unanimously on a recommendation by the Commission and after consulting the European Parliament, shall make all adjustments required by reason of accession to the conventions and protocols referred to in paragraph 4 and publish the adapted texts in the Official Journal of the European Union.

6. Croatia undertakes in respect of the conventions and protocols referred to in paragraph 4 to introduce administrative and other arrangements, such as those adopted by the date of accession by the present Member States or by the Council, and to facilitate practical cooperation between the Member States' institutions and organisations.

7. The Council, acting unanimously on a proposal from the Commission, may supplement Annex I with the relevant conventions, agreements and protocols signed before the date of accession.

ARTICLE 4

1. The provisions of the Schengen *acquis* as referred to in the Protocol on the Schengen *acquis* integrated into the framework of the European Union (hereinafter referred to as the 'Schengen Protocol'), annexed to the TEU and the TFEU, and the acts building upon it or otherwise related to it, listed in Annex II, as well as any further such acts adopted before the date of accession, shall be binding on and applicable in Croatia from the date of accession.

2. Those provisions of the Schengen *acquis* as integrated into the framework of the European Union and the acts building upon it or otherwise related to it not referred to in paragraph 1, while binding on Croatia from the date of accession, shall only apply in Croatia pursuant to a Council decision to that effect, after verification, in accordance with the applicable Schengen evaluation procedures, that the necessary conditions for the application of all parts of the relevant *acquis* concerned have been met in Croatia, including the effective application of all Schengen rules in accordance with the agreed common standards and with fundamental principles. This decision shall be taken by the Council, in accordance with the applicable Schengen procedures and while taking into account a Commission report confirming that Croatia continues to fulfil the commitments undertaken in its accession negotiations that are relevant for the Schengen *acquis*.

   The Council shall take its decision, after consulting the European Parliament, acting with the unanimity of its members representing the Governments of the Member States in respect of which the provisions referred to in this paragraph have already been put into effect and of the representative of the Government of the Republic of Croatia. The members of the Council representing the Governments of Ireland and of the United Kingdom of Great Britain and Northern Ireland shall take part in such a decision insofar as it relates to the provisions of the Schengen *acquis* and the acts building upon it or otherwise related to it in which these Member States participate.

ARTICLE 5

Croatia shall participate in the Economic and Monetary Union from the date of accession as a Member State with a derogation within the meaning of Article 139 of the TFEU.

ARTICLE 6

1. The agreements concluded or provisionally applied by the Union with one or more third countries, with an international organisation or with a national of a third country shall, under the conditions laid down in the original Treaties and in this Act, be binding on Croatia.

2. Croatia undertakes to accede, under the conditions laid down in this Act, to the agreements concluded or signed by the present Member States and the Union with one or more third countries or with an international organisation.

   Unless otherwise provided for in specific agreements referred to in the first subparagraph, the accession of Croatia to such agreements shall be agreed by the conclusion of a protocol to such agreements between the Council, acting unanimously on behalf of the Member States, and the third country or countries or international organisation concerned. The Commission, or the High Representative of the Union for Foreign Affairs and Security Policy where the agreement relates exclusively or principally to the common foreign and security policy, shall negotiate these protocols on behalf of the Member States on the basis of negotiating directives approved by the Council, acting unanimously, and in consultation with a committee comprised of the representatives of the Member States. It shall submit a draft of the protocols for conclusion to the Council.

   This procedure is without prejudice to the exercise of the Union's own competences and does not affect the allocation of powers between the Union and the Member States as regards the conclusion of such agreements in the future or any other amendments not related to accession.

3. As from the date of accession, and pending the entry into force of the necessary protocols referred to in the second subparagraph of paragraph 2, Croatia shall apply the provisions of the agreements referred to in the first subparagraph of paragraph 2 concluded or provisionally applied before the date of accession, with the exception of the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons[1].

Pending the entry into force of the protocols referred to in the second subparagraph of paragraph 2, the Union and the Member States, acting jointly as appropriate in the framework of their respective competences, shall take any appropriate measure.

4. Croatia accedes to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000[2], as well as to the agreements amending that Agreement, signed in Luxembourg on 25 June 2005[3] and opened for signature in Ouagadougou on 22 June 2010[4].

5. Croatia undertakes to accede, under the conditions laid down in this Act, to the Agreement on the European Economic Area[5], in accordance with Article 128 of that Agreement.

6. As from the date of accession, Croatia shall apply the bilateral textile agreements and arrangements concluded by the Union with third countries.

The quantitative restrictions applied by the Union on imports of textile and clothing products shall be adjusted to take account of the accession of Croatia to the Union. To that effect, amendments to the bilateral agreements and arrangements referred to in the first subparagraph may be negotiated by the Union with the third countries concerned prior to the date of accession.

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1 OJ L 114, 30.4.2002, p. 6
2 OJ L 317, 15.12.2000, p. 3.
3 OJ L 209, 11.8.2005, p. 27, OJ L 287, 28.10.2005, p. 4 and OJ L 168M, 21.6.2006, p. 33.
4 OJ L 287, 4.11.2010, p. 3.
5 OJ L 1, 3.1.1994, p. 3.

Should the amendments to the bilateral textile agreements and arrangements not have entered into force by the date of accession, the Union shall make the necessary adjustments to its rules for the import of textile and clothing products from third countries to take into account the accession of Croatia.

7. The quantitative restrictions applied by the Union on imports of steel and steel products shall be adjusted on the basis of imports of Croatia over recent years of steel products originating in the supplier countries concerned.

To that effect, the necessary amendments to the bilateral steel agreements and arrangements concluded by the Union with third countries shall be negotiated prior to the date of accession.

Should the amendments to the bilateral agreements and arrangements not have entered into force by the date of accession, the provisions of the first subparagraph shall apply.

8. As from the date of accession, fisheries agreements concluded before accession by Croatia with third countries shall be managed by the Union.

The rights and obligations resulting for Croatia from those agreements shall not be affected during the period in which the provisions of those agreements are provisionally maintained.

As soon as possible, and in any event before the expiry of the agreements referred to in the first subparagraph, appropriate decisions for the continuation of fishing activities resulting from those agreements shall be adopted in each case by the Council acting by qualified majority on a proposal from the Commission, including the possibility of extending certain agreements for periods not exceeding one year.

9. Croatia shall withdraw from any free trade agreements with third countries, including the Central European Free Trade Agreement as amended.

To the extent that agreements between Croatia on the one hand, and one or more third countries on the other, are not compatible with the obligations arising from this Act, Croatia shall take all appropriate steps to eliminate the incompatibilities established. If Croatia encounters difficulties in adjusting an agreement concluded with one or more third countries, it shall withdraw from that agreement.

Croatia shall take all the necessary measures to ensure compliance with the obligations of this paragraph as from the date of accession.

10. Croatia accedes under the conditions laid down in this Act to the internal agreements concluded by the present Member States for the purpose of implementing the agreements referred to in paragraphs 2 and 4.

11. Croatia shall take appropriate measures, where necessary, to adjust its position in relation to international organisations, and to those international agreements to which the Union or to which other Member States are also parties, to the rights and obligations arising from Croatia's accession to the Union.

Croatia shall in particular withdraw from international fisheries agreements and organisations to which the Union is also a party, unless its membership relates to matters other than fisheries.

Croatia shall take all necessary measures to ensure compliance with the obligations of this paragraph as from the date of accession.

ARTICLE 7

1. The provisions of this Act may not, unless otherwise provided herein, be suspended, amended or repealed other than by means of the procedure laid down in the original Treaties enabling those Treaties to be revised.

2. Acts adopted by the institutions to which the transitional provisions laid down in this Act relate shall retain their status in law; in particular, the procedures for amending those acts shall continue to apply.

3. Provisions of this Act the purpose or effect of which is to repeal or amend acts adopted by the institutions, otherwise than as a transitional measure, shall have the same status in law as the provisions which they repeal or amend and shall be subject to the same rules as those provisions.

ARTICLE 8

The application of the original Treaties and acts adopted by the institutions shall, as a transitional measure, be subject to the derogations provided for in this Act.

PART TWO

ADJUSTMENTS TO THE TREATIES

TITLE I

INSTITUTIONAL PROVISIONS

ARTICLE 9

The Protocol on the Statute of the Court of Justice of the European Union, annexed to the TFEU and the EAEC Treaty, shall be amended as follows:

1. In Article 9, the first paragraph shall be replaced by the following:

   'When, every three years, the Judges are partially replaced, 14 Judges shall be replaced.'

2. Article 48 shall be replaced by the following:

   'The General Court shall consist of 28 Judges.'.

ARTICLE 10

The Protocol on the Statute of the European Investment Bank, annexed to the TEU, the TFEU and the EAEC Treaty shall be amended as follows:

1. In Article 4(1), first subparagraph:

(a) the introductory sentence shall be replaced by the following:

'1. The capital of the Bank shall be EUR 233 247 390 000, subscribed by the Member States as follows:'

(b) the following shall be inserted between the entries for Romania and Slovakia:

'Croatia EUR 854 400 000 '.

2. In Article 9(2), the first, second and third subparagraphs shall be replaced by the following:

'2. The Board of Directors shall consist of twenty-nine directors and nineteen alternate directors.

The directors shall be appointed by the Board of Governors for five years, one nominated by each Member State, and one nominated by the Commission.

The alternate directors shall be appointed by the Board of Governors for five years as shown below:

– two alternates nominated by the Federal Republic of Germany,

– two alternates nominated by the French Republic,

– two alternates nominated by the Italian Republic,

– two alternates nominated by the United Kingdom of Great Britain and Northern Ireland,

– one alternate nominated by common accord of the Kingdom of Spain and the Portuguese Republic,

– one alternate nominated by common accord of the Kingdom of Belgium, the Grand Duchy of Luxembourg and the Kingdom of the Netherlands,

– two alternates nominated by common accord of the Kingdom of Denmark, the Hellenic Republic, Ireland and Romania,

– two alternates nominated by common accord of the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden,

– four alternates nominated by common accord of the Republic of Bulgaria, the Czech Republic, the Republic of Croatia, the Republic of Cyprus, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic,

– one alternate nominated by the Commission.'.

ARTICLE 11

Article 134(2), first subparagraph, of the EAEC Treaty on the composition of the Scientific and Technical Committee shall be replaced by the following:

'2. The Committee shall consist of forty-two members, appointed by the Council after consultation with the Commission.'.

TITLE II

OTHER ADJUSTMENTS

ARTICLE 12

In Article 64(1) of the TFEU, the following sentence is added:

'In respect of restrictions existing under national law in Croatia, the relevant date shall be 31 December 2002.'.

ARTICLE 13

Article 52(1) of the TEU shall be replaced by the following:

'1. The Treaties shall apply to the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Croatia, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, Romania, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.'.

ARTICLE 14

1. Article 55(1) of the TEU shall be replaced by the following:

'1. This Treaty, drawn up in a single original in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, the texts in each of these languages being equally authentic, shall be deposited in the archives of the Government of the Italian Republic, which will transmit a certified copy to each of the governments of the other signatory States.'.

2. Article 225, second paragraph, of the EAEC Treaty shall be replaced by the following:

'Pursuant to the Accession Treaties, the Bulgarian, Croatian, Czech, Danish, English, Estonian, Finnish, Greek, Hungarian, Irish, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish versions of this Treaty shall also be authentic.'.

PART THREE

PERMANENT PROVISIONS

ARTICLE 15

The acts listed in Annex III to this Act shall be adapted as specified in that Annex.

ARTICLE 16

The measures listed in Annex IV to this Act shall be applied under the conditions laid down in that Annex.

ARTICLE 17

The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, may make the adaptations to the provisions of this Act relating to the common agricultural policy which may prove necessary as a result of a modification in Union rules.

PART FOUR

TEMPORARY PROVISIONS

TITLE I

TRANSITIONAL MEASURES

ARTICLE 18

The measures listed in Annex V to this Act shall apply in respect of Croatia under the conditions laid down in that Annex.

TITLE II

INSTITUTIONAL PROVISIONS

ARTICLE 19

1. By way of derogation from Article 2 of the Protocol on transitional provisions annexed to the TEU, the TFEU and the EAEC Treaty and by way of derogation from the maximum number of seats provided for in the first subparagraph of Article 14(2) of the TEU, the number of members of the European Parliament shall be increased to take account of the accession of Croatia with the following number of members from Croatia for the period running from the date of accession until the end of the 2009-2014 term of the European Parliament:

Croatia	12.

2. By way of derogation from Article 14(3) of the TEU, Croatia shall, before the date of accession, hold *ad hoc* elections to the European Parliament, by direct universal suffrage of its people, for the number of members fixed in paragraph 1, I n accordance with the provisions of the *acquis*. However, if the date of accession is less than six months before the next elections to the European Parliament, the members of the European Parliament representing the citizens of Croatia may be designated by the national Parliament of Croatia, from its midst, provided that the persons in question have been elected by direct universal suffrage.

ARTICLE 20

Article 3(3) of the Protocol on transitional provisions annexed to the TEU, the TFEU and the EAEC Treaty shall be replaced by the following:

'3. Until 31 October 2014, the following provisions shall remain in force, without prejudice to the second subparagraph of Article 235(1) of the Treaty on the Functioning of the European Union.

For acts of the European Council and of the Council requiring a qualified majority, members' votes shall be weighted as follows:

Belgium	12
Bulgaria	10
Czech Republic	12
Denmark	7
Germany	29
Estonia	4
Ireland	7
Greece	12
Spain	27
France	29
Croatia	7
Italy	29
Cyprus	4
Latvia	4
Lithuania	7
Luxembourg	4
Hungary	12
Malta	3
Netherlands	13
Austria	10
Poland	27
Portugal	12
Romania	14
Slovenia	4
Slovakia	7
Finland	7
Sweden	10
United Kingdom	29

Acts shall be adopted if there are at least 260 votes in favour representing a majority of the members where, under the Treaties, they must be adopted on a proposal from the Commission. In other cases decisions shall be adopted if there are at least 260 votes in favour representing at least two thirds of the members.

A member of the European Council or the Council may request that, where an act is adopted by the European Council or the Council by a qualified majority, a check is made to ensure that the Member States comprising the qualified majority represent at least 62% of the total population of the Union. If that proves not to be the case, the act shall not be adopted.'

ARTICLE 21

1. With effect for the period running from the date of accession until 31 October 2014, a national of Croatia shall be appointed to the Commission as from the date of accession. The new Member of the Commission shall be appointed by the Council, acting by qualified majority and by common accord with the President of the Commission, after consulting the European Parliament and in accordance with the criteria set out in the second subparagraph of Article 17(3) of the TEU.

2. The term of office of the Member appointed in accordance with paragraph 1 shall expire at the same time as those of the Members in office at the time of accession.

ARTICLE 22

1. The term of office of the Judge of the Court of Justice and the Judge of the General Court appointed from Croatia upon its accession in accordance with the third subparagraph of Article 19(2) of the TEU shall expire, respectively, on 6 October 2015 and 31 August 2013.

2. For the purpose of judging cases pending before the Courts on the date of accession in respect of which oral proceedings have started before that date, the full Courts or the Chambers shall be composed as before accession and shall apply the Rules of Procedure in force on the day preceding the date of accession.

ARTICLE 23

1. By way of derogation from the maximum number of members of the Economic and Social Committee provided for in Article 301, first paragraph, of the TFEU, Article 7 of the Protocol on transitional provisions annexed to the TEU, the TFEU and the EAEC Treaty, on the composition of the Economic and Social Committee, shall be replaced by the following:

'Article 7

Until the entry into force of the decision referred to in Article 301 of the Treaty on the Functioning of the European Union, the allocation of members of the Economic and Social Committee shall be as follows:

Belgium	12
Bulgaria	12
Czech Republic	12
Denmark	9
Germany	24
Estonia	7
Ireland	9
Greece	12
Spain	21
France	24
Croatia	9
Italy	24
Cyprus	6
Latvia	7
Lithuania	9
Luxembourg	6
Hungary	12
Malta	5
Netherlands	12
Austria	12
Poland	21
Portugal	12
Romania	15
Slovenia	7
Slovakia	9
Finland	9
Sweden	12
United Kingdom	24'

2. The number of members of the Economic and Social Committee shall be temporarily increased to 353 to take account of the accession of Croatia for the period running from the date of accession until the end of the term of office during which Croatia accedes to the European Union or until the entry into force of the decision referred to in Article 301, second paragraph, of the TFEU, whichever comes first.

3. If the decision referred to in Article 301, second paragraph, of the TFEU has already been adopted by the date of accession, by way of derogation from the maximum number of members of the Economic and Social Committee provided for in Article 301, first paragraph, of the TFEU, Croatia shall be temporarily allocated an appropriate number of members until the end of the term of office during which it accedes to the Union.

ARTICLE 24

1. By way of derogation from the maximum number of members of the Committee of the Regions provided for in Article 305, first paragraph, of the TFEU, Article 8 of the Protocol on transitional provisions, annexed to the TEU, the TFEU and the EAEC Treaty, on the composition of the Committee of the Regions, shall be replaced by the following:

'Article 8

Until the entry into force of the decision referred to in Article 305 of the Treaty on the Functioning of the European Union, the allocation of members of the Committee of the Regions shall be as follows:

Belgium	12
Bulgaria	12
Czech Republic	12
Denmark	9
Germany	24
Estonia	7
Ireland	9
Greece	12
Spain	21
France	24
Croatia	9
Italy	24
Cyprus	6
Latvia	7
Lithuania	9
Luxembourg	6
Hungary	12
Malta	5
Netherlands	12
Austria	12
Poland	21
Portugal	12
Romania	15
Slovenia	7
Slovakia	9
Finland	9
Sweden	12
United Kingdom	24'

2. The number of members of the Committee of the Regions shall be temporarily increased to 353 to take account of the accession of Croatia for the period running from the date of accession until the end of the term of office during which Croatia accedes to the Union or until the entry into force of the decision referred to in Article 305, second paragraph, of the TFEU, whichever comes first.

3. If the decision referred to in Article 305, second paragraph, of the TFEU has already been adopted by the date of accession, by way of derogation from the maximum number of members of the Committee of the Regions provided for in Article 305, first paragraph, of the TFEU, Croatia shall be temporarily allocated an appropriate number of members until the end of the term of office during which it accedes to the Union.

ARTICLE 25

The term of office of the director of the Board of Directors of the European Investment Bank, nominated by Croatia and appointed upon accession as provided for in the second subparagraph of Article 9(2) of the Protocol on the statute of the European Investment Bank shall expire at the end of the annual meeting of the Board of Governors during which the annual report for the 2017 financial year is examined.

ARTICLE 26

1. New members of the committees, groups, agencies or other bodies created by the original Treaties or by an act of the institutions shall be appointed under the conditions and according to the procedures laid down for the appointment of members of these committees, groups, agencies or other bodies. The terms of office of the newly appointed members shall expire at the same time as those of the members in office at the time of accession.

2. The membership of the committees, groups, agencies or other bodies created by the original Treaties or by an act of the institutions with a number of members fixed irrespective of the number of Member States shall be completely renewed upon accession, unless the terms of office of the present members expire within 12 months following accession.

TITLE III

FINANCIAL PROVISIONS

ARTICLE 27

1. From the date of accession, Croatia shall pay the following amount corresponding to its share of the capital paid in for the subscribed capital as defined in Article 4 of the Statute of the European Investment Bank:

Croatia	EUR 42 720 000

The contribution shall be paid in eight equal instalments falling due on 30 November 2013, 30 November 2014, 30 November 2015, 31 May 2016, 30 November 2016, 31 May 2017, 30 November 2017 and 31 May 2018.

2. Croatia shall contribute, in eight equal instalments falling due on the dates provided for in paragraph 1, to the reserves and provisions equivalent to reserves, as well as to the amount still to be appropriated to the reserves and provisions, comprising the balance of the profit and loss account, established at the end of the month preceding accession, as entered on the balance sheet of the Bank, in amounts corresponding to the following percentage of the reserves and provisions:

Croatia 0.368 %

3. The capital and payments provided for in paragraphs 1 and 2 shall be paid in by Croatia in cash in euro, save by way of derogation decided unanimously by the Board of Governors.

4. The figures for Croatia referred to in paragraph 1 as well as in Article 10, point 1, may be adapted by decision of the European Investment Bank governing bodies on the basis of the latest final data of GDP published by Eurostat before accession.

ARTICLE 28

1. Croatia shall pay the following amount to the Research Fund for Coal and Steel referred to in Decision 2002/234/ECSC of the Representatives of the Governments of the Member States, meeting within the Council, of 27 February 2002 on the financial consequences of the expiry of the ECSC Treaty and on the Research Fund for Coal and Steel[1]

(EUR, current prices)

Croatia	494 000

2. The contribution to the Research Fund for Coal and Steel shall be made in four instalments starting in 2015 and paid as follows, in each case on the first working day of the first month of each year:

2015: 15%
2016: 20%
2017: 30%
2018: 35%.

[1] OJ L 79, 22.3.2002, p. 42.

ARTICLE 29

1. Procurement, grant awards and payments for pre-accession financial assistance under the IPA Transition Assistance and Institution Building Component and the IPA Cross-Border Cooperation Component of the Instrument for Pre-Accession Assistance (IPA)[1], for funds committed before accession, with the exclusion of the cross-border programmes Croatia-Hungary and Croatia-Slovenia, and for assistance under the Transition Facility referred to in Article 30, shall be managed by Croatian implementing agencies as of the date of accession.

The *ex ante* control by the Commission over procurement and grant awards shall be waived by a Commission decision to that effect, after the Commission has satisfied itself of the effective functioning of the management and control system concerned in accordance with the criteria and conditions laid down in Article 56(2) of the Financial Regulation applicable to the general budget of the European Union[2] and in Article 18 of the IPA Implementing Regulation[3].

If this Commission decision to waive *ex ante* control has not been taken before the date of accession, any contracts signed between the date of accession and the date on which the Commission decision is taken shall not be eligible under the pre-accession financial assistance and the Transition Facility referred to in the first subparagraph.

2. Budgetary commitments made before the date of accession under the pre-accession financial assistance and the Transition Facility referred to in paragraph 1, including the conclusion and registration of subsequent individual legal commitments and payments made after accession, shall continue to be governed by the rules applying to the pre-accession financial instruments and be charged to the corresponding budget chapters until closure of the programmes and projects concerned.

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1 Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA) (OJ L 210, 31.7.2006, p. 82).

2 Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248, 19.9.2002, p. 1).

3 Commission Regulation (EC) No 718/2007 of 12 June 2007 implementing Council Regulation (EC) No 1085/2006 establishing an instrument for pre–accession assistance (IPA) (OJ L 170, 29.6.2007, p.1).

3. The provisions on the implementation of budgetary commitments of financing agreements concerning the pre-accession financial assistance referred to in paragraph 1, first subparagraph, and the IPA Rural Development component, relating to financing decisions taken before accession, shall continue to be applicable after the date of accession. They shall be governed by the rules applying to the pre-accession financial instruments. Notwithstanding this, public procurement procedures initiated after accession shall be carried out in accordance with the relevant European Union Directives.

4. Pre-accession funds to cover administrative costs, as defined in Article 44, may be committed in the first two years after accession. For audit and evaluation costs, pre-accession funds may be committed up to five years after accession.

ARTICLE 30

1. For the first year after accession, the Union shall provide temporary financial assistance, hereinafter referred to as the "Transition Facility", to Croatia to develop and strengthen its administrative and judicial capacity to implement and enforce Union legislation and to foster exchange of best practice among peers. This assistance shall fund institution-building projects and limited small-scale investments ancillary thereto.

2. Assistance shall address the continued need for strengthening institutional capacity in certain areas through action which cannot be financed by the Structural Funds or by the Rural Development funds.

3. For twinning projects between public administrations for the purpose of institution building, the procedure for call for proposals through the network of contact points in the Member States shall continue to apply.

4. The commitment appropriations for the Transition Facility, at current prices, for Croatia shall be EUR 29 million in total in 2013 to address national and horizontal priorities.

5. Assistance under the Transition Facility shall be decided and implemented in accordance with Council Regulation (EC) No 1085/2006 or on the basis of other technical provisions necessary for the operation of the Transition Facility, to be adopted by the Commission.

6. Particular attention shall be paid to ensuring appropriate complementarity with the envisaged European Social Fund support for administrative reform and institutional capacity.

ARTICLE 31

1. A Schengen Facility (hereinafter referred to as "the temporary Schengen Facility") is hereby created as a temporary instrument to help Croatia between the date of accession and the end of 2014 to finance actions at the new external borders of the Union for the implementation of the Schengen *acquis* and external border control.

2. For the period 1 July 2013 to 2014, the following amounts (current prices) shall be made available to Croatia in the form of lump-sum payments under the temporary Schengen Facility:

(EUR million, current prices)

	2013	2014
Croatia	40	80

3. The annual amount for 2013 shall be payable to Croatia on 1 July 2013 and the annual amount for 2014 shall be made available on the first working day after 1 January 2014.

4. The lump-sum payments shall be used within three years from the first payment. Croatia shall submit, no later than six months after expiry of this three-year period, a comprehensive report on the final execution of the payments under the temporary Schengen Facility with a statement justifying the expenditure. Any unused or unjustifiably spent funds shall be recovered by the Commission.

5. The Commission may adopt any technical provisions necessary for the operation of the temporary Schengen Facility.

ARTICLE 32

1. A Cash-flow Facility (hereinafter referred to as "the temporary Cash-flow Facility") is hereby created as a temporary instrument to help Croatia between the date of accession and the end of 2014 to improve the cash-flow in the national budget.

2. For the period 1 July 2013 to 31 December 2014, the following amounts (current prices) shall be made available to Croatia in the form of lump-sum payments under the temporary Cash-flow Facility:

(EUR million, current prices)

	2013	2014
Croatia	75	28,6

3. Each annual amount shall be divided into equal monthly instalments, payable on the first working day of each month.

ARTICLE 33

1. An allocation of EUR 449,4 million (current prices) in commitment appropriations will be reserved for Croatia under the Structural and Cohesion Funds in 2013.

2. One third of the allocation referred to in paragraph 1 shall be reserved for the Cohesion Fund.

3. For the period covered by the next financial framework, Croatia's allocations under Structural and Cohesion funding shall be calculated based on the then applicable *acquis*. These amounts shall be adjusted in accordance with the following phasing-in schedule:

- 70% in 2014
- 90% in 2015
- 100% as of 2016.

4. Insofar as the limits of the new *acquis* allow, an adjustment shall be made to ensure an increase of funds for Croatia in 2014 of 2.33 times the 2013 allocation, and in 2015 of 3 times the 2013 allocation.

ARTICLE 34

1. The total allocation to be made available to Croatia under the European Fisheries Fund in 2013 shall be EUR 8,7 million (current prices) in commitment appropriations.

2. Pre-financing under the European Fisheries Fund shall amount to 25 % of the total allocation referred to in paragraph 1. This amount shall be paid in one instalment.

3. For the period covered by the next financial framework, Croatia's allocations shall be calculated based on the then applicable *acquis*. These amounts shall be adjusted in accordance with the following phasing-in schedule:

- 70% in 2014
- 90% in 2015
- 100% as of 2016.

4. Insofar as the limits of the new *acquis* allow, an adjustment shall be made to ensure an increase of funds for Croatia in 2014 of 2.33 times the 2013 allocation, and in 2015 of 3 times the 2013 allocation.

ARTICLE 35

1. Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)[1] shall not apply to Croatia for the whole programming period 2007-2013.

   In the year 2013, Croatia shall be allocated EUR 27,7 million under the Rural Development Component referred to in Article 12 of Council Regulation (EC) No 1085/2006.

2. Temporary additional rural development measures for Croatia are laid out in Annex VI.

3. The Commission may, by means of implementing acts, adopt rules necessary for the application of the provisions of Annex VI. Those implementing acts shall be adopted in accordance with the procedure laid down in Article 90(2) of Council Regulation (EC) No 1698/2005 in conjunction with Article 13(1)(b) of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[2] or the relevant procedure as determined in the applicable legislation.

4. The Council, acting on a proposal from the Commission, and after consulting the European Parliament, shall make any adaptations to the provisions of Annex VI, where necessary, to ensure coherence with the regulations concerning rural development.

[1] OJ L 277, 21.10.2005, p. 1 and OJ L 286M, 4.11.2010, p. 26.
[2] OJ L 55, 28.2.2011, p. 13.

TITLE IV

OTHER PROVISIONS

ARTICLE 36

1. The Commission shall closely monitor all commitments undertaken by Croatia in the accession negotiations, including those which must be achieved before or by the date of accession. The Commission's monitoring shall consist of regularly updated monitoring tables, the dialogue under the Stabilisation and Association Agreement (SAA)[1], peer assessment missions, the pre-accession economic programme, fiscal notifications and, when necessary, early warning letters to the Croatian authorities. A Progress Report and a Comprehensive Monitoring Report shall be presented to the Council and the European Parliament in the autumn of 2011 and 2012, respectively. The Commission shall also draw on input from Member States and take into consideration input from international and civil society organisations as appropriate, throughout the monitoring process.

   The Commission's monitoring shall focus in particular on commitments undertaken by Croatia in the area of the judiciary and fundamental rights (Annex VII), including the continued development of track records on judicial reform and efficiency, impartial handling of war crimes cases, and the fight against corruption.

   In addition, the Commission's monitoring shall focus on the area of justice, freedom and security, including the implementation and enforcement of Union requirements with respect to external border management, police cooperation, the fight against organised crime, and judicial cooperation in civil and criminal matters, as well as on commitments in the area of competition policy including the restructuring of the shipbuilding industry (Annex VIII) and the restructuring of the steel sector (Annex IX).

[1] [OJ reference to be inserted]

The Commission shall issue six-monthly assessments up to the accession of Croatia on the commitments undertaken by Croatia in these areas as an integral part of its regular monitoring tables and reports.

2. The Council, acting by qualified majority on a proposal from the Commission, may take all appropriate measures if issues of concern are identified during the monitoring process. The measures shall be maintained no longer than strictly necessary and, in any case, shall be lifted by the Council, acting in accordance with the same procedure, when the relevant issues of concern have been effectively addressed.

ARTICLE 37

1. If, until the end of a period of up to three years after accession, difficulties arise which are serious and liable to persist in any sector of the economy or which could bring about serious deterioration in the economic situation of a given area, Croatia may apply for authorisation to take protective measures in order to rectify the situation and adjust the sector concerned to the economy of the internal market.

   In the same circumstances, any present Member State may apply for authorisation to take protective measures with regard to Croatia.

2. Upon request by the State concerned, the Commission shall, by emergency procedure, determine the protective measures which it considers necessary, specifying the conditions and modalities in which they are to be put into effect.

   In the event of serious economic difficulties and at the express request of the Member State concerned, the Commission shall act within five working days of the receipt of the request accompanied by the relevant background information. The measures thus decided on shall be applicable forthwith, shall take into account the interest of all parties concerned and shall not entail frontier controls.

3. The measures authorised under this article may involve derogations from the rules of the TEU, the TFEU and this Act to such an extent and for such periods as are strictly necessary in order to attain the objectives of this safeguard. Priority shall be given to such measures as will least disturb the functioning of the internal market.

ARTICLE 38

If Croatia has failed to implement commitments undertaken in the context of the accession negotiations, including commitments in any sectoral policy which concerns economic activities with cross-border effect, causing a serious breach of the functioning of the internal market or a threat to the Union's financial interests or an imminent risk of such a breach or threat, the Commission may, until the end of a period of up to three years after accession, upon reasoned request of a Member State or on its own initiative, take appropriate measures.

These measures shall be proportional and priority shall be given to measures which least disturb the functioning of the internal market and, where appropriate, to the application of the existing sectoral safeguard mechanisms. The safeguard measures under this article shall not be invoked as a means of arbitrary discrimination or a disguised restriction on trade between Member States. The safeguard clause may be invoked even before accession on the basis of the monitoring findings and the measures adopted shall enter into force as of the date of accession unless they provide for a later date. The measures shall be maintained no longer than strictly necessary and, in any case, shall be lifted when the relevant commitment is implemented. They may however be applied beyond the period specified in the first paragraph as long as the relevant commitments have not been fulfilled. In response to progress made by Croatia in fulfilling its commitments, the Commission may adapt the measures as appropriate. The Commission shall inform the Council in good time before revoking the safeguard measures, and it shall take duly into account any observations of the Council in this respect.

ARTICLE 39

If there are serious shortcomings or any imminent risks of such shortcomings in Croatia in the transposition or state of implementation of acts adopted by the institutions pursuant to Part Three, Title V of the TFEU as well as of acts adopted by the institutions before the entry into force of the Treaty of Lisbon pursuant to Title VI of the TEU or pursuant to Part Three, Title IV of the Treaty establishing the European Community, the Commission may, until the end of a period of up to three years after accession, upon the reasoned request of a Member State or on its own initiative and after consulting the Member States, adopt appropriate measures and specify the conditions and modalities under which these measures are put into effect.

These measures may take the form of temporary suspension of the application of relevant provisions and decisions in the relations between Croatia and any other Member State or Member States, without prejudice to the continuation of close judicial cooperation. The safeguard clause may be invoked even before accession on the basis of the monitoring findings and the measures adopted shall enter into force as of the date of accession unless they provide for a later date. The measures shall be maintained no longer than strictly necessary and, in any case, shall be lifted when the shortcomings are remedied. They may however be applied beyond the period specified in the first paragraph as long as these shortcomings persist. In response to progress made by Croatia in rectifying the identified shortcomings, the Commission may adapt the measures as appropriate after consulting the Member States. The Commission shall inform the Council in good time before revoking the safeguard measures, and it shall take duly into account any observations of the Council in this respect.

ARTICLE 40

In order not to hamper the proper functioning of the internal market, the enforcement of Croatia's national rules during the transitional periods referred to in Annex V shall not lead to border controls between Member States.

ARTICLE 41

If transitional measures are necessary to facilitate the transition from the existing regime in Croatia to that resulting from the application of the common agricultural policy under the conditions set out in this Act, they shall be adopted by the Commission in accordance with the procedure referred to in Article 195(2) of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)[1] in conjunction with Article 13(1)(b) of European Parliament and Council Regulation (EU) No 182/2011[2] or the relevant procedure as determined in the applicable legislation. They may be adopted during a period of three years following the date of accession and their application shall be limited to that period. The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, may extend this period.

Transitional measures referred to in the first subparagraph may also be adopted prior to the date of accession, if necessary. Such measures shall be adopted by the Council acting by qualified majority on a proposal from the Commission or, where they affect instruments initially adopted by the Commission, they shall be adopted by the Commission in accordance with the procedures required for adopting the instruments in question.

ARTICLE 42

If transitional measures are necessary to facilitate the transition from the existing regime in Croatia to that resulting from the application of the European Union veterinary, phytosanitary and food safety rules, such measures shall be adopted by the Commission in accordance with the relevant procedure as determined in the applicable legislation. These measures shall be taken during a period of three years following the date of accession and their application shall be limited to that period.

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 55, 28.2.2011, p. 13.

ARTICLE 43

The Council, acting by a qualified majority on a proposal from the Commission, shall define the terms under which:

(a) the requirement for an exit summary declaration may be waived for the products referred to in Article 28(2) of the TFEU leaving Croatia to cross the territory of Bosnia and Herzegovina at Neum ('Neum corridor');

(b) the requirement for an entry summary declaration may be waived for the products in the situation under point (a) when they re-enter the territory of Croatia after having crossed the territory of Bosnia and Herzegovina at Neum.

ARTICLE 44

The Commission may take all appropriate measures to ensure that the necessary statutory staff is maintained in Croatia for a maximum of 18 months following accession. During this period, officials, temporary staff and contract staff assigned to posts in Croatia before accession and who are required to remain in service in Croatia after the date of accession shall benefit from the same financial and material conditions as were applied before accession in accordance with the Staff Regulations of officials of the European Communities and the Conditions of Employment of other servants of the European Communities laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[1]. The administrative expenditure, including salaries for other necessary staff, shall be covered by the general budget of the European Union.

[1] OJ L 56, 4.3.1968, p. 1.

PART FIVE

PROVISIONS RELATING TO THE IMPLEMENTATION OF THIS ACT

TITLE I

ADAPTATIONS TO THE RULES OF THE INSTITUTIONS AND COMMITTEES

ARTICLE 45

The Union's institutions shall, in accordance with the respective procedures provided for in the original Treaties, make such adaptations to their Rules of Procedure as are rendered necessary by accession.

Adaptations to the rules of the Committees established by the original Treaties and to their Rules of Procedure as are rendered necessary by accession shall be made as soon as possible after accession.

TITLE II

APPLICABILITY OF THE ACTS OF THE INSTITUTIONS

ARTICLE 46

Upon accession, Croatia shall be considered as being an addressee, in accordance with the original Treaties, of directives and decisions within the meaning of Article 288 of the TFEU. Except with regard to directives and decisions which have entered into force pursuant to the third subparagraph of Article 297(1) and the second subparagraph of Article 297(2) of the TFEU, Croatia shall be considered as having received notification of such directives and decisions upon accession.

ARTICLE 47

1. Croatia shall put into effect the measures necessary for it to comply, from the date of accession, with the provisions of directives and decisions within the meaning of Article 288 of the TFEU, unless another time limit is provided for in this Act. Croatia shall communicate those measures to the Commission at the latest by the date of accession or, where later, by the time limit provided for in this Act.

2. To the extent that amendments to directives within the meaning of Article 288 of the TFEU introduced by this Act require modification of the laws, regulations or administrative provisions of the present Member States, the present Member States shall put into effect the measures necessary to comply, from the date of accession of Croatia, with the amended directives, unless another time limit is provided for in this Act. They shall communicate those measures to the Commission by the date of accession or, where later, by the time limit provided for in this Act.

ARTICLE 48

Provisions laid down by legislation, regulation or administrative action designed to ensure the protection of the health of workers and the general public in the territory of Croatia against the dangers arising from ionising radiations shall, in accordance with Article 33 of the EAEC Treaty, be communicated by Croatia to the Commission within three months of accession.

ARTICLE 49

At the duly substantiated request of Croatia submitted to the Commission no later than the date of accession, the Council acting on a proposal from the Commission, or the Commission, if the original act was adopted by the Commission, may take measures consisting of temporary derogations from acts adopted by the institutions between 1 July 2011 and the date of accession. The measures shall be adopted according to the voting rules governing the adoption of the act from which a temporary derogation is sought. Where these derogations are adopted after accession they may be applied as from the date of accession.

ARTICLE 50

Where acts of the institutions adopted prior to accession require adaptation by reason of accession, and the necessary adaptations have not been provided for in this Act or its Annexes, the Council, acting by a qualified majority on a proposal from the Commission, or the Commission, if the original act was adopted by the Commission, shall to this end adopt the necessary acts. Where these adaptations are adopted after accession they may be applied as from the date of accession.

ARTICLE 51

Unless otherwise stipulated in this Act, the Council, acting by a qualified majority on a proposal from the Commission, shall adopt the necessary measures to implement the provisions of this Act.

ARTICLE 52

The texts of the acts of the institutions adopted before accession and drawn up by these institutions in the Croatian language shall, from the date of accession, be authentic under the same conditions as the texts drawn up in the present official languages. They shall be published in the *Official Journal of the European Union* if the texts in the present languages were so published.

TITLE III

FINAL PROVISIONS

ARTICLE 53

Annexes I to IX, the Appendices thereto and the Protocol shall form an integral part of this Act.

ARTICLE 54

The Government of the Italian Republic shall remit to the Government of the Republic of Croatia a certified copy of the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, and the Treaties amending or supplementing them, including the Treaty concerning the accession of the Kingdom of Denmark, Ireland and the United Kingdom of Great Britain and Northern Ireland, the Treaty concerning the accession of the Hellenic Republic, the Treaty concerning the accession of the Kingdom of Spain and the Portuguese Republic, the Treaty concerning the accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden, the Treaty concerning the accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the Treaty concerning the accession of the Republic of Bulgaria and Romania, in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages.

The texts of those Treaties, drawn up in the Croatian language, shall be annexed to this Act. Those texts shall be authentic under the same conditions as the texts of the Treaties referred to in the first paragraph, drawn up in the present languages.

ARTICLE 55

A certified copy of the international agreements deposited in the archives of the General Secretariat of the Council of the European Union shall be remitted to the Government of the Republic of Croatia by the Secretary General.

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ANNEX I

List of conventions and protocols to which the Republic of Croatia accedes upon accession (referred to in Article 3(4) of the Act of Accession)

1. Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (OJ L 225, 20.8.1990, p. 10)

   – Convention of 21 December 1995 on the accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden to the Convention on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (OJ C 26, 31.1.1996, p. 1)

   – Protocol of 25 May 1999 amending the Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (OJ C 202, 16.7.1999, p. 1)

   – Convention of 8 December 2004 on the accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic to the Convention on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (OJ C 160, 30.6.2005, p. 1)

2. Convention of 26 July 1995, drawn up on the basis of Article K.3 of the Treaty on European Union, on the protection of the European Communities' financial interests (OJ C 316, 27.11.1995, p. 49)

   – Protocol of 27 September 1996, drawn up on the basis of Article K.3 of the Treaty on European Union, to the Convention on the protection of the European Communities' financial interests (OJ C 313, 23.10.1996, p. 2)

– Protocol of 29 November 1996, drawn up on the basis of Article K.3 of the Treaty on European Union, on the interpretation, by way of preliminary rulings, by the Court of Justice of the European Communities of the Convention on the protection of the European Communities' financial interests (OJ C 151, 20.5.1997, p. 2)

– Second Protocol of 19 June 1997, drawn up on the basis of Article K.3 of the Treaty on European Union, to the Convention on the protection of the European Communities' financial interests (OJ C 221, 19.7.1997, p. 12)

3. Convention of 26 May 1997, drawn up on the basis of Article K.3(2)(c) of the Treaty on European Union, on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union (OJ C 195, 25.6.1997, p. 2)

4. Convention of 18 December 1997, drawn up on the basis of Article K.3 of the Treaty on European Union, on mutual assistance and cooperation between customs administrations (OJ C 24, 23.1.1998, p. 2)

5. Convention of 17 June 1998, drawn up on the basis of Article K.3 of the Treaty on European Union, on driving disqualifications (OJ C 216, 10.7.1998, p. 2)

6. Convention of 29 May 2000, established by the Council in accordance with Article 34 of the Treaty on European Union, on Mutual Assistance in Criminal Matters between the Member States of the European Union (OJ C 197, 12.7.2000, p. 3)

– Protocol of 16 October 2001, established by the Council in accordance with Article 34 of the Treaty on European Union, to the Convention on Mutual Assistance in Criminal Matters between the Member States of the European Union (OJ C 326, 21.11.2001, p. 2)

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ANNEX II

List of provisions of the Schengen *acquis* as integrated into the framework of the European Union and the acts building upon it or otherwise related to it, to be binding on and applicable in the Republic of Croatia as from accession (referred to in Article 4(1) of the Act of Accession)

1. The Agreement between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders dated 14 June 1985[1].

2. The following provisions of the Convention signed in Schengen on 19 June 1990 implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at their common borders, its related Final Act and Joint Declarations[2], as amended by certain of the acts listed in paragraph 8 below:

   Article 1 to the extent that it relates to the provisions of this paragraph; Article 26; Article 39; Articles 44 to 49 (with the exception of Article 47(4) and Article 49(a)), Article 51, Articles 54 to 58; Article 62(3); Articles 67 to 69; Articles 71 and 72; Articles 75 and 76; Article 82; Article 91; Articles 126 to 130 to the extent that they relate to the provisions of this paragraph; and Article 136; Joint Declarations 1 and 3 of the Final Act.

3. The following provisions of the Agreements on Accession to the Convention signed in Schengen on 19 June 1990 implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at their common borders, their Final Acts and the related Declarations, as amended by certain of the acts listed in paragraph 8 below:

[1] OJ L 239, 22.9.2000, p. 13.
[2] OJ L 239, 22.9.2000, p. 19.

(a) the Agreement signed on 19 December 1996 on the Accession of the Kingdom of Denmark:

– Articles 5(2) and 6,

(b) the Agreement signed on 19 December 1996 on the Accession of the Republic of Finland:

– Article 5,
– Declaration by the Government of the Republic of Finland on the Åland islands in Part III of the Final Act;

(c) the Agreement signed on 19 December 1996 on the Accession of the Kingdom of Sweden:

– Article 5.

4. The following agreements and arrangements which build upon the Schengen *acquis* or otherwise relate to it:

– the Agreement of 18 May 1999 concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latters' association with the implementation, application and development of the Schengen *acquis*, including the Annexes, its Final Act, Declarations and the Exchanges of Letters annexed thereto, approved by Council Decision 1999/439/EC (OJ L 176, 10.7.1999, p. 35)

– the Agreement of 30 June 1999 concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway on the establishment of rights and obligations between Ireland and the United Kingdom of Great Britain and Northern Ireland, on the one hand, and the Republic of Iceland and the Kingdom of Norway, on the other, in areas of the Schengen *acquis* which apply to these States, approved by Council Decision 2000/29/EC (OJ L 15, 20.1.2000, p. 1)

– the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* signed on 26 October 2004 and approved by Council Decision 2008/146/EC and Council Decision 2008/149/JHA (OJ L 53, 27.2.2008, p. 1 and p. 50)

– the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* signed on 28 February 2008[1]

– the Arrangement between the European Community and the Republic of Iceland and the Kingdom of Norway on the modalities of the participation by those States in the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union, including the Joint Declaration annexed thereto, signed on 1 February 2007 and approved by Council Decision 2007/511/EC (OJ L 188, 20.7.2007, p. 15)

– the Arrangement between the European Community, of the one part, and the Swiss Confederation and the Principality of Liechtenstein, of the other part, on the modalities of the participation by those States in the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union, including the Annex and Joint Declarations annexed thereto, signed on 30 September 2009 and approved by Council Decision 2010/490/EU (OJ L 243, 16.9.2010, p. 2)

[1] As long as this Protocol is not yet concluded, insofar as it applies only provisionally. Council Decisions on the signature have been published in OJ L 83 of 26.3.2008, p.3 and p.5.

– the Agreement between the European Community and the Republic of Iceland, the Kingdom of Norway, the Swiss Confederation and the Principality of Liechtenstein on supplementary rules in relation to the External Borders Fund for the period 2007 to 2013, including the Declarations annexed thereto, signed on 19 March 2010 and provisionally applied pursuant to Council Decision 2010/374/EC (OJ L 169, 3.7.2010, p. 22)[1].

5. The provisions of the following Decisions of the Executive Committee established by the Convention signed in Schengen on 19 June 1990 implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at their common borders, as amended by certain of the acts listed in paragraph 8 below:

SCH/Com-ex (93) 10 Decision of the Executive Committee of 14 December 1993 concerning the declarations by the Ministers and State Secretaries

SCH/Com-ex (93) 14 Decision of the Executive Committee of 14 December 1993 on improving practical judicial cooperation for combating drug trafficking

SCH/Com-ex (94) 16 rev Decision of the Executive Committee of 21 November 1994 on the acquisition of common entry and exit stamps

SCH/Com-ex (94) 28 rev Decision of the Executive Committee of 22 December 1994 on the certificate provided for in Article 75 to carry narcotic drugs and psychotropic substances

SCH/Com-ex (94) 29 rev 2 Decision of the Executive Committee of 22 December 1994 on bringing into force the Convention implementing the Schengen Agreement of 19 June 1990

SCH/Com-ex (95) 21 Decision of the Executive Committee of 20 December 1995 on the swift exchange between the Schengen States of statistical and specific data on possible malfunctions at the external borders

[1] As long as this Agreement is not yet concluded, insofar as it applies provisionally.

SCH/Com-ex (98) 1 rev 2 Decision of the Executive Committee of 21 April 1998 on the activities of the Task Force, insofar as it relates to the provisions in paragraph 2 above

SCH/Com-ex (98) 26 def Decision of the Executive Committee of 16 September 1998 setting up a Standing Committee on the evaluation and implementation of Schengen

SCH/Com-ex (98) 37 def 2 Decision of the Executive Committee of 27 October 1998 on the adoption of measures to fight illegal immigration, insofar as it relates to the provisions in paragraph 2 above

SCH/Com-ex (98) 52 Decision of the Executive Committee of 16 December 1998 on the Handbook on cross-border police-cooperation, insofar as it relates to the provisions in paragraph 2 above

SCH/Com-ex (98) 59 rev Decision of the Executive Committee of 16 December 1998 on coordinated deployment of document advisers

SCH/Com-ex (99) 1 rev 2 Decision of the Executive Committee of 28 April 1999 on the drugs situation

SCH/Com-ex (99) 6 Decision of the Executive Committee of 28 April 1999 on the Schengen *acquis* relating to telecommunications

SCH/Com-ex (99) 7 rev 2 Decision of the Executive Committee of 28 April 1999 on liaison officers

SCH/Com-ex (99) 8 rev 2 Decision of the Executive Committee of 28 April 1999 on general principles governing the payment of informers

SCH/Com-ex (99) 10 Decision of the Executive Committee of 28 April 1999 on the illegal trade in firearms.

6. The following Declarations of the Executive Committee established by the Convention signed in Schengen on 19 June 1990 implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at their common borders, to the extent that they relate to the provisions in paragraph 2 above:

SCH/Com-ex (96) decl 6 rev 2 Declaration of the Executive Committee of 26 June 1996 on extradition

SCH/Com-ex (97) decl 13 rev 2 Declaration of the Executive Committee of 9 February 1998 on the abduction of minors.

7. The following Decisions of the Central Group established by the Convention signed in Schengen on 19 June 1990 implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at their common borders, to the extent that they relate to the provisions in paragraph 2 above:

SCH/C (98) 117 Decision of the Central Group of 27 October 1998 on the adoption of measures to fight illegal immigration

SCH/C (99) 25 Decision of the Central Group of 22 March 1999 on general principles governing the payment of informers.

8. The following acts which build upon the Schengen *acquis* or otherwise relate to it:

Council Regulation (EC) No 1683/95 of 29 May 1995 laying down a uniform format for visas (OJ L 164, 14.7.1995, p. 1)

Council Decision 1999/307/EC of 1 May 1999 laying down the detailed arrangements for the integration of the Schengen Secretariat into the General Secretariat of the Council (OJ L 119, 7.5.1999, p. 49)

Council Decision 1999/435/EC of 20 May 1999 concerning the definition of the Schengen *acquis* for the purpose of determining, in conformity with the relevant provisions of the Treaty establishing the European Community and the Treaty on European Union, the legal basis for each of the provisions or decisions which constitute the *acquis* (OJ L 176, 10.7.1999, p. 1)

Council Decision 1999/436/EC of 20 May 1999 determining, in conformity with the relevant provisions of the Treaty establishing the European Community and the Treaty on European Union, the legal basis for each of the provisions or decisions which constitute the Schengen *acquis* (OJ L 176, 10.7.1999, p. 17)

Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two states with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31)

Council Decision 1999/848/EC of 13 December 1999 on the full application of the Schengen *acquis* in Greece (OJ L 327, 21.12.1999, p. 58)

Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* (OJ L 131, 1.6.2000, p. 43)

Council Decision 2000/586/JHA of 28 September 2000 establishing a procedure for amending Articles 40(4) and (5), 41(7) and 65(2) of the Convention implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at common borders (OJ L 248, 3.10.2000, p. 1)

Council Decision 2000/777/EC of 1 December 2000 on the application of the Schengen *acquis* in Denmark, Finland and Sweden, and in Iceland and Norway (OJ L 309, 9.12.2000, p. 24)

Council Regulation (EC) No 539/2001 of 15 March 2001 listing the third countries whose nationals must be in possession of visas when crossing the external borders and those whose nationals are exempt from that requirement (OJ L 81, 21.3.2001, p. 1)

Council Directive 2001/51/EC of 28 June 2001 supplementing the provisions of Article 26 of the Convention implementing the Schengen Agreement of 14 June 1985 (OJ L 187, 10.7.2001, p. 45)

Council Regulation (EC) No 333/2002 of 18 February 2002 on a uniform format for forms for affixing the visa issued by Member States to persons holding travel documents not recognised by the Member State drawing up the form (OJ L 53, 23.2.2002, p. 4)

Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20)

Council Regulation (EC) No 1030/2002 of 13 June 2002 laying down a uniform format for residence permits for third-country nationals (OJ L 157, 15.6.2002, p. 1)

Council Framework Decision 2002/946/JHA of 28 November 2002 on the strengthening of the penal framework to prevent the facilitation of unauthorised entry, transit and residence (OJ L 328, 5.12.2002, p. 1)

Council Directive 2002/90/EC of 28 November 2002 defining the facilitation of unauthorised entry, transit and residence (OJ L 328, 5.12.2002, p. 17)

Council Decision 2003/170/JHA of 27 February 2003 on the common use of liaison officers posted abroad by the law enforcement agencies of the Member States (OJ L 67, 12.3.2003, p. 27)

Council Decision 2003/725/JHA of 2 October 2003 amending the provisions of Article 40(1) and (7) of the Convention implementing the Schengen Agreement of 14 June 1985 on the gradual abolition of checks at common borders (OJ L 260, 11.10.2003, p. 37)

Council Directive 2003/110/EC of 25 November 2003 on assistance in cases of transit for the purposes of removal by air (OJ L 321, 6.12.2003, p. 26)

Council Regulation (EC) No 377/2004 of 19 February 2004 on the creation of an immigration liaison officers network (OJ L 64, 2.3.2004, p. 1)

Council Directive 2004/82/EC of 29 April 2004 on the obligation of carriers to communicate passenger data (OJ L 261, 6.8.2004, p. 24)

Council Decision 2004/573/EC of 29 April 2004 on the organisation of joint flights for removals from the territory of two or more Member States, of third-country nationals who are subjects of individual removal orders (OJ L 261, 6.8.2004, p. 28)

Council Decision 2004/512/EC of 8 June 2004 establishing the Visa Information System (VIS) (OJ L 213, 15.6.2004, p. 5 and OJ L 142M, 30.5.2006, p. 60)

Council Regulation (EC) No 2007/2004 of 26 October 2004 establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (OJ L 349, 25.11.2004, p. 1 and OJ L 153M, 7.6.2006, p. 136)

Council Regulation (EC) No 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States (OJ L 385, 29.12.2004, p. 1 and OJ L 153M, 7.6.2006, p. 375)

Council Decision 2004/926/EC of 22 December 2004 on the putting into effect of parts of the Schengen *acquis* by the United Kingdom of Great Britain and Northern Ireland (OJ L 395, 31.12.2004, p. 70)

Council Decision 2005/267/EC of 16 March 2005 establishing a secure web-based Information and Coordination Network for Member States' Migration Management Services (OJ L 83,1.4.2005, p. 48 and OJ L 159M, 13.6.2006, p. 288)

Regulation (EC) No 562/2006 of the European Parliament and of the Council of 15 March 2006 establishing a Community Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 105, 13.4.2006, p.1), except the first sentence of Article 1, Article 5(4)(a), Title III and the provisions of Title II and the annexes thereto referring to the Schengen Information System (SIS)

Council Framework Decision 2006/960/JHA of 18 December 2006 on simplifying the exchange of information and intelligence between law enforcement authorities of the Member States of the European Union (OJ L 386, 29.12.2006, p. 89)

Regulation (EC) No 1931/2006 of the European Parliament and of the Council of 20 December 2006 laying down rules on local border traffic at the external land borders of the Member States and amending the provisions of the Schengen Convention (OJ L 405, 30.12.2006, p. 1), except Articles 4 (b) and 9 (c)

Council Decision 2007/471/EC of 12 June 2007 on the application of the provisions of the Schengen *acquis* relating to the Schengen Information System in the Czech Republic, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic (OJ L 179, 7.7.2007, p. 46)

Regulation (EC) No 863/2007 of the European Parliament and of the Council of 11 July 2007 establishing a mechanism for the creation of Rapid Border Intervention Teams and amending Council Regulation (EC) No 2007/2004 as regards that mechanism and regulating the tasks and powers of guest officers (OJ L 199, 31.7.2007, p. 30), except the provisions of Article 6(8) and (9) to the extent that they refer to access being given to the Schengen Information System

Council Decision 2007/801/EC of 6 December 2007 on the full application of the provisions of the Schengen *acquis* in the Czech Republic, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic (OJ L 323, 8.12.2007, p. 34)

Council Decision 2008/421/EC of 5 June 2008 on the application of the provisions of the Schengen *acquis* relating to the Schengen Information System in the Swiss Confederation (OJ L 149, 7.6.2008, p. 74)

Article 6 of Council Decision 2008/633/JHA of 23 June 2008 concerning access for consultation of the Visa Information System (VIS) by designated authorities of Member States and by Europol for the purposes of the prevention, detection and investigation of terrorist offences and of other serious criminal offences (OJ L 218, 13.8.2008, p. 129)

Council Decision 2008/903/EC of 27 November 2008 on the full application of the provisions of the Schengen *acquis* in the Swiss Confederation (OJ L 327, 5.12.2008, p. 15)

Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters (OJ L 350, 30.12.2008, p. 60)

Directive 2008/115/EC of the European Parliament and of the Council of 16 December 2008 on common standards and procedures in Member States for returning illegally staying third-country nationals (OJ L 348, 24.12.2008, p. 98)

Article 3 of Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas (Visa Code) (OJ L 243, 15.9.2009, p. 1)

Council Decision 2010/252/EU of 26 April 2010 supplementing the Schengen Borders Code as regards the surveillance of the sea external borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (OJ L 111, 4.5.2010, p. 20)

Council Decision 2010/365/EU of 29 June 2010 on the application of the provisions of the Schengen *acquis* relating to the Schengen Information System in the Republic of Bulgaria and Romania (OJ L 166, 1.7.2010, p. 17).

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ANNEX III

List referred to in Article 15 of the Act of Accession: adaptations to acts adopted by the institutions

1. FREEDOM TO PROVIDE SERVICES

32005 L 0036: Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

(a) Article 23(5) is replaced by the following:

'5. Without prejudice to Article 43(b), each Member State shall recognise evidence of formal qualifications as doctor giving access to the professional activities of doctor with basic training and specialised doctor, as nurse responsible for general care, as dental practitioner, as specialised dental practitioner, as veterinary surgeon, as midwife, as pharmacist and as architect held by nationals of the Member States and issued by the former Yugoslavia, or whose training commenced,

(a) for Slovenia, before 25 June 1991, and
(b) for Croatia, before 8 October 1991,

where the authorities of the aforementioned Member States attest that such evidence has the same legal validity within their territory as the evidence which they issue and, with respect to architects, as the evidence of formal qualifications specified for those Member States in Annex VI, point 6, as regards access to the professional activities of doctor with basic training, specialised doctor, nurse responsible for general care, dental practitioner, specialised dental practitioner, veterinary surgeon, midwife, pharmacist with respect to the activities referred to in Article 45(2), and architect with respect to the activities referred to in Article 48, and the pursuit of such activities.

Such an attestation must be accompanied by a certificate issued by those same authorities stating that such persons have effectively and lawfully been engaged in the activities in question within their territory for at least three consecutive years during the five years prior to the date of issue of the certificate.'

(b) The following Article is inserted:

'*Article 43(b)*

Acquired rights in midwifery shall not apply to the following qualifications which were obtained in Croatia before 1 July 2013: viša medicinska sestra ginekološko- opstetričkog smjera (High Gynaecology-Obstetrical Nurse), medicinska sestra ginekološko-opstetričkog smjera (Gynaecology-Obstetrical Nurse), viša medicinska sestra primaljskog smjera (High Nurse with Midwifery Degree), medicinska sestra primaljskog smjera (Nurse with Midwifery Degree), ginekološko-opstetrička primalja (Gynaecology-Obstetrical Midwife) and primalja (Midwife).'

2. **INTELLECTUAL PROPERTY LAW**

I. COMMUNITY TRADE MARK

32009 R 0207: Council Regulation (EC) No 207/2009 of 27 February 2009 on the Community trade mark (OJ L 78, 24.3.2009, p. 1).

Article 165(1) is replaced by the following:

'1. As from the date of accession of Bulgaria, the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovenia and Slovakia (hereinafter referred to as "new Member State(s)"), a Community trade mark registered or applied for pursuant to this Regulation before the respective dates of accession shall be extended to the territory of those Member States in order to have equal effect throughout the Community.'

II. SUPPLEMENTARY PROTECTION CERTIFICATES

1. 31996 R 1610: Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ L 198, 8.8.1996, p. 30).

(a) The following point is added to Article 19a:

'(m) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months of the date of accession.'

(b) Article 20(2) is replaced by the following:

'2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession.'

2. 32009 R 0469: Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

(a) The following point is added to Article 20:

'(m) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2003 may be granted a certificate in Croatia, provided that the application for a certificate is lodged within six months of the date of accession.'

(b) Article 21(2) is replaced by the following:

'2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession.'

III. COMMUNITY DESIGNS

32002 R 0006: Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (OJ L 3, 5.1.2002, p. 1).

Article 110a(1) is replaced by the following:

'1. As from the date of accession of Bulgaria, the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovenia and Slovakia (hereinafter referred to as "new Member State(s)"), a Community design protected or applied for pursuant to this Regulation before the respective date of accession shall be extended to the territory of those Member States in order to have equal effect throughout the Community.'

3. FINANCIAL SERVICES

32006 L 0048: Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions (OJ L 177, 30.6.2006, p. 1).

In Article 2, the following is inserted after the entry for France:

'– in Croatia, the 'kreditne unije' and the 'Hrvatska banka za obnovu i razvitak','

4. **AGRICULTURE**

1. 31991 R 1601: Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails (OJ L 149, 14.6.1991, p. 1).

   In Annex II, the following is inserted after the geographical designation "Nürnberger Glühwein":

   'Samoborski bermet'

2. 32007 R 1234: Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

(a) In Article 66, the following paragraph is inserted:

   '4a. For Croatia a special restructuring reserve shall be established as set out in point 2 of Annex IX. This reserve shall be released as from 1 April of the first quota year after accession to the extent that the on-farm consumption of milk and milk products in Croatia has decreased in the period 2008-2012.

   The decision on releasing the reserve and of its distribution to the deliveries and direct sales quota shall be taken by the Commission in accordance with the procedure referred to in Article 195(2) on the basis of an assessment of a report to be submitted by Croatia by 31 December 2013. This report shall detail the results and trends of the actual restructuring process in Croatia's dairy sector, and in particular the shift from production for on-farm consumption to production for the market.'

(b) In Article 103k(1), the following subparagraph is added:

'This paragraph shall not apply to Croatia for the financial year 2013. Croatia shall submit to the Commission a draft five-year support programme for the 2014-2018 programme period.'

(c) In Annex III, Part II, point 13 is replaced by the following:

'13. "full-time refiner" means a production unit:

– of which the sole activity consists of refining imported raw cane sugar,

or

– which refined in the marketing year 2004/2005 a quantity of at least 15 000 tonnes of imported raw cane sugar. For the purpose of this indent, in the case of Croatia the marketing year shall be that of 2007/2008.'

(d) Annex VI is replaced by the following:

'ANNEX VI

NATIONAL AND REGIONAL QUOTAS

from the 2010/2011 marketing year onwards

(*in tonnes*)

Member States or regions (1)	Sugar (2)	Isoglucose (3)	Inulin syrup (4)
Belgium	676 235,0	114 580, 2	0
Bulgaria	0	89 198,0	
Czech Republic	372 459,3		
Denmark	372 383,0		
Germany	2 898 255,7	56 638,2	
Ireland	0		
Greece	158 702,0	0	
Spain	498 480,2	53 810,2	
France (metropolitan)	3 004 811, 15		0
French overseas departments	432 220, 05		
Croatia	192 877,0		
Italy	508 379,0	32 492,5	
Latvia	0		
Lithuania	90 252,0		
Hungary	105 420,0	220 265,8	
Netherlands	804 888,0	0	0
Austria	351 027,4		
Poland	1 405 608,1	42 861,4	
Portugal (mainland)	0	12 500,0	
Autonomous Region of the Azores	9 953,0		
Romania	104 688,8	0	
Slovenia	0		
Slovakia	112 319,5	68 094,5	
Finland	80 999,0	0	
Sweden	293 186,0		
United Kingdom	1 056 474,0	0	
TOTAL	13 529 618,20	690 440,8	0

'

(e) In Annex IX, point 1, the following is inserted after the entry for France in the columns relating to the production years 2013/14 and 2014/15:

'

Member State	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
Croatia						765 000	765 000

'

(f) In Annex IX, point 2, the table is replaced by the following:

'

Member State	Tonnes
Bulgaria	39 180
Croatia	15 000
Romania	188 400

'

(g) In Annex X, the following is inserted after the entry for France:

'

Croatia	40,70

'

(h) In Annex Xb, the following table is added:

' *in 1 000 EUR*

Budget year	2013	2014	2015	2016	from 2017 onwards
HR	0	11 885	11 885	11 885	10 832

'

(i) In paragraph 2 of the Appendix to Annex XIb, the following point is added:

'(h) in Croatia, the areas planted with vines in the following sub-regions: Moslavina, Prigorje-Bilogora, Plešivica, Pokuplje and Zagorje-Međimurje.'

(j) In paragraph 3 of the Appendix to Annex XIb, the following point is added:

'(h) in Croatia, areas planted with vines in the following sub-regions: Hrvatsko Podunavlje and Slavonija.'

(k) In paragraph 4 of the Appendix to Annex XIb, the following point is added:

'(g) in Croatia, areas planted with vines in the following sub-regions: Hrvatska Istra, Hrvatsko primorje, Dalmatinska zagora, Sjeverna Dalmacija and Srednja i Južna Dalmacija.'

3. 32008 R 0110: Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

(a) In Article 20, the following paragraph is added:

'4. The deadline referred to in paragraph 1 for submission of technical files shall also apply to the geographical indications of Croatia listed in Annex III.'

(b) In Annex III, point 9, the following geographical indications are added:

'

	Hrvatska loza	Croatia
	Hrvatska stara šljivovica	Croatia
	Slavonska šljivovica	Croatia

'

(c) In Annex III, point 32, the following geographical indication is added:

'

	Hrvatski pelinkovac	Croatia

'

(d) In Annex III, the following point is inserted:

'

39. *Maraschino/ Marrasquino/ Maraskino*	*Zadarski maraschino*	*Croatia*

'

(e) In Annex III, under product category "Other spirit drinks", the following geographical indication is added:

'

	Hrvatska travarica	Croatia

'

4. 32009 R 0073: Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 (OJ L 30, 31.1.2009, p. 16).

(a) Article 2(g) is replaced by the following:

'(g) "new Member States" means Bulgaria, the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovenia and Slovakia;'

(b) In Article 6(2), the first subparagraph is replaced by the following:

'2. The Member States other than the new Member States shall ensure that land which was under permanent pasture at the date provided for the area aid applications for 2003 is maintained under permanent pasture. The new Member States other than Bulgaria, Croatia and Romania shall ensure that land which was under permanent pasture on 1 May 2004 is maintained under permanent pasture. Bulgaria and Romania shall ensure that land which was under permanent pasture on 1 January 2007 is maintained under permanent pasture. Croatia shall ensure that land which was under permanent pasture on 1 July 2013 is maintained under permanent pasture.'

(c) Article 33(1)(b)(iv) is replaced by the following:

'(iv) pursuant to Article 47(2), Article 57a, Article 59, the third subparagraph of Article 64(2), Article 65 and Article 68(4)(c).'

(d) In Article 51(1), the following subparagraph is added:

'Croatia may decide to make use of the options provided for in Article 52 and Article 53(1) of this Regulation. This decision shall be notified to the Commission by 15 July 2013.'

(e) In Article 51(2), the following subparagraph is added:

'By way of derogation from the second subparagraph, in the case of Croatia, this ceiling is determined on the basis of the national ceilings set out in Articles 104(4) and 112(5) of this Regulation as regards respectively sheepmeat and goatmeat payments and beef and veal payments referred to in Articles 52 and 53, taking into account the schedule of introduction of direct payments laid down in Article 121.'

(f) In Article 52, the following subparagraph is inserted after the first subparagraph:

'By way of derogation from the first subparagraph, Croatia may retain up to 50 % of the amount resulting from the ceiling referred to in the third subparagraph of Article 51(2) in order to make, on a yearly basis, an additional payment to farmers.'

(g) In Article 53(1), the following subparagraph is inserted after the first subparagraph:

'By way of derogation from the first subparagraph, Croatia may retain all or part of the amount resulting from the ceiling referred to in the third subparagraph of Article 51(2) in order to make, on a yearly basis, an additional payment to farmers.'

(h) The title of Chapter 3 is replaced by the following:

'Implementation in the new Member States having applied the single area payment scheme and in Croatia'

(i) The title of Article 55 is replaced by the following:

'Introduction of the single payment scheme in the Members States having applied the single area payment scheme and in Croatia'

(j) In Article 55(1), the first subparagraph is replaced by the following:

'1. Save as otherwise provided for in this Chapter, this Title shall apply to the new Member States having applied the single area payment scheme provided for in Chapter 2 of Title V and to Croatia.'

(k) In Article 57(1), the following sentence is added:

'For Croatia this reduction shall not be higher than 20 % of the annual ceiling as indicated in table 3 of Annex VIII.'

(l) In Article 57(3), the following sentence is added:

'In Croatia, the use of the national reserve shall be subject to authorisation by the Commission by means of an implementing act without the assistance of the Committee referred to in Article 141. The Commission shall examine, in particular, the establishment of any national direct payment scheme applicable prior to the date of accession and the conditions under which it applied. The request to authorise the national reserve shall be sent by Croatia to the Commission by 15 July 2013.'

(m) The following Article is inserted:

'Article 57a

Special national de-mining reserve in Croatia

1. Croatia shall create a special national de-mining reserve which shall be used for the purpose of allocating, during a period of ten years after accession and in accordance with objective criteria and in such a way as to ensure equal treatment between farmers and to avoid market and competition distortions, payment entitlements to farmers with de-mined land returning to use for agricultural activities.

2. Land eligible for allocation of payment entitlements under this Article shall not be eligible for allocation of payment entitlements under Articles 59 and 61.

3. The value of the payment entitlements established under this Article shall not be higher than the value of the payment entitlements established in accordance with Articles 59 and 61, respectively.

4. The maximum amount allocated to the special national de-mining reserve shall be EUR 9 600 000 and shall be subject to the schedule of introduction of direct payments set out in Article 121. The maximum amounts per year shall be as follows:

(EUR 1 000)

Croatia	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Maximum amount for the specific national de-mining reserve	2 400	2 880	3 360	3 840	4 800	5 760	6 720	7 680	8 640	9 600

5. In the first year of implementation of the single payment scheme Croatia shall allocate payment entitlements to the farmers on the basis of the land which has been de-mined and declared by farmers in the aid applications submitted in the first year of implementation of the single payment scheme and returned to use for agricultural activities between 1 January 2005 and 31 December 2012.

6. For the years 2013 to 2022, payment entitlements shall be allocated to farmers on the basis of the de-mined land declared by the farmers in the year in question on condition that such land was returned to use for agricultural activities during the previous calendar year, and which has been notified to the Commission in accordance with paragraph 9.

7. In order to ensure an appropriate use of Union funds, the Commission shall, in accordance with the procedure referred to in Article 141(2), modify the ceiling in table 3 of Annex VIII in order to add thereto the amounts from the special national de-mining reserve which have been allocated by 31 December 2022.

8. All land declared for the purpose of this Article shall comply with the definition of eligible hectare provided for in Article 34(2).

9. By 15 July 2013, Croatia shall notify the Commission of the area of land eligible according to paragraph 5, indicating both land eligible for the support levels according to Article 59, and land eligible for the support levels according to Article 61. This notification shall also include information on the corresponding budgetary envelopes and the unused amounts. From 2014 onwards, a communication with the same information shall be sent to the Commission no later than 31 January every year and shall cover the previous calendar year, specifying areas returned to use for agricultural activities and the corresponding budgetary envelopes.

10. By 31 December 2012, all mined and de-mined land on which farmers might receive payment entitlement from this special national de-mining reserve shall be identified in the integrated administration and control system established in accordance with Chapter 4 of Title II.'

(n) In Article 59, the following paragraph is added:

'4. The Commission shall, in accordance with the procedure referred to in Article 141(2), adopt rules on the initial allocation of payment entitlements in Croatia.'

(o) In Article 61, the following paragraph is added:

"For Croatia, the above mentioned dates shall be 30 June 2011.'

(p) In Article 69(1), the following is added to the first subparagraph:

'Croatia may decide, by the date of accession, to use from the first year of implementation of the single payment scheme as provided for in Article 59(2) up to 10% of the national ceiling referred to in Article 40 as indicated in table 3 of Annex VIII.'

(q) In Article 69(9), the following is inserted to the first subparagraph:

'(aa) specified for the year 2022 in the case of Croatia.'

(r) Article 104(4) is replaced by the following:

'4. The following national ceilings shall apply:

Member States	National ceiling
Bulgaria	2 058 483
Czech Republic	66 733
Denmark	104 000
Estonia	48 000
Spain	19 580 000
France	7 842 000
Croatia	542 651
Cyprus	472 401
Latvia	18 437
Lithuania	17 304
Hungary	1 146 000
Poland	335 880
Portugal	2 690 000
Romania	5 880 620
Slovenia	84 909
Slovakia	305 756
Finland	80 000
Total	41 273 174

'

(s) In Article 112(5), the following is inserted after the entry for France:

'

Croatia	105 270

'

(t) Article 121 is replaced by the following:

'*Article 121*

Introduction of direct payments

In the new Member States other than Bulgaria, Croatia and Romania, direct payments shall be introduced in accordance with the following schedule of increments expressed as a percentage of the then applicable level of such payments in the Member States other than the new Member States:

— 60 % in 2009,
— 70 % in 2010,
— 80 % in 2011,
— 90 % in 2012,
— 100 % as from 2013.

In Bulgaria and Romania, direct payments shall be introduced in accordance with the following schedule of increments expressed as a percentage of the then applicable level of such payments in the Member States other than the new Member States:

- 35 % in 2009,
- 40 % in 2010,
- 50 % in 2011,
- 60 % in 2012,
- 70 % in 2013,
- 80 % in 2014,
- 90 % in 2015,
- 100 % as from 2016.

In Croatia, direct payments shall be introduced in accordance with the following schedule of increments expressed as a percentage of the then applicable level of such payments in the Member States other than the new Member States:

- 25 % in 2013,
- 30 % in 2014,
- 35 % in 2015,
- 40 % in 2016,
- 50 % in 2017,
- 60 % in 2018,
- 70 % in 2019,
- 80 % in 2020,
- 90 % in 2021,
- 100 % as from 2022.'

(u) In Article 132(2), the following point is added:

'(c) By way of derogation from points (a) and (b), Croatia shall have the possibility to complement direct payments up to 100% of the level applicable in Member States other than the new Member States,'.

(v) In Annex VII, the following is inserted after the entry for France:

'

Croatia	100	1

'

(w) In Annex VIII, the following table is added:

'*Table 3(*)*

Member State	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Croatia	93 250	111 900	130 550	149 200	186 500	223 800	261 100	298 400	335 700	373 000

(*) Ceilings calculated taking into account of the schedule of increments provided for in Article 121.'

5. **FISHERIES**

1. 32002 R 2371: Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2002, p. 59).

(a) In Annex I, the following parts are added:

'11. COASTAL WATERS OF CROATIA*

Geographical area	Member State	Species	Importance or particular characteristics
12 miles limited to the sea area under the sovereignty of Croatia situated to the north of the 45 degrees and 10 minutes parallel north latitude along the west Istrian coast, from the outer limit of the territorial sea of Croatia, where this parallel touches the land of the west Istrian coast (the cape Grgatov rt Funtana)	Slovenia	Demersal and small pelagic species including sardine and anchovy	100 tonnes for a maximum number of 25 fishing vessels which includes 5 fishing vessels equipped with trawl nets

* The above mentioned regime shall apply from the full implementation of the arbitration award resulting from the Arbitration Agreement between Slovenia and Croatia, signed in Stockholm on 4 November 2009.

12. COASTAL WATERS OF SLOVENIA*

Geographical area	Member State	Species	Importance or particular characteristics
12 miles limited to the sea area under the sovereignty of Slovenia situated to the north of the 45 degrees and 10 minutes parallel north latitude along the west Istrian coast, from the outer limit of the territorial sea of Croatia, where this parallel touches the land of the west Istrian coast (the cape Grgatov rt Funtana)	Croatia	Demersal and small pelagic species including sardine and anchovy	100 tonnes for a maximum number of 25 fishing vessels which includes 5 fishing vessels equipped with trawl nets

* The above mentioned regime shall apply from the full implementation of the arbitration award resulting from the Arbitration Agreement between Slovenia and Croatia, signed in Stockholm on 4 November 2009.'

2. 32006 R 1198: Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund (OJ L 223, 15.8.2006, p. 1).

(a) In Article 27, the following paragraph is added:

'5. The EFF may contribute to the financing of a scheme of individual premiums for fishers who will benefit from the access regime laid down in Part 11 of Annex I of Regulation (EC) No 2371/2002 as amended by the Act of Accession. The scheme may only apply during the period 2014 to 2015 or, if this occurs earlier, up until the date of the full implementation of the arbitration award resulting from the Arbitration Agreement between Slovenia and Croatia, signed in Stockholm on 4 November 2009.'

(b) Article 29(3) is replaced by the following:

'3. By way of derogation from paragraph 2, in the outermost regions and the outlying Greek islands as well as in the Croatian islands Dugi otok, Vis, Mljet and Lastovo, aid may be granted to all enterprises.'

(c) Article 35(4) is replaced by the following:

'4. By way of derogation from paragraph 3, in the outermost regions and the outlying Greek islands as well as in the Croatian islands Dugi otok, Vis, Mljet and Lastovo, aid may be granted to all enterprises.'

(d) In Article 53(9), the first subparagraph is replaced by the following:

'9. When operations are financed by the EFF in the outlying Greek islands which are under a handicap due to distant location and in the outermost regions as well as in the Croatian islands Dugi otok, Vis, Mljet and Lastovo, the ceiling for the contribution from the EFF for each priority axis shall be increased by up to 10 percentage points in the regions eligible under the Convergence objective and by up to 35 percentage points for the regions not eligible under the Convergence objective.'

(e) In Annex II, point (a), the table is replaced by the following:

'

	Group 1	Group 2	Group 3	Group 4
Regions covered by the Convergence objective and outlying Greek islands and the Croatian islands Dugi otok, Vis, Mljet and Lastovo	A ≤ 100 % B ≥ 0 %	A ≤ 40 % B ≥ 60 % (*) (**)	A ≤ 80 % B ≥ 20 %	A ≤ 60 % B ≥ 40 % (***)
Regions not covered by the Convergence objective	A ≤ 100 % B ≥ 0 %	A ≤ 40 % B ≥ 60 % (*) (**)	A ≤ 60 % B ≥ 40 %	A ≤ 40 % B ≥ 60 % (***)
Outermost regions	A ≤ 100 % B ≥ 0 %	A ≤ 50 % B ≥ 50 % (*) (**)	A ≤ 80 % B ≥ 20 %	A ≤ 75 % B ≥ 25 %

(*) In the case of operations referred to in Article 25(3), the (B) rates for Group 2 are increased by 20 percentage points. The (A) rates are reduced accordingly.

(**) In the case of operations referred to in Article 26(2) (investment on board within the meaning of Article 25 in small scale coastal fishing vessels), the (B) rates for Group 2 may be reduced by 20 percentage points. The (A) rates are increased accordingly.

(***) In case of operations referred to in Articles 29 and 35 when undertaken by enterprises not covered by the definition in Article 3(f) with less than 750 employees or with a turnover of less than EUR 200 million, the (B) rates are increased in the regions covered by the Convergence objective, with the exception of the outlying Greek islands and the Croatian islands Dugi otok, Vis, Mljet and Lastovo, by 30 percentage points and in the regions not covered by the Convergence objective by 20 percentage points. The (A) rates are reduced accordingly.'

(f) In Annex II, point (a), the second paragraph of sub-title "Group 2" is replaced by the following:

'Following the application of (*) and (**) where the EFF finances operations referred to in Article 25(3) in favour of small scale coastal fishing vessels, the (B) rates for Group 2 will be:

— for the regions covered by the Convergence objective, the outlying Greek islands and the Croatian islands Dugi otok, Vis, Mljet and Lastovo and the regions not covered by the Convergence objective equal or more than 60 percentage points (B ≥ 60 %),

and

— for the outermost regions equal or more than 50 percentage points (B ≥ 50 %).'

6. **TAXATION**

1. 32006 L 0112: Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1).

In Article 287, the following is added:

'(19) Croatia: EUR 35 000.'

2. 32008 L 0118: Council Directive 2008/118/EC of 16 December 2008 concerning the general arrangements for excise duty and repealing Directive 92/12/EEC (OJ L 9, 14.1.2009, p. 12).

Article 46(3) is replaced by the following:

'3. Without prejudice to Article 32, Member States not referred to in the third and fourth subparagraphs of Article 2(2) of Directive 92/79/EEC may, as regards cigarettes which may be brought into their territory without further payment of excise duties, apply from 1 January 2014 a quantitative limit of not less than 300 items with respect to cigarettes brought in from a Member State which applies, in accordance with the third and fourth subparagraphs of Article 2(2) of that Directive, lower excise duties than those resulting from the first subparagraph of Article 2(2) thereof.

Member States referred to in the third and fourth subparagraphs of Article 2(2) of Directive 92/79/EEC which levy an excise duty of at least EUR 77 per 1 000 cigarettes irrespective of the weighted average retail selling price, may, from 1 January 2014, apply a quantitative limit of not less than 300 items as regards cigarettes brought into their territory without further payment of excise duties from a Member State which applies a lower excise duty in accordance with the third subparagraph of Article 2(2) of that Directive.

Member States which apply a quantitative limit in accordance with the first and the second subparagraphs of this paragraph shall inform the Commission thereof. They may carry out the necessary checks provided that these checks do not affect the proper functioning of the internal market.'

7. REGIONAL POLICY AND COORDINATION OF STRUCTURAL INSTRUMENTS

1. 32006 R 1083: Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999 (OJ L 210, 31.7.2006, p. 25).

1. In Article 15 (4), the following subparagraph is inserted after the second subparagraph:

'The Commission shall, in cooperation with Croatia, verify additionality *ex post* on 31 December 2017.'

2. In Article 18(1), the first subparagraph is replaced by the following:

'1. The resources available for commitment from the Funds for the period 2007 to 2013 shall be EUR 308 417 037 817 at 2004 prices in accordance with the annual breakdown shown in Annex I.'

3. Article 19 is replaced by the following:

'*Article 19*

Resources for the Convergence objective

Overall resources for the Convergence objective shall amount to 81,56 % of the resources referred to in Article 18(1) (i.e. a total of EUR 251 529 800 379) and shall be distributed between the different components as follows:

(a) 70,50% (i.e. a total of EUR 177 324 921 223) for the financing referred to in Article 5(1), using eligible population, regional prosperity, national prosperity and unemployment rate as the criteria for calculating the indicative breakdowns by Member State;

(b) 4,98 % (i.e. a total of EUR 12 521 289 405) for the transitional and specific support referred to in Article 8(1), using eligible population, regional prosperity, national prosperity and unemployment rate as the criteria for calculating the indicative breakdowns by Member State;

(c) 23,23 % (i.e. a total of EUR 58 433 589 750) for the financing referred to in Article 5(2), using population, national prosperity, and surface area as the criteria for calculating the indicative breakdowns by Member State;

(d) 1,29 % (i.e. a total of EUR 3 250 000 000) for the transitional and specific support referred to in Article 8(3).'

4. In Article 20, the first subparagraph is replaced by the following:

'Overall resources for the Regional competitiveness and employment objective shall amount to 15,93 % of the resources referred to in Article 18(1) (i.e. a total of EUR 49 127 784 318) and shall be distributed between the different components as follows:'

5. In Article 21, paragraphs 1 and 2 are replaced by the following:

'1. Overall resources for the European territorial cooperation objective shall amount to 2,52 % of the resources referred to in Article 18(1) (i.e. a total of EUR 7 759 453 120) and, excluding the amount referred to in paragraph 22 of Annex II, shall be distributed between the different components as follows:

(a) 73,86 % (i.e. a total of EUR 5 583 386 893) for the financing of cross-border cooperation referred to in Article 7(1), using eligible population as the criterion for calculating the indicative breakdowns by Member State;

(b) 20,95 % (i.e. a total of EUR 1 583 594 654) for the financing of transnational cooperation referred to in Article 7(2), using eligible population as the criterion for calculating the indicative breakdowns by Member State;

(c) 5,19 % (i.e. a total of EUR 392 471 574) for the financing of interregional cooperation, cooperation networks and exchange of experience referred to in Article 7(3).

2. The contribution from the ERDF to the cross-border and sea-basin programmes under the European Neighbourhood and Partnership Instrument and to the cross-border programmes under the Instrument for Pre-Accession Assistance pursuant to Regulation (EC) No 1085/2006 shall be EUR 817 691 234, as a result of the indication of each Member State concerned, deducted from their allocations under paragraph 1(a). These ERDF contributions shall not be subject to reallocation between the Member States concerned.'

6. In Article 22, the following subparagraph is added:

'By way of derogation from the first subparagraph, Croatia may distribute its financial allocation under the European territorial cooperation objective among the three components referred to in Article 21(1)(a) to (c) with a view of a high level of efficiency and simplification.'

7. Article 23 is replaced by the following:

'*Article 23*

Resources for the performance reserve

Three per cent of the resources referred to in Article 19(a) and (b) and Article 20 may be allocated by the Member States, with the exception of Croatia, in accordance with Article 50.'

8. Article 28 is amended as follows:

(a) In paragraph 1, the following subparagraph is inserted between the first and second subparagraphs:

'For Croatia, the national strategic reference framework shall cover the period from the date of accession to 31 December 2013.'

(b) In paragraph 2, the following subparagraph is inserted between the first and second subparagraphs:

'Croatia shall transmit its national strategic reference framework to the Commission within three months following the date of accession.'

9. In Article 29, the following paragraph is added:

'5. Paragraphs 1 to 4 shall not apply to Croatia.'

10. In Article 32(3), the following subparagraph is added:

'For Croatia, the Commission shall adopt the Decision approving an Operational Programme to be financed under the programming period 2007-2013 not later than 31 December 2013. The submission of this operational programme by Croatia shall be made not later than three months following the date of accession, provided that any observations made by the Commission have been taken into account.'

11. In Article 33(1), the following subparagraph is added:

'For Croatia, operational programmes adopted before the date of accession may be revised for the sole purpose of a better alignment with this Regulation.'

12. In Article 49(3), the following subparagraph is added:

'For Croatia's operational programmes *ex post* evaluation shall be completed by 31 December 2016.'

13. The following Article is inserted:

'*Article 51a*

Articles 50 and 51 shall not apply to Croatia.'

14. Article 53(3) is replaced by the following:

'3. For operational programmes under the European territorial cooperation objective in which at least one participant belongs to a Member State whose average GDP per capita for the period 2001 to 2003 was below 85 % of the EU-25 average during the same period, or for such programmes where Croatia is a participating country, the contribution from the ERDF shall not be higher than 85 % of the eligible expenditure. For all other operational programmes, the contribution from the ERDF shall not be higher than 75 % of the eligible expenditure co-financed by the ERDF.'

15. In Article 56(1), the following subparagraph is added:

'For Croatia, expenditure shall be eligible for a contribution from the Funds between the starting date of eligibility of expenditure as fixed in accordance with the instruments adopted under Regulation (EC) No 1085/2006 and 31 December 2016. However, for operational programmes adopted after the date of accession, expenditure for a contribution from the Funds shall be eligible from the date of accession, unless a later date is specified in the Decision on the operational programme concerned.'

16. In Article 56(3), the following subparagraph is added:

'Notwithstanding specific provisions on eligibility as laid down in Article 105a, the criteria fixed by the monitoring committee of operational programmes for Croatia shall not apply to operations for which the approval decision has been adopted before the date of accession and which have been part of the instruments adopted under Regulation (EC) No 1085/2006.'

17. Article 62(1) is amended as follows:

(a) In point (c), the following subparagraph is inserted between the first and second subparagraphs:

'For Croatia, the audit authority of an operational programme shall submit to the Commission an update of the annual audit work plan as referred to in Article 29(2)(a) of Commission Regulation (EC) No 718/2007 of 12 June 2007 implementing Council Regulation (EC) No 1085/2006 establishing an instrument for pre-accession assistance (IPA)[1] within three months from the date of accession.'

(b) In point (d) (i), the following subparagraph is added:

'For Croatia, the first annual control report shall be submitted by 31 December 2013 covering the period from 1 October 2012 until 30 June 2013. The following reports covering the periods from 1 July 2013 to 30 June 2014, from 1 July 2014 to 30 June 2015 and from 1 July 2015 to 30 June 2016 shall be submitted to the Commission by 31 December 2014, 31 December 2015 and 31 December 2016, respectively. The information concerning the audits carried out after 1 July 2016 shall be included in the final control report supporting the closure declaration referred to in point (e);'

[1] OJ L 170, 29.6.2007, p. 1.

(c) In point (e), the following subparagraph is added:

'For Croatia, a closure declaration supported by the final control report, shall be submitted to the Commission by 31 March 2018.'

18. In Article 67(1), the following subparagraph is added:

'For Croatia, the managing authority shall send a final report on the implementation of the operational programme by 31 March 2018.'

19. Article 71 is amended as follows:

(a) The following paragraph is inserted:

'1a. Notwithstanding paragraph 1, as soon as possible following the date of its accession or, at the latest, before any payment by the Commission is made, Croatia shall submit to the Commission a description of the systems, covering the elements set out in points (a) and (b) of that paragraph.'

(b) The following paragraph is inserted:

'2a. Paragraph 2 shall apply *mutatis mutandis* to Croatia. The report referred to in the first subparagraph shall be deemed to be accepted under the same conditions as set out in the second subparagraph. However, such acceptance shall be a pre-requisite for the pre-financing amount referred to in Article 82.'

20. In Article 75, the following paragraph is inserted:

'1a. For Croatia, the respective budget commitments from the ERDF, the Cohesion Fund and the ESF for 2013 shall be made based on the decision referred to in Article 28(3) before the Commission takes any decision on the revision of an adopted programme. The decision referred to in Article 28(3) shall constitute a financing decision in the meaning of Article 75 of Regulation (EC, Euratom) No 1605/2002 for any budget commitment in favour of Croatia.'

21. In Article 78(2)(c), the following sentence is added:

'For Croatia, they shall be covered by expenditure paid by beneficiaries in implementing the project and supported by receipted invoices or accounting documents of equivalent probative value at the latest three years after the year of the payment of the advance or on 31 December 2016, whichever is the earlier; if they are not, the next statement of expenditure shall be corrected accordingly.'

22. In Article 82, the following paragraph 1a is inserted:

'1a. For Croatia, following the acceptance of the report as referred to in Article 71(2a) and following the respective budget commitments as referred to in Article 75(1a), a single pre-financing amount for the rest of the 2007 to 2013 period shall be paid in a single instalment and will represent 30 % of the contribution from the Structural Funds and 40 % of the contribution from the Cohesion Fund to the operational programme.'

23. In Article 89(1) the following subparagraph is added:

'For Croatia, an application for payment comprising the documents listed in point (a) (i) to (iii) shall be sent by 31 March 2018.'

24. In Article 93, the following paragraph is inserted:

'3a. By way of derogation from paragraphs 1 to 3, for Croatia the Commission shall apply the de-commitment mechanism set out in paragraph 1 in the following way:

(i) the deadline for any open part of the 2010 commitment shall be 31 December 2013;

(ii) the deadline for any open part of the 2011 commitment shall be 31 December 2014;

(iii) the deadline for any open part of the 2012 commitment shall be 31 December 2015;

(iv) any part of 2013 commitments still open on 31 December 2016 shall be automatically de-committed if the Commission has not received an acceptable application for payment for it by 31 March 2018.'

25. In Article 95, the following subparagraph is inserted after the second subparagraph:

'By way of derogation from the first and second subparagraphs, for Croatia the deadlines referred to in Article 93(3a) shall be interrupted under the conditions set out in the first subparagraph of this paragraph in respect of the amount relating to the operations concerned.'

26. In Article 98(2), the following subparagraph is added:

'For Croatia, the resources from the Funds released in this way may be reused by Croatia until 31 December 2016.'

27. The following Article is inserted:

'*Article 105a*

Specific provisions following the accession of Croatia

1. Programmes and major projects which, on the date of accession of Croatia, have been approved under Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA)[1] and the implementation of which has not been completed by that date, shall be considered to have been approved by the Commission under this Regulation, with the exception of programmes approved under the components referred to in Article 3(1) (a) and (e), of that Regulation.

In addition, the following programmes falling under the component referred to in Article 3 (1) (b) of Regulation (EC) No 1085/2006 shall be excluded as well:

a) the "IPA Adriatic cross-border co-operation programme";
b) the cross-border programme "Croatia – Bosnia and Herzegovina ";
c) the cross-border programme "Croatia – Montenegro";
d) the cross-border programme "Croatia – Serbia".

Without prejudice to paragraphs 2 to 7, the provisions governing the implementation of operations and major projects approved pursuant to this Regulation shall apply to these operations and major projects.

[1] OJ L 210, 31.7.2006, p. 82.

2. Any procurement procedure relating to operations within the programmes or relating to major projects referred to in paragraph 1 which, on the date of accession, has already been the subject of an invitation to tender published in the *Official Journal of the European Union* shall be implemented in accordance with the rules laid down in that invitation to tender. The provisions contained in Article 165 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities[1] shall not apply.

Any procurement procedure relating to operations within the programmes or relating to major projects referred to in paragraph 1 which, on the date of accession, has not yet been the subject of an invitation to tender published in the *Official Journal of the European Union* shall be implemented in compliance with the provisions of the Treaties or of the acts adopted under the Treaties as well as in compliance with Article 9 of this Regulation.

Other operations than those referred to in the first and second subparagraphs and for which calls for proposals were launched in accordance with Article 158 of Commission Regulation (EC) No 718/2007 of 12 June 2007 implementing Council Regulation (EC) No 1085/2006 or for which applications had been submitted to the competent authorities before the date of accession, and for which the contracting could only be finalised after that date, shall be implemented in accordance with the conditions and eligibility rules published in the relevant call for proposal or those communicated in advance to potential beneficiaries.

3. Payments made by the Commission under programmes referred to in paragraph 1 shall be considered as a contribution from the Funds under this Regulation and shall be posted to the earliest open commitment including IPA commitments.

Any part of commitments made by the Commission under programmes referred to in paragraph 1 still open on the date of accession shall be governed by this Regulation from the date of accession.

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1 OJ L 248, 16.9.2002, p.1.

4. For the operations approved under Council Regulation (EC) No 1085/2006 for which the approval was given or for which the respective grant agreements with final beneficiaries were signed before the date of accession, the rules governing the eligibility of expenditure in accordance with or based on Commission Regulation (EC) No 718/2007 shall remain applicable, except in duly justified cases to be decided on by the Commission at the request of Croatia.

The eligibility rule established in the first subparagraph applies also to major projects referred to in paragraph 1 for which bilateral project agreements were signed before the date of accession.

5. Concerning Croatia, any reference to the Funds as defined in the second subparagraph of Article 1 shall be construed as also including the Instrument for Pre-accession Assistance referred to in Council Regulation (EC) No 1085/2006.

6. Specific deadlines applicable to Croatia shall also apply to the following cross-border programmes falling under the component referred to in Article 3(1) (b) of Regulation (EC) No 1085/2006, where Croatia is a participating country:

a) the cross-border programme "Hungary – Croatia", and

b) the cross-border programme "Slovenia – Croatia".

Specific deadlines applicable to Croatia under this Regulation do not apply to operational programmes under the transnational and interregional components under the European territorial cooperation objective, where Croatia is a participating country.

7. If any measures are necessary to facilitate the transition of Croatia from the pre-accession regime to that resulting from the application of this Article, the Commission shall adopt the required measures.'

28. Annex I is replaced by the following:

'ANNEX I

Annual breakdown of commitment appropriations for 2007 to 2013
(referred to in Article 18)

(EUR, 2004 prices)

2007	2008	2009	2010	2011	2012	2013
42 863 000 000	43 318 000 000	43 862 000 000	43 860 000 000	44 073 000 000	44 723 000 000	45 718 037 817

'

29. Annex II is amended as follows:

(a) In paragraph 5, first subparagraph, the following points are added:

'(c) for Croatia, the resources for the financing of cross-border cooperation shall be EUR 7 028 744 at 2004 prices;

(d) for Croatia, the resources for the financing of transnational cooperation shall be EUR 1 874 332 at 2004 prices.'

(b) The following paragraph is inserted:

'7a. For Croatia, the maximum level of transfer from the Funds will be 3,5240% of its GDP.'

(c) 'The following paragraph is inserted:

'9a. For Croatia, calculations of the GDP by the Commission will be based on statistics and projections published in May 2011.'

30. Annex III is replaced by the following:

'ANNEX III

Ceilings applicable to co-financing rates

(referred to in Article 53)

Criteria	Member States	ERDF and ESF Percentage of eligible expenditure	Cohesion Fund Percentage of eligible expenditure
1. Member States whose average GDP per capita for the period 2001 to 2003 was below **85 %** of the EU-25 average during the same period	Bulgaria, Czech Republic, Estonia, Greece, Croatia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Portugal, Romania, Slovenia, Slovakia	**85 %** for the Convergence and Regional competitiveness and employment objectives	**85 %**
2. Member States other than those under (1) eligible for the transitional regime of the Cohesion Fund on 1 January 2007	Spain	**80 %** for the Convergence and the phasing-in regions under the Regional competitiveness and employment objective **50 %** for the Regional competitiveness and employment objective outside phasing-in regions	**85 %**
3. Member States other than those referred to under (1) and (2)	Belgium, Denmark, Germany, France, Ireland, Italy, Luxemburg, the Netherlands, Austria, Finland, Sweden and United Kingdom	**75 %** for the Convergence objective	

4. Member States other than those referred to under (1) and (2)	Belgium, Denmark, Germany, France, Ireland, Italy, Luxemburg, the Netherlands, Austria, Finland, Sweden and United Kingdom	**50 %** for the Regional competitiveness and employment objective
5. Outermost regions referred to in Article 349 of the TFEU benefiting from the additional allocation for these regions provided for in paragraph 20 of Annex II	Spain, France and Portugal	**50 %**
6. Outermost Regions referred to in Article 349 of the TFEU	Spain, France and Portugal	**85 %** under the Convergence and Regional competitiveness and employment objectives

2. 32006 R 1084: Council Regulation (EC) No 1084/2006 of 11 July 2006 establishing a Cohesion Fund and repealing Regulation (EC) No 1164/94 (OJ L 210, 31.7.2006, p. 79).

The following Article is inserted:

'Article 5a

Specific provisions following the accession of Croatia

1. Measures which, on the date of accession of Croatia, have been the subject of Commission decisions on assistance under Council Regulation (EC) No 1267/1999 of 21 June 1999 establishing an Instrument for Structural Policies for Pre-accession (ISPA)[1] and the implementation of which has not been completed by that date shall be considered to have been approved by the Commission under this Regulation.

Without prejudice to paragraphs 2 to 5, the provisions governing the implementation of actions approved pursuant to this Regulation and to Council Regulation (EC) No 1083/2006 shall apply to these measures.

2. Any procurement procedure relating to measures referred to in paragraph 1 which, on the date of accession, has already been the subject of an invitation to tender published in the *Official Journal of the European Union* shall be implemented in accordance with the rules laid down in that invitation to tender. The provisions contained in Article 165 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities[2] shall not apply.

Any procurement procedure relating to a measure referred to in paragraph 1 which, on the date of accession, has not yet been the subject of an invitation to tender published in the *Official Journal of the European Union* shall be implemented in compliance with the provisions of the Treaties or of the acts adopted under the Treaties as well as in compliance with Article 9 of Council Regulation (EC) No 1083/2006.

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1 OJ L 161, 26.6.1999, p. 73.
2 OJ L 248, 16.9.2002, p. 1.

3. Payments made by the Commission under a measure referred to in paragraph 1 shall be considered as a contribution from the Fund under this Regulation.

Payments made by the Commission under a measure referred to in paragraph 1 shall be posted to the earliest open commitment made in the first instance pursuant to Council Regulation (EC) No 1267/1999, and then pursuant to this Regulation and to Council Regulation (EC) No 1083/2006.

The conditions for interim payments or for the final balance are those set out in paragraph 2 (b) to (d) and paragraphs 3 to 5 of Article D in Annex II of Council Regulation (EC) No 1164/94.

4. For the measures referred to in paragraph 1, the rules governing the eligibility of expenditure pursuant to Council Regulation (EC) No 1267/1999 or specifically established in the relevant financing agreements shall remain applicable, except in duly justified cases to be decided on by the Commission at the request of Croatia.

5. If any measures are necessary to facilitate the transition of Croatia from the pre-accession regime to that resulting from the application of this Article, the Commission shall adopt the required measures.'

8. **ENVIRONMENT**

1. 32003 L 0087: Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (OJ L 275, 25.10.2003, p. 32).

(a) In Article 9, the following is added to the first subparagraph:

'The Community-wide quantity of allowances will be increased as a result of Croatia's accession only by the quantity of allowances that Croatia shall auction pursuant to Article 10(1).'

(b) In Annex IIa, the following is inserted before the entry for Italy:

'Croatia 26 %'.

2. 32009 D 0406: Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020 (OJ L 140, 5.6.2009, p. 136).

In Annex II, the following is inserted before the entry for Italy:

'Croatia 11%'.

ANNEX IV

List referred to in Article 16 of the Act of Accession: other permanent provisions

1. INTELLECTUAL PROPERTY LAW

Treaty on the Functioning of the European Union, Part Three, Title II, Free Movement of Goods

SPECIFIC MECHANISM

With regard to Croatia, the holder, or his beneficiary, of a patent or Supplementary Protection Certificate (SPC) for a pharmaceutical product filed in a Member State at the time when such protection could not be obtained in Croatia for that product, may rely on the rights granted by that patent or SPC in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent or SPC protection, even if this product was put on the market in Croatia for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the first paragraph in a Member State where the product enjoys patent or SPC protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.

2. COMPETITION POLICY

Treaty on the Functioning of European Union, Part Three, Title VII, Chapter 1, Rules on Competition

1. The following aid schemes and individual aid put into effect in Croatia before the date of accession and still applicable after that date shall be regarded upon accession as existing aid within the meaning of Article 108(1) of the TFEU:

   a) aid measures put into effect before 1 March 2002;

   b) aid measures listed in the Appendix to this Annex;

   c) aid measures which prior to the date of accession were assessed by the Croatian Competition Agency and found to be compatible with the *acquis*, and to which the Commission did not raise an objection on the ground of serious doubts as to the compatibility of the measure with the internal market, pursuant to the procedure set out in paragraph 2.

   All measures still applicable after the date of accession which constitute State aid and which do not fulfil the conditions set out above shall be considered as new aid upon accession for the purpose of the application of Article 108(3) of the TFEU.

   The above provisions do not apply to aid to activities linked to the production, processing or marketing of products listed in Annex I to the TFEU.

2. To the extent that Croatia wishes the Commission to examine an aid measure under the procedure described in paragraph 1(c), it shall provide the Commission regularly with:

a) a list of existing aid measures which have been assessed by the Croatian Competition Agency and which that authority has found to be compatible with the *acquis*; and

b) any other information which is essential for the assessment of the compatibility of the aid measure to be examined,

in accordance with the concrete reporting format provided by the Commission.

If the Commission does not object to the existing aid measure on the ground of serious doubts as to the compatibility of the measure with the internal market, within three months of receipt of complete information on that measure or of receipt of the statement of Croatia in which it informs the Commission that it considers the information provided to be complete because the additional information requested is not available or has been already provided, the Commission shall be deemed not to have raised an objection.

All aid measures submitted under the procedure described in paragraph 1(c) prior to the date of accession to the Commission are subject to the above procedure irrespective of the fact that in the period of examination Croatia has already become member of the Union.

3. A Commission decision to object to a measure, within the meaning of paragraph 1(c), shall be regarded as a decision to initiate the formal investigation procedure within the meaning of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty[1] (now Article 108 of the TFEU).

If such a decision is taken before the date of accession, the decision will only come into effect upon the date of accession.

[1] OJ L 83, 27.3.99, p. 1.

3. AGRICULTURE

(a) Treaty on the Functioning of the European Union, Part Three, Title III, Agriculture and Fisheries

1. Public stocks held at the date of accession by Croatia and resulting from its market-support policy shall be taken over by the Union at the value resulting from the application of Article 4(1)(d) and Annex VIII of Commission Regulation (EC) No 884/2006 of 21 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 1290/2005 as regards the financing by the European Agricultural Guarantee Fund (EAGF) of intervention measures in the form of public storage operations and the accounting of public storage operations by the paying agencies of the Member States[1]**.** The said stocks shall be taken over only on condition that public intervention for the products in question is operated in the Union and that the stocks meet the Union intervention requirements.

2. For any stocks, private as well as public, in free circulation at the date of accession in Croatia exceeding the level of what can be considered as normal carry-over of stock Croatia shall be charged with a payment to the general budget of the European Union.

   The amount of the payment shall be fixed at a level which reflects the cost related to the effects of the surplus stock on the markets of agricultural products.

   The level of the surplus stock shall be determined for each product taking into account the characteristics of each product and the relevant markets as well as the Union legislation applicable to it.

3. The stocks referred to in paragraph 1 shall be deducted from the quantity exceeding the normal carry-over of stocks.

[1] OJ L 171, 23.6.2006, p. 35 and OJ L 326 M, 10.12.2010, p. 70.

4. The Commission shall implement and apply the arrangements outlined in paragraphs 1 to 3 in accordance with the procedure laid down in Article 41(2) of Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy[1] or, as appropriate, in accordance with the procedure referred to in Article 195(2) of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)[2] or the relevant committee procedure as determined in the applicable legislation.

(b) **Treaty on the Functioning of the European Union, Part Three, Title VII, Chapter 1, Rules on competition**

Without prejudice to the procedures concerning existing aid provided for in Article 108 of the TFEU, aid schemes and individual aid granted to activities linked to the production of and trade in products listed in Annex I to the TEU and the TFEU with the exception of fisheries products and products derived therefrom, put into effect in Croatia before the date of accession and still applicable after that date, shall be regarded as existing aid within the meaning of Article 108(1) of the TFEU subject to the following conditions:

– the aid measures shall be communicated to the Commission within four months from the date of accession. This communication shall include information on the legal basis for each measure. Existing aid measures and plans to grant or alter aids communicated to the Commission prior to the date of accession shall be deemed to have been communicated on the date of accession. The Commission shall publish a list of such aids.

These aid measures shall be regarded as 'existing' aid within the meaning of Article 108(1) of the TFEU during a period of three years from the date of accession.

1 OJ L 209, 11.08.2005, p. 1.
2 OJ L 299, 16.11.2007, p. 1.

Croatia shall, where necessary, amend these aid measures in order to comply with the guidelines applied by the Commission within three years of the date of accession. After that period, any aid found to be incompatible with those guidelines shall be considered as new aid.

4. FISHERIES

Treaty on the Functioning of the European Union, Part Three, Title VII, Chapter 1, Rules on competition

Without prejudice to the procedures concerning existing aid provided for in Article 108 of the TFEU, aid schemes and individual aid granted to activities linked to the production of and trade in fisheries products and products derived therefrom listed in Annex I to the TEU and the TFEU, put into effect in Croatia before the date of its accession and still applicable after that date, shall be regarded as existing aid within the meaning of Article 108(1) of the TFEU subject to the following conditions:

– the aid measures shall be communicated to the Commission within four months from the date of accession. This communication shall include information on the legal basis for each measure. Existing aid measures and plans to grant or alter aids communicated to the Commission prior to the date of accession shall be deemed to have been communicated on the date of accession. The Commission shall publish a list of such aids.

These aid measures shall be regarded as 'existing' aid within the meaning of Article 108(1) of the TFEU during a period of three years from the date of accession.

Croatia shall, where necessary, amend these aid measures in order to comply with the guidelines applied by the Commission within three years of the date of accession. After that period, any aid found to be incompatible with those guidelines shall be considered as new aid.

5. CUSTOMS UNION

Treaty on the Functioning of the European Union, Part Three, Title II, Free Movement of Goods, Chapter 1, The Customs union

31992 R 2913: Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

31993 R 2454: Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).

Regulation (EEC) No 2913/92 and Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions.

PROOF OF UNION STATUS (TRADE WITHIN THE ENLARGED UNION)

1. Notwithstanding Article 20 of Regulation (EEC) No 2913/92, goods which on the date of accession are in temporary storage or under one of the customs treatments and procedures referred to in Article 4(15)(b) and (16)(b) to (h) of that Regulation in the enlarged Union, or which are in transport after having been the subject of export formalities within the enlarged Union, shall be free of customs duties and other customs measures when declared for release for free circulation within the enlarged Union on condition that one of the following is presented:

   (a) proof of preferential origin properly issued or made out prior to the date of accession under the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Croatia, of the other part (the Stabilisation and Association Agreement)[1];

[1] OJ L 26, 28.1.2005, p. 3.

(b) any of the means of proof of Union status referred to in Article 314c of Regulation (EEC) No 2454/93;

(c) an ATA carnet issued before the date of accession in a present Member State or in Croatia.

2. For the purpose of issuing the proofs referred to in paragraph 1(b) above, with reference to the situation at the date of accession and in addition to the provisions of Article 4(7) of Regulation (EEC) No 2913/92, "Community goods" shall mean goods:

– wholly obtained in the territory of Croatia under conditions identical to those of Article 23 of Regulation (EEC) No 2913/92 and not incorporating goods imported from other countries or territories;

– imported from countries or territories other than Croatia, and released for free circulation in Croatia; or
– obtained or produced in Croatia, either from goods referred to in the second indent of this paragraph alone or from goods referred to in the first and second indent of this paragraph.

3. For the purpose of verifying the proofs referred to in paragraph 1(a) above, the provisions concerning the definition of the concept of "originating products" and methods of administrative cooperation under the Stabilisation and Association Agreement shall apply. Requests for subsequent verification of those proofs shall be accepted by the competent customs authorities of the present Member States and of Croatia for a period of three years after the issue or making out of the proof of origin concerned and may be made by those authorities for a period of three years after acceptance of the proof of origin in support of a declaration of free circulation.

PROOF OF PREFERENTIAL ORIGIN (TRADE WITH THIRD COUNTRIES, INCLUDING TURKEY, IN THE FRAMEWORK OF THE PREFERENTIAL AGREEMENTS ON AGRICULTURE, COAL AND STEEL PRODUCTS)

4. Without prejudice to the application of any measure deriving from the common commercial policy, proof of origin properly issued by third countries or made out in the framework of preferential agreements concluded by Croatia with those countries shall be accepted in Croatia, provided that:

   (a) the acquisition of such origin confers preferential tariff treatment on the basis of the preferential tariff measures contained in agreements or arrangements which the Union has concluded with, or adopted in respect of, those third countries or groups of countries, as referred to in Article 20(3)(d) and (e) of Regulation (EEC) No 2913/92;

   (b) the proof of origin and the transport documents were issued or made out no later than the day before the date of accession; and

   (c) the proof of origin is submitted to the customs authorities within the period of four months from the date of accession.

Where goods were declared for release for free circulation in Croatia prior to the date of accession, proof of origin issued or made out retrospectively under preferential agreements in force in Croatia at the date of the release for free circulation may also be accepted in Croatia, provided that it is submitted to the customs authorities within a period of four months from the date of accession.

5. Croatia is authorised to retain the authorisations with which the status of "approved exporters" has been granted in the framework of agreements concluded with third countries, provided that:

(a) such a provision is also provided for in the agreements concluded prior to the date of accession by those third countries with the Union; and

(b) the approved exporters apply the rules of origin provided for in those agreements.

These authorisations shall be replaced by Croatia, no later than one year after the date of accession, by new authorisations issued under the conditions of Union legislation.

6. For the purpose of verifying the proofs referred to in paragraph 4, the provisions concerning the definition of the concept of "originating products" and methods of administrative cooperation of the relevant agreements or arrangements shall apply. Requests for subsequent verification of those proofs shall be accepted by the competent customs authorities of the present Member States and of Croatia for a period of three years after the issue or making out of the proof of origin concerned and may be made by those authorities for a period of three years after acceptance of the proof of origin in support of a declaration of free circulation.

7. Without prejudice to the application of any measure deriving from the common commercial policy, proof of origin issued or made out retrospectively by third countries in the framework of preferential agreements or arrangements which the Union has concluded with, or adopted in respect of, these countries shall be accepted in Croatia for the release for free circulation of goods which on the date of accession are either in transport or in temporary storage, in a customs warehouse or in a free zone in one of these third countries or in Croatia, provided that Croatia had no free trade agreement in force with the third country, for the products concerned, at the moment when the transport documents where issued, and provided that:

(a) the acquisition of such origin confers preferential tariff treatment on the basis of the preferential tariff measures contained in agreements or arrangements which the Union has concluded with, or adopted in respect of, third countries or groups of countries, as referred to in Article 20(3)(d) and (e) of Regulation (EEC) No 2913/92;

(b) the transport documents were issued no later than the day before the date of accession; and

(c) the proof of origin issued or made out retrospectively is submitted to the customs authorities within four months from the date of accession.

8. For the purpose of verifying the proofs referred to in paragraph 7, the provisions concerning the definition of the concept of "originating products" and methods of administrative cooperation of the relevant agreements or arrangements shall apply.

PROOF OF STATUS UNDER THE PROVISIONS ON FREE CIRCULATION FOR INDUSTRIAL PRODUCTS WITHIN THE EC-TURKEY CUSTOMS UNION

9. Proofs of origin properly issued by either Turkey or Croatia or made out in the framework of preferential trade agreements applied between them and providing for a prohibition of drawback of, or exemption from, customs duties on the goods concerned shall be accepted in the respective countries as a proof of status under the provisions on free circulation for industrial products, laid down in Decision No 1/95 of the EC-Turkey Association Council[1], provided that:

(a) the proof of origin and the transport documents were issued or made out no later than the day before the date of accession; and

[1] Decision No 1/95 of the EC-Turkey Association Council of 22.12.1995 on implementing the final phase of the Customs Union (OJ L 35, 13.2.1996, p. 1).

(b) the proof of origin is submitted to the customs authorities within a period of four months from the date of accession.

Where goods were declared for release for free circulation in either Turkey or Croatia, prior to the date of accession, in the framework of preferential trade agreements referred to in the first subparagraph, proof of origin issued or made out retrospectively under those agreements may also be accepted provided that it is submitted to the customs authorities within a period of four months from the date of accession.

10. For the purpose of verifying the proofs referred to in paragraph 9, the provisions concerning the definition of the concept of "originating products" and methods of administrative cooperation of the relevant preferential agreements shall apply. Requests for subsequent verification of those proofs shall be accepted by the competent customs authorities of the present Member States and of Croatia for a period of three years after the issue or making out of the proof of origin concerned and may be made by those authorities for a period of three years after acceptance of the proof of origin in support of a declaration of free circulation.

11. Without prejudice to the application of any measure deriving from the common commercial policy, an A.TR movement certificate issued under the provisions on free circulation for industrial products, laid down in Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995, shall be accepted in Croatia for the release for free circulation of goods which on the date of accession are either in transport after having been the subject of export formalities within the Union or Turkey or are in temporary storage or under a customs procedure referred to in Article 4(16)(b) to (h) of Regulation (EEC) No 2913/92 in Turkey or in Croatia, provided that:

(a) no proof of origin as referred to in paragraph 9 is submitted for the goods concerned;

(b) the goods comply with the conditions for the implementation of the provisions on free circulation for industrial products;

(c) the transport documents were issued no later than the day before the date of accession; and

(d) the A.TR movement certificate is submitted to the customs authorities within four months from the date of accession.

12. For the purpose of verifying the A.TR movement certificates referred to in paragraph 11, the provisions concerning the issue of A.TR movement certificates and methods of administrative cooperation under Decision No 1/2006 of the EC-Turkey Customs Cooperation Committee[1] shall apply.

CUSTOMS PROCEDURES

13. Temporary storage and customs procedures referred to in Article 4(16) (b) to (h) of Regulation (EEC) No 2913/92 which have begun before accession shall be ended or discharged under the conditions of Union legislation.

Where the end or discharge gives rise to a customs debt, the amount of import duty to be paid shall be that in force at the time when the customs debt is incurred in accordance with the Common Customs Tariff and the amount paid shall be considered as own resources of the Union.

[1] Decision No 1/2006 of the EC-Turkey Customs Cooperation Committee of 26 September 2006 laying down detailed rules for the application of Decision No 1/95 of the EC-Turkey Association Council (OJ L 265, 26.9.2006, p. 18).

14. The procedures governing customs warehousing laid down in Articles 84 to 90 and 98 to 113 of Regulation (EEC) No 2913/92 and Articles 496 to 535 of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– where the amount of a customs debt is determined on the basis of the nature of the import goods and where the declaration placing the goods under the procedure was accepted prior to the date of accession, the tariff classification, quantity, value for customs purposes and origin of the import goods at the time they were placed under the procedure shall result from the legislation applicable in Croatia at the date of acceptance of the declaration by the customs authorities.

15. The procedures governing inward processing laid down in Articles 84 to 90 and 114 to 129 of Regulation (EEC) No 2913/92 and Articles 496 to 523 and 536 to 550 of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– where the amount of a customs debt is determined on the basis of the nature of the import goods and where the declaration placing the goods under the procedure was accepted prior to the date of accession, the tariff classification, quantity, value for customs purposes and origin of the import goods at the time they were placed under the procedure shall result from the legislation applicable in Croatia at the date of acceptance of the declaration by the customs authorities;

– where the discharge gives rise to a customs debt, in order to maintain the equity between the holders of authorisations established in the present Member States and those in Croatia, compensatory interest shall be paid on the import duties due under the conditions of Union legislation from the date of accession;

– if the declaration for inward processing was accepted under a drawback system, the drawback shall be effected under the conditions of Union legislation, by and at the expense of Croatia, where the customs debt in respect of which the drawback is requested was incurred before the date of accession.

16. The procedures governing temporary importation laid down in Articles 84 to 90 and 137 to 144 of Regulation (EEC) No 2913/92 and Articles 496 to 523 and 553 to 584 of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– where the amount of a customs debt is determined on the basis of the nature of the import goods and where the declaration placing the goods under the procedure was accepted prior to the date of accession, the tariff classification, quantity, value for customs purposes and origin of the import goods at the time they were placed under the procedure shall result from the legislation applicable in Croatia at the date of acceptance of the declaration by the customs authorities;

– where the discharge gives rise to a customs debt, in order to maintain equity between the holders of authorisations established in the present Member States and those in Croatia, compensatory interest shall be paid on the import duties due under the conditions of Union legislation from the date of accession.

17. The procedures governing outward processing laid down in Articles 84 to 90 and 145 to 160 of Regulation (EEC) No 2913/92 and Articles 496 to 523 and 585 to 592 of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– Article 591, second paragraph, of Regulation (EEC) No 2454/93 shall apply mutatis mutandis to temporary export goods which have been exported temporarily before the date of accession from Croatia.

OTHER PROVISIONS

18. Authorisations which have been granted by Croatia before the date of accession for the use of the customs procedures referred to in Article 4(16)(d), (e) and (g) or the status of Authorised Economic Operators referred to in Article 5a(2) of Regulation (EEC) No 2913/92 shall be valid until the end of their validity or one year after the date of accession, whichever is the earlier.

19. The procedures governing incurrence of a customs debt, entry in the accounts and post-clearance recovery laid down in Articles 201 to 232 of Regulation (EEC) No 2913/92 and Articles 859 to 876a of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– recovery shall be effected under the conditions of Union legislation. However, where the customs debt was incurred before the date of accession, recovery shall be effected under the conditions in force in Croatia before accession, by it and in its own favour.

20. The procedures governing repayment and remission of duty laid down in Articles 235 to 242 of Regulation (EEC) No 2913/92 and Articles 877 to 912 of Regulation (EEC) No 2454/93 shall apply to Croatia subject to the following specific provisions:

– repayment and remission of duties shall be effected under the conditions of Union legislation. However, where the duties of which repayment or remission is requested relate to a customs debt which was incurred before the date of accession, the repayment and remission of duties shall be effected under the conditions in force in Croatia before accession, by it and at its own expense.

Appendix to Annex IV

List of existing aid measures referred to in paragraph 1(b) of the existing aid mechanism provided for in Chapter 2 of Annex IV

Note: The aid measures listed in this Appendix are only to be considered as existing aid for the purpose of the application of the existing aid mechanism set out in Chapter 2 of Annex IV to the extent that they do fall within the scope of paragraph 1 thereof.

No.			Title (original)	Date of approval by the Croatian Competition Agency	Duration
MS	Nb	Yr			
HR	1	2011	Zakon o slobodnim zonama (NN 44/96, 92/05 i 85/08)	17/06/2008	31/12/2016
HR	3	2011	Zakon o Hrvatskoj radioteleviziji (NN 137/10)	21/10/2010	Unlimited
HR	4	2011	Odluka o otvorenosti Zračne luke Osijek d.o.o. u razdoblju od 2009. do 2013. godine, od 20. veljače 2009. i 24. travnja 2009	25/05/2009	31/12/2013
HR	5	2011	Program financiranja nakladništva od 2011. do 2013	10/02/2011	31/12/2013
HR	6	2011	Naknadno odobrenje državnih potpora poduzetniku Rockwool Adriatic d.o.o.	30/12/2010	31/12/2015
HR	9	2011	Zakon o znanstvenoj djelatnosti i visokom obrazovanju (NN 123/03, 198/03, 105/04, 174/04, 46/07)	01/02/2007	31/12/ 2014
HR	10	2011	Odluka o obvezi otvorenosti Zračne luke Rijeka d.o.o. za javni zračni promet u razdoblju od 2010. do 2014., od 25. siječnja 2010. i 3. studenoga 2010	10/03/2011	31/12/ 2014

ANNEX V

List referred to in Article 18 of the Act of Accession: transitional measures

1. FREE MOVEMENT OF GOODS

32001 L 0083: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

By way of derogation from the requirements of quality, safety and efficacy laid down in Directive 2001/83/EC, marketing authorisations for medicinal products, which are not subject to Article 3(1) of Regulation (EC) No 726/2004 and which are on the list (in the Appendix to this Annex as provided by Croatia in one language) issued under Croatian law prior to the date of accession shall remain valid until they are renewed in compliance with the *acquis* or until four years from the date of accession, whichever is earlier.

The marketing authorisations covered by this derogation shall not benefit from mutual recognition in the Member States as long as these products have not been authorised according to Directive 2001/83/EC.

The national marketing authorisations granted under the national law before accession and not covered by this derogation and every new marketing authorisation shall, as from the date of accession, be in compliance with Directive 2001/83/EC.

2. FREEDOM OF MOVEMENT FOR PERSONS

Treaty on the Functioning of the European Union

31996 L 0071: Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services (OJ L 18, 21.1.1997, p. 1);

32004 L 0038: Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77);

32011 R 0492: Regulation (EU) No 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union (OJ L 141, 27.5.2011, p. 1).

1. Article 45 and the first paragraph of Article 56 of the TFEU shall fully apply only, in relation to the freedom of movement of workers and the freedom to provide services involving temporary movement of workers as defined in Article 1 of Directive 96/71/EC, between Croatia on the one hand and each of the present Member States on the other hand, subject to the transitional provisions laid down in paragraphs 2 to 13.

2. By way of derogation from Articles 1 to 6 of Regulation (EU) No 492/2011 and until the end of the two year period following the date of accession, the present Member States will apply national measures, or those resulting from bilateral agreements, regulating access to their labour markets by Croatian nationals. The present Member States may continue to apply such measures until the end of the five year period following the date of accession.

Croatian nationals legally working in a present Member State at the date of accession and admitted to the labour market of that Member State for an uninterrupted period of 12 months or longer will enjoy access to the labour market of that Member State but not to the labour market of other Member States applying national measures.

Croatian nationals admitted to the labour market of a present Member State following accession for an uninterrupted period of 12 months or longer shall also enjoy the same rights.

The Croatian nationals referred to in the second and third subparagraphs shall cease to enjoy the rights contained in those subparagraphs if they voluntarily leave the labour market of the present Member State in question.

Croatian nationals legally working in a present Member State at the date of accession, or during a period when national measures are applied, and who were admitted to the labour market of that Member State for a period of less than 12 months shall not enjoy these rights.

3. Before the end of the two year period following the date of accession, the Council shall review the functioning of the transitional provisions laid down in paragraph 2, on the basis of a report from the Commission.

On completion of this review, and no later than at the end of the two year period following the date of accession, the present Member States shall notify the Commission whether they will continue to apply national measures or measures resulting from bilateral agreements, or whether they will apply Articles 1 to 6 of Regulation (EU) No 492/2011 henceforth. In the absence of such notification, Articles 1 to 6 of Regulation (EU) No 492/2011 shall apply.

4. Upon the request of Croatia, one further review may be held. The procedure referred to in paragraph 3 shall apply and shall be completed within six months of receipt of the request from Croatia.

5. A Member State maintaining national measures or measures resulting from bilateral agreements at the end of the five year period referred to in paragraph 2 may, in case of serious disturbances of its labour market or threat thereof and after notifying the Commission, continue to apply these measures until the end of the seven year period following the date of accession. In the absence of such notification, Articles 1 to 6 of Regulation (EU) No 492/2011 shall apply.

6. During the seven year period following the date of accession, those Member States in which, by virtue of paragraphs 3, 4 or 5, Articles 1 to 6 of Regulation (EU) No 492/2011 apply as regards Croatian nationals, and which are issuing work permits to nationals of Croatia for monitoring purposes during this period, will do so automatically.

7. Those Member States in which, by virtue of paragraphs 3, 4 or 5, Articles 1 to 6 of Regulation (EU) No 492/2011 apply as regards Croatian nationals, may resort to the procedures set out in the second and third subparagraphs until the end of the seven year period following the date of accession.

When a Member State referred to in the first subparagraph undergoes or foresees disturbances on its labour market which could seriously threaten the standard of living or level of employment in a given region or occupation, that Member State shall inform the Commission and the other Member States thereof and shall supply them with all relevant particulars. On the basis of this information, the Member State may request the Commission to state that the application of Articles 1 to 6 of Regulation (EU) No 492/2011 be wholly or partially suspended in order to restore to normal the situation in that region or occupation. The Commission shall decide on the suspension and on the duration and scope thereof not later than two weeks after receiving such a request and shall notify the Council of such a decision. Any Member State may, within two weeks from the date of the Commission's Decision, request the Council to annul or amend the Decision. The Council shall act on such a request within two weeks, by qualified majority.

A Member State referred to in the first subparagraph may, in urgent and exceptional cases, suspend the application of Articles 1 to 6 of Regulation (EU) No 492/2011, followed by a reasoned ex-post notification to the Commission.

8. As long as the application of Articles 1 to 6 of Regulation (EU) No 492/2011 is suspended by virtue of paragraphs 2 to 5 and 7 above, Article 23 of Directive 2004/38/EC shall apply in Croatia with regard to nationals of the present Member States, and in the present Member States with regard to Croatian nationals, under the following conditions, so far as the right of family members of workers to take up employment is concerned:

- the spouse of a worker and their descendants who are under 21 years of age or are dependants, legally residing with the worker in the territory of a Member State at the date of accession, shall have, upon accession, immediate access to the labour market of that Member State. This does not apply to family members of a worker legally admitted to the labour market of that Member State for a period of less than 12 months;

- the spouse of a worker and their descendants who are under 21 years of age or are dependants, legally residing with the worker in the territory of a Member State from a date later than the date of accession, but during the period of application of the transitional provisions laid down above, shall have access to the labour market of the Member State concerned once they have been resident in the Member State concerned for at least 18 months or from the third year following the date of accession, whichever is earlier.

These provisions shall be without prejudice to more favourable measures whether national or resulting from bilateral agreements.

9. Insofar as provisions of Directive 2004/38/EC which take over provisions of Directive 68/360/EEC[1] may not be dissociated from those of Regulation (EU) No 492/2011 whose application is deferred pursuant to paragraphs 2 to 5 and 7 and 8, Croatia and the present Member States may derogate from those provisions to the extent necessary for the application of paragraphs 2 to 5 and 7 and 8.

10. Whenever national measures, or those resulting from bilateral agreements, are applied by the present Member States by virtue of the transitional provisions laid down above, Croatia may maintain in force equivalent measures with regard to the nationals of the Member State or States in question.

11. Any present Member State applying national measures in accordance with paragraphs 2 to 5 and 7 to 9, may introduce, under national law, greater freedom of movement than that existing at the date of accession, including full labour market access. From the third year following the date of accession, any present Member State applying national measures may at any time decide to apply Articles 1 to 6 of Regulation (EU) No 492/2011 instead. The Commission shall be informed of any such decision.

12. In order to address serious disturbances or the threat thereof in specific sensitive service sectors on their labour markets, which could arise in certain regions from the transnational provision of services, as defined in Article 1 of Directive 96/71/EC, and as long as they apply, by virtue of the transitional provisions laid down above, national measures or those resulting from bilateral agreements to the free movement of Croatian workers, Germany and Austria may, after notifying the Commission, derogate from the first paragraph of Article 56 of the TFEU with a view to limit in the context of the provision of services by companies established in Croatia, the temporary movement of workers whose right to take up work in Germany and Austria is subject to national measures.

[1] Council Directive 68/360/EEC of 15 October 1968 on the abolition of restrictions on movement and residence within the Community for workers of Member States and their families (OJ L 257, 19.10.1968, p. 13). Directive as last amended by the 2003 Act of Accession (OJ L 236, 23.9.2003, p. 33) and repealed with effect from 30 April 2006 by Directive 2004/38/EC of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 77).

The list of service sectors which may be covered by this derogation is as follows:

– in Germany:

Sector	NACE (*) code, unless otherwise specified
Construction, including related branches	45.1 to 4; Activities listed in the Annex to Directive 96/71/EC
Industrial cleaning	74.70 Industrial cleaning
Other Services	74.87 Only activities of interior decorators

(*) NACE: see 31990 R 3037: Council Regulation (EEC) No 3037/90 of 9 October 1990 on the statistical classification of economic activities in the European Community (OJ L 293, 24.10.1990, p. 1)

– in Austria:

Sector	NACE (*) code, unless otherwise specified
Horticultural service activities	01.41
Cutting, shaping and finishing of stone	26.7
Manufacture of metal structures and parts of structures	28.11
Construction, including related branches	45.1 to 4; Activities listed in the Annex to Directive 96/71/EC
Security activities	74.60
Industrial cleaning	74.70
Home nursing	85.14
Social work and activities without accommodations	85.32

(*) NACE: see 31990 R 3037: Council Regulation (EEC) No 3037/90 of 9 October 1990 on the statistical classification of economic activities in the European Community (OJ L 293, 24.10.1990, p. 1).

To the extent that Germany or Austria derogate from the first paragraph of Article 56 of the TFEU in accordance with the preceding subparagraphs, Croatia may, after notifying the Commission, take equivalent measures.

The effect of the application of this paragraph shall not result in conditions for the temporary movement of workers in the context of the transnational provision of services between Germany or Austria and Croatia which are more restrictive than those prevailing on the date of signature of the Treaty of Accession.

13. The effect of the application of paragraphs 2 to 5 and 7 to 11 shall not result in conditions for access of Croatian nationals to the labour markets of the present Member States which are more restrictive than those prevailing on the date of signature of the Treaty of Accession.

Notwithstanding the application of the provisions laid down in paragraphs 1 to 12, the present Member States shall, during any period when national measures or those resulting from bilateral agreements are applied, give preference to workers who are nationals of the Member States over workers who are nationals of third countries as regards access to their labour market.

Croatian migrant workers and their families legally resident and working in another Member State or migrant workers from other Member States and their families legally resident and working in Croatia shall not be treated in a more restrictive way than those from third countries resident and working in that Member State or Croatia respectively. Furthermore, in application of the principle of Union preference, migrant workers from third countries resident and working in Croatia shall not be treated more favourably than nationals of Croatia.

3. FREE MOVEMENT OF CAPITAL

Treaty on European Union,

Treaty on the Functioning of the European Union.

Notwithstanding the obligations under the Treaties on which the European Union is founded, Croatia may maintain in force for seven years from the date of accession the restrictions laid down in its Agricultural Land Act (OG 152/08), as in force on the date of signature of the Treaty of Accession, on the acquisition of agricultural land by nationals of another Member State, by nationals of the States which are a party to the European Economic Area Agreement (EEAA) and by legal persons formed in accordance with the laws of another Member State or an EEAA State. However, a national of a Member State or a legal person formed in accordance with the laws of another Member State may in no instance be treated less favourably in respect of the acquisition of agricultural land than such a national or person would have been treated at the date of signature of the Accession Treaty or be treated in a more restrictive way than a national or a legal person of a third country.

Self-employed farmers, who are nationals of another Member State and who wish to establish themselves and reside in Croatia, shall not be subject to the provisions of the preceding paragraph or to any rules and procedures other than those to which nationals of Croatia are subject.

A general review of this transitional measure shall be held by the end of the third year following the date of accession. To this effect, the Commission shall submit a report to the Council. The Council may, acting unanimously on a proposal from the Commission, decide to shorten or terminate the transitional period indicated in the first paragraph.

If there is sufficient evidence that, upon expiry of the transitional period, there will be serious disturbances or a threat of serious disturbances on the agricultural land market of Croatia, the Commission, at the request of Croatia, shall decide upon the extension of the transitional period for three years. This extension might be limited to selected geographical areas particularly affected.

4. **AGRICULTURE**

I.TRANSITIONAL MEASURES FOR CROATIA

1. 32001 L 0113: Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67).

   By way of derogation from the obligation laid down in Article 8, the marketing of products designated under the names "domaća marmelada" and "ekstra domaća marmelada" shall be permitted on the Croatian market until clearance of the stock existing at the date of accession.

2. 32006 R 0510: Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ L 93, 31.03.2006, p. 12 and OJ L 335M, 13.12.2008, p. 213).

   (a) In Article 5(8), the second subparagraph is replaced by the following:

   'Bulgaria, Romania and Croatia shall introduce the said laws, regulations or administrative provisions not later than one year after their respective date of accession.'

   (b) In Article 5(11), the first subparagraph is replaced by the following:

   '11. In the case of Bulgaria, Romania and Croatia, the national protection of geographical indications and designations of origin existing on the date of their accession may continue for twelve months from their respective date of accession.'

3. 32007 R 1234: Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

(a) In Article 118m, the following paragraph is added:

'5. By way of derogation from paragraphs 1 to 4, Croatia shall be allowed to place on the market in Croatia or export to third countries, wines with the denomination "Mlado vino portugizac", until clearance of the stocks that were available at the date of accession. Croatia shall set up a computerised databank with information of the stocks available at the date of accession, and shall ensure that these stocks are verified and declared to the Commission.'

(b) In Article 118s, the following paragraph is added:

'5. For Croatia, the wine names published in OJ C 116 of 14 April 2011 shall be protected under this Regulation, subject to a favourable outcome of the objection procedure. The Commission shall list them in the register provided for in Article 118n.

Paragraphs 2 to 4 of this Article shall apply, subject to the following: The deadline referred to in paragraph 3 shall be one year from the date of accession of Croatia. The deadline referred to in paragraph 4 shall be four years from the date of accession of Croatia. '

4. 32009 R 0073: Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 (OJ L 30, 31.1.2009, p. 16).

(a) By way of derogation from the obligation laid down in Article 4(1) of Regulation (EC) No 73/2009 to respect the statutory management requirements listed in Annex II of that Regulation, farmers in Croatia receiving direct payments shall include into the scope of cross compliance the statutory management requirements laid down in Points A, B and C of Annex II according to the following time schedule: as of 1 January 2014 for Point A, as of 1 January 2016 for Point B and as of 1 January 2018 for Point C.

(b) After Chapter 1 in title V of Regulation (EC) No 73/2009, the following Chapter heading and Article are inserted:

'CHAPTER 1a

Single payment scheme

Article 121a

Single payment scheme in Croatia

For Croatia, the application of Articles 4, 5, 23, 24 and 25 shall be optional until 31 December 2013 insofar as those provisions relate to statutory management requirements. As from 1 January 2014 a farmer receiving payments under the single payment scheme in Croatia shall fulfil the statutory management requirements referred to in Annex II in accordance with the following timetable:

(a) requirements referred to in Point A of Annex II shall apply from 1 January 2014;
(b) requirements referred to in Point B of Annex II shall apply from 1 January 2016;
(c) requirements referred to in Point C of Annex II shall apply from 1 January 2018.'

II. TRANSITIONAL TARIFF QUOTA FOR RAW CANE SUGAR FOR REFINING

An annual autonomous *erga omnes* import quota of 40 000 tonnes of raw cane sugar for refining shall be reserved for Croatia for a period of up to three marketing years following its accession at an import duty of EUR 98,00 per tonne. Should negotiations with other Members of the World Trade Organisation according to Article XXIV.6 of the General Agreement on Tariffs and Trade on compensatory adjustment following the accession of Croatia result in the opening of compensatory sugar quotas before the end of the transitional period, the quota of 40 000 tonnes allocated to Croatia shall be terminated, wholly or partially, upon the opening of the compensatory sugar quotas. The Commission shall adopt necessary implementing measures in accordance with the procedure referred to in Article 195(2) of Council Regulation (EC) No1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) in conjunction with Article 13(1)(b) of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

III. TEMPORARY DIRECT PAYMENTS MEASURES FOR CROATIA

The reimbursement of direct payments granted to farmers for the year 2013 shall be conditional on the application by Croatia, before accession, of rules identical to those set out for such direct payments in Council Regulation (EC) 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003[1], and in Commission Regulations (EC) No 1120/2009, (EC) No 1121/2009 and (EC) No 1122/2009[2].

5. FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY

I. LAYING HENS

31999 L 0074: Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p. 53).

By way of derogation from Article 6 of Council Directive 1999/74//EC, laying hens in lay at the date of accession may be kept in cages which are not in conformity with the structural requirements laid down in that Article. Croatia shall ensure that the use of such cages stops at the latest 12 months after accession.

[1] OJ L 30, 31.1.2009, p. 16.

[2] Commission Regulation (EC) No 1120/2009 of 29 October 2009 laying down detailed rules for the implementation of the single payment scheme provided for in Title III of Council Regulation (EC) No 73/2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, Commission Regulation (EC) No 1121/2009 of 29 October 2009 laying down detailed rules for the application of Council Regulation (EC) No 73/2009 as regards the support schemes for farmers provided for in Titles IV and V thereof and Commission Regulation (EC) No 1122/2009 of 30 November 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector (OJ L 316, 2.12.2009, p. 1, 27 and 65).

Eggs from those un-enriched cages shall only be placed on the national market of Croatia. Such eggs and their packs shall be clearly identified with a special mark, which allows for the necessary controls. A clear description of this special mark shall be communicated to the Commission not later than one year before the date of accession.

II. ESTABLISHMENTS (MEAT, MILK, FISH AND ANIMAL BY-PRODUCTS)

32004 R 0852: Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1);

32004 R 0853: Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

32009 R 1069: Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

a) The structural requirements laid down in:

i) Regulation (EC) No 852/2004:
- Annex II, Chapter II;

ii) Regulation (EC) No 853/2004:

- Annex III, Section I, Chapters II and III,

- Annex III, Section II, Chapters II and III,

- Annex III, Section V, Chapter I;

iii) Regulation (EU) No 142/2011:

- Annex IV, Chapter I,

- Annex IX, Chapters I, II and III,

- Annex X, Chapters I and II, and

- Annex XIII;

shall not apply to certain establishments in the meat, milk, fish and animal by-products sectors in Croatia until 31 December 2015, subject to the conditions laid down below.

b) As long as the establishments referred to in paragraph (a) benefit from the provisions of that paragraph, products originating from those establishments shall only be placed on the national market of Croatia or on markets of third countries in accordance with relevant Union legislation, or used for further processing in establishments in Croatia also covered by the provisions of paragraph (a), irrespective of the date of marketing.

c) Food from establishments referred to in paragraph (a) above shall bear a different health or identification mark to that provided for in Article 5 of Regulation (EC) No 853/2004. A clear description of the different health or identification mark shall be communicated to the Commission not later than one year before the date of accession.

d) Paragraphs (b) and (c) also apply to all products originating from integrated meat, milk or fishery establishments where a part of the establishment is subject to the provisions of paragraph (a).

e) Croatia shall continuously monitor the implementation of the national programme for upgrading establishments and shall provide the Commission with an annual plan of progress in this respect. Croatia shall ensure that an individual upgrading plan for each of these establishments with deadlines for the correction of the structural requirements is elaborated and made available to the Commission on request.

f) The Commission shall in good time before accession establish a list of the establishments referred to in paragraph (a). This list shall be made public and include the name and address of each establishment.

Croatia shall ensure that any establishments, which by the time of accession fail fully to comply with the food safety *acquis*, except where covered by the provisions of this transitional measure, terminate their activities.

Implementing rules to ensure the smooth operation of the transitional regime with respect to Regulations (EC) No 852/2004 and No 853/2004, may be adopted in accordance with the second paragraph of Article 12 and the second paragraph of Article 9 respectively thereof.

Implementing rules to ensure the smooth operation of the transitional regime with respect to Regulation (EC) No 1069/2009 may be adopted in accordance with Article 52(4) thereof.

III. MARKETING OF SEEDS

32002 L 0053: Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1);

32002 L 0055: Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

Croatia may postpone until 31 December 2014 the application of Article 4(1) of Directive 2002/53/EC and Article 4(1) of Directive 2002/55/EC with regard to the marketing in its territory of seeds of varieties listed in its respective national catalogues of varieties of agricultural plant species and varieties of vegetable plant species which have not been officially accepted in accordance with the provisions of those Directives. During that period, such seeds shall not be marketed in the territory of other Member States.

IV. NEUM

31997 L 0078: Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

Article 1 is replaced by the following:

"Article 1

1. Veterinary checks on products from third countries introduced into one of the territories listed in Annex I shall be carried out by Member States in accordance with this Directive and with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(1)].

2. By way of derogation from paragraph 1, consignments of products coming from the territory of Croatia and transiting through the territory of Bosnia and Herzegovina at Neum ('Neum corridor') before re-entering the territory of Croatia via the points of entry at Klek or Zaton Doli, may be exempted from the veterinary checks, subject to compliance with the following requirements:

(a) Croatia must have in place on or before the date of accession points of entry to the north and south of the Neum corridor that are equipped, staffed and prepared to ensure compliance with the requirements of this paragraph;

(b) Croatia must ensure that:
(i) only closed vehicles are used for transporting the consignments;
(ii) vehicles transporting consignments are sealed with uniquely numbered seals before transiting the Neum corridor;
(iii) a register is made, detailing which numbered seals have been attached to which vehicles, which allows for the necessary controls;
(iv) the date and time of leaving and re-entering the territory of Croatia of the vehicles transporting consignments are recorded, so that the total time of transit can be calculated.

(c) Croatia shall ensure that consignment must not be allowed to re-enter its territory where:
(i) a vehicle's seal has been broken or replaced during transiting the Neum corridor; and/or
(ii) the total time of transit considerably exceeds the acceptable total time of transit, given the total distance of transit unless the competent authority has carried out an assessment of the risks to animal and public health and has adopted effective, proportionate and targeted measures based on that assessment.

(d) Croatia must regularly and as necessary inform the Commission of any non-compliance with the requirements of point (b) and of the measures it has taken under point (c).

(e) Where necessary, a decision to suspend or withdraw the derogation from paragraph 1 shall be adopted in accordance with the procedure laid down in Article 29.

(f) Where necessary, detailed rules for the application of this paragraph may be adopted in accordance with the procedure laid down in Article 29.'

6. **FISHERIES**

32006 R 1967: Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea, amending Regulation (EEC) No 2847/93 and repealing Regulation (EC) No 1626/94 (OJ L 409, 30.12.2006, p. 11. Corrected version in OJ L 36, 8.2.2007, p. 6).

(a) By way of derogation from Article 13(1) and (2), at depths less than 50 meters vessels registered and operating only in the Western Istria region shall be temporarily allowed, until 30 June 2014, to use bottom trawls at the minimum distance of 1,5 nautical miles from the coast.

This derogation shall apply in the area designated as Western Istria, defined from the point with geographic coordinates φ=44.52135 and λ=14.29244 with a line due north and a line due west.

For vessels of less than 15 meters length overall, at depths over 50 meters Croatia shall be temporarily allowed, until 30 June 2014, to use bottom trawls at the minimum distance of 1 nautical mile from the coast, maintaining all other spatial and temporal restrictions applied on the date of accession.

(b) By way of derogation from Article 17 (1), a limited number of vessels included in the specific category of non-commercial fisheries "small scale artisanal fishing for personal needs", which shall not exceed 2 000 vessels, shall be allowed to use maximum 200 meters of gillnets until 31 December 2014, provided that all other restrictions in place on the date of accession continue to apply. Croatia shall submit to the Commission on the date of accession, at the latest, the list of vessels covered by this transitional period, including their characteristics and capacity, expressed in terms of GT and kW.

7. **TRANSPORT POLICY**

1. 31992 R 3577: Council Regulation (EEC) No 3577/92 of 7 December 1992 applying the principle of freedom to provide services to maritime transport within Member States (maritime cabotage) (OJ L 364, 12.12.1992, p. 7).

In Article 6, the following paragraphs are added:

'4. By way of derogation from the second subparagraph of Article 4(1), public service contracts concluded before the date of Croatia's accession may continue to be applied until 31 December 2016.

5. By way of derogation from Article 1(1), until 31 December 2014 cruise services carried out between Croatian ports by ships smaller than 650 gross tonnes shall be reserved to ships registered in, and flying the flag of, Croatia, which are operated by shipping companies, established in accordance with Croatian law, and whose principal place of business is situated, and effective control exercised, in Croatia.

6. By way of derogation from Article 1(1), and for the transitional period until 31 December 2014, the Commission may, upon a substantiated request by a Member State, decide, within 30 working days of receipt of the relevant request, that ships benefiting from the derogation set out in paragraph 5 of this Article shall not carry out cruise services between ports of certain areas of a Member State other than Croatia where it is demonstrated that the operation of these services seriously disturbs or threatens to seriously disturb the internal transport market in the areas concerned. If after the period of 30 working days the Commission has taken no decision, the Member State concerned shall be entitled to apply safeguard measures until the Commission has taken its decision. In the event of an emergency, the Member State may unilaterally adopt appropriate provisional measures which may remain in force for no more than three months. The Commission shall be immediately informed. The Commission may abrogate the measures or confirm them until it takes its final decision. Member States shall be kept informed.'

2. 32009 R 1072: Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market (OJ L 300, 14.11.2009, p. 72).

By way of derogation from Article 8 of Regulation (EC) No 1072/2009, the following shall apply:

– for a period of two years after the date of Croatia's accession, undertakings established in Croatia shall be excluded from cabotage in the other Member States;

– for a period of two years after the date of Croatia's accession, other Member States may notify the Commission on whether they intend to prolong the transitional period mentioned in the first indent for a maximum of two years or whether they intend to apply Article 8 of Regulation (EC) No 1072/2009 in relation to undertakings established in Croatia. In the absence of such notification, Article 8 shall apply;

– any of the present 27 Member States may at any time during a period of two years from the date of Croatia's accession notify the Commission of its intention to apply Article 8 of Regulation (EC) No 1072/2009 in relation to undertakings established in Croatia;

– only carriers established in Member States where Article 8 of Regulation (EC) No 1072/2009 applies in relation to undertakings established in Croatia may perform cabotage in Croatia;

– for a period of four years after the date of Croatia's accession, any Member State applying Article 8 of Regulation (EC) No 1072/2009 may, in case of serious disturbance of its national market or parts thereof due to or aggravated by cabotage, such as serious excess of supply over demand or a threat to the financial stability or survival of a significant number of road haulage undertakings, request the Commission to suspend in whole or in part the application of Article 8 of Regulation (EC) No 1072/2009 in relation to undertakings established in Croatia. In this case, Article 10 of Regulation (EC) No 1072/2009 shall apply.

Member States that apply the transitional measure referred to in the first and second indents of the first paragraph may progressively exchange cabotage authorisations on the basis of bilateral agreements with Croatia.

The transitional arrangements referred to in the first and second paragraphs shall not lead to more restrictive access for Croatian carriers to cabotage in any Member State than that prevailing at the time of the signature of the Accession Treaty.

8. **TAXATION**

1. 31992 L 0079: Council Directive 92/79/EEC of 19 October 1992 on the approximation of taxes on cigarettes (OJ L 316, 31.10.1992, p. 8).

In Article 2(2), the following subparagraph is added:

'Croatia shall be allowed a transitional period until 31 December 2017 in order to reach the requirements laid down in the first and second subparagraphs. However, as from 1 January 2014 the excise duty shall not be less than EUR 77 per 1 000 cigarettes irrespective of the weighted average retail selling price.'

2. 32006 L 0112: Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1).

(a) Article 13(2) is replaced by the following:

'2. Member States may regard activities, exempt under Articles 132, 135, 136 and 371, Articles 374 to 377, Article 378(2), Article 379(2) or Articles 380 to 390c, engaged in by bodies governed by public law as activities in which those bodies engage as public authorities.'

(b) Article 80 (1)(b) is replaced by the following:

'(b) where the consideration is lower than the open market value and the supplier does not have a full right of deduction under Articles 167 to 171 and Articles 173 to 177 and the supply is subject to an exemption under Articles 132, 135, 136, 371, 375, 376, 377, 378(2), 379(2) or Articles 380 to 390c;'

(c) Article 136, subparagraph (a), is replaced by the following:

'(a) the supply of goods used solely for an activity exempted under Articles 132, 135, 371, 375, 376 and 377, Article 378(2), Article 379(2) and Articles 380 to 390c, if those goods have not given rise to deductibility;'

(d) Article 221(3) is replaced by the following:

'3. Member States may release taxable persons from the obligation laid down in Article 220 to issue an invoice in respect of supplies of goods or services which they have made in their territory and which are exempt, with or without deductibility of the VAT paid at the preceding stage, pursuant to Articles 110 and 111, Article 125(1), Article 127, Article 128(1), Articles 132, 135, 136, 371, 375, 376 and 377, Article 378(2), Article 379(2) and Articles 380 to 390c.'

(e) The following Article is inserted after Article 390b:

'*Article 390c*

Croatia may, in accordance with the conditions applying in that Member State on the date of its accession, continue to exempt the following transactions:

(a) the supply of building land, with or without buildings built on it, as referred to in point (j) of Article 135(1) and in point (9) of Annex X, Part B, non-renewable, until 31 December 2014;

(b) the international transport of passengers, as referred to in point (10) of Annex X, Part B, for as long as the same exemption is applied in any of the Member States which were members of the Union before the accession of Croatia.'

(f) Article 391 is replaced by the following:

'*Article 391*

Member States which exempt the transactions referred to in Articles 371, 375, 376 or 377, Article 378(2), Article 379(2) or Articles 380 to 390c may grant taxable persons the right to opt for taxation of those transactions.'

(g) The Title of Annex X (also, correspondingly, in the Table of contents) is replaced by the following:

'LIST OF TRANSACTIONS COVERED BY THE DEROGATIONS REFERRED TO IN ARTICLES 370 AND 371 AND ARTICLES 375 TO 390c'.

9. **JUSTICE, FREEDOM AND SECURITY**

32006 R 0562: Regulation (EC) No 562/2006 of the European Parliament and of the Council of 15 March 2006 establishing a Community Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 105, 13.4.2006, p. 1).

The following Article is inserted after Article 19:

'*Article 19a*

By derogation from the provisions of this Regulation relating to the establishment of border crossing points, and until the entry into force of a decision by the Council of the European Union on the full application of the provisions of the Schengen *acquis* in Croatia pursuant to Article 4(2) of the Act of Accession or until this Regulation is amended to include provisions governing border control at common border crossing points, whichever is the earlier, Croatia may maintain the common border crossing points at its border with Bosnia and Herzegovina. At these common border crossing points, border guards of one party shall carry out entry and exit checks on the territory of the other party. All entry and exit checks by Croatian border guards shall be carried out in compliance with the *acquis* of the Union, including Member States' obligations as regards international protection and non-refoulement. The relevant bilateral agreements establishing the common border crossing points in question shall, if necessary, be amended to that end.'

10. **ENVIRONMENT**

I. HORIZONTAL LEGISLATION

1. 32003 L 0087: Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (OJ L 275, 25.10.2003, p. 32).

(a) With regard to all flights between two aerodromes situated in the Croatian territory, and all flights between an aerodrome situated in the Croatian territory and an aerodrome situated in a country outside the EEA area (referred to as "additional aviation activities"), the following shall apply:

(i) By way of derogation from Article 3c(2), the period referred to in Article 13(1) and beginning on 1 January 2013 shall start on 1 January 2014 for the additional aviation activities.

(ii) By way of derogation from Article 3c(4), the Commission shall decide, following the procedure referred to in that same provision, on the historical aviation emissions for the additional aviation activities within six months from the date of accession.

(iii) By way of derogation from Article 3d(2), from 1 January 2014, the percentage of allowances to be auctioned for the additional aviation activities shall be the proportion of the allowances remaining after having calculated the number of allowances to be allocated free of charge under point (d) of Article 3e(3) and the number of allowances to be set aside in a special reserve under Article 3f.

(iv) By way of derogation from Article 3d(3), the attributed aviation emissions from additional aviation activities shall be decided upon by the Commission for the reference year 2010 on the basis of the best available data. The number of allowances to be auctioned by Member States whose total attributed aviation emissions include those from flights arriving from a Croatian aerodrome, shall be adjusted from 1 July 2013, in order to reallocate auctioning rights related to these emissions, to Croatia.

(v) By way of derogation from Article 3e(1), the monitoring year for the additional aviation activities shall be 2012, and any application for an allocation of allowances shall be made to the Croatian competent authorities by 31 March 2013.

(vi) By way of derogation from Article 3e(2), Croatia shall submit to the Commission applications related to the additional aviation activities by 1 July 2013.

(vii) By way of derogation from Article 3e(3), the Commission shall adopt a decision on the matters referred to in points (a) to (e) thereof, in relation to the additional aviation activities by 30 September 2013.

(viii) By way of derogation from point (d) of Article 3e(3), for the additional aviation activities the number of allowances to be allocated free of charge shall be calculated by multiplying the benchmark specified in point (e) by the sum of the tonne-kilometre data included in the applications submitted to the Commission in accordance with Article 3e(2) adjusted to account for the average change in aviation tonne-kilometre activity covered by the EU ETS relative to 2010 levels. If necessary, the benchmark may be subject to a uniform correction factor to be applied by the Commission.

(ix) By way of derogation from Article 3e(3), for the additional aviation activities, the benchmark referred to in point (e) thereof shall be the same as that calculated for aviation activities covered by the EU ETS from 1 January 2012.

(x) By way of derogation from Article 3e(5), the date of issue of allowances for the additional aviation activities shall be 28 February 2014.

(xi) By way of derogation from Article 3f, with regard to additional aviation activities, any reference to the second calendar year of the period starting in 2013 shall be read as a reference to 2014 and any references to the third calendar year of that period shall be read as a reference to 2015.

(xii) By way of derogation from Article 14(3), for the additional aviation activities, the date set therein shall be 1 July 2013.

(xiii) By way of derogation from Article 18a(1), the reattribution of administrative responsibilities for aircraft operators to Croatia shall take place during the year 2014, after fulfilment by the operator of its 2013 obligations, unless a different date is agreed between the former administering authority and Croatia following a request by the aircraft operator within six months from the date the Commission publishes an update of the list of operators which takes into account the accession of Croatia. In this case, reallocation shall take place no later than the year 2020 with regard to the trading period beginning in 2021.

(xiv) By way of derogation from point 6 of Annex I, additional aviation activities shall be included as from 1 January 2014.

(b) Without prejudice to the above derogations, Croatia shall bring into force the laws, regulations and administrative provisions necessary to ensure that it can comply with the Directive as of accession for the whole year 2013.

2. 32010 R 0920: Commission Regulation (EU) No 920/2010 of 7 October 2010 for a standardised and secured system of registries pursuant to Directive 2003/87/EC of the European Parliament and of the Council and Decision No 280/2004/EC of the European Parliament and of the Council (OJ L 270, 14.10.2010, p. 1).

Articles 16, 29, 41, 46 and 54, and Annex VIII, relating to the aviation activities, shall apply in Croatia as from 1 January 2014.

II. AIR QUALITY

32008 L 0050: Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p.1).

(a) By way of derogation from Annex XIV, the reference year of point A, first paragraph shall be the second year after the end of the year of Croatia's accession. The Average Exposure Indicator for that reference year shall be the mean concentration of the year of accession and the first and the second year after the year of accession.

(b) By way of derogation from Annex XIV, point B, the exposure reduction target shall be calculated in relation to the Average Exposure Indicator in the reference year which is the second year after the end of the year of Croatia's accession.

III. WASTE MANAGEMENT

31999 L 0031: Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1).

(a) By way of derogation from points (a), (b) and (c) of the first subparagraph of Article 5(2), the requirement to reduce the amount of biodegradable municipal waste going to landfills to respectively 75 %, 50 % and 35 % of the total amount (by weight) of biodegradable municipal waste produced in 1997 shall apply in Croatia in accordance with the deadlines specified below.

Croatia shall ensure a gradual decrease in the amount of biodegradable municipal waste going to landfills according to the following scheme:

(i) by 31 December 2013, the share of biodegradable municipal waste deposited on landfills will be reduced to 75 % of the total amount (by weight) of biodegradable municipal waste produced in 1997;

(ii) by 31 December 2016, the share of biodegradable municipal waste deposited on landfills will be reduced to 50 % of the total amount (by weight) of biodegradable municipal waste produced in 1997;

(iii) by 31 December 2020, the share of biodegradable municipal waste deposited on landfills will be reduced to 35 % of the total amount (by weight) of biodegradable municipal waste produced in 1997.

(b) By way of derogation from Article 14 (c), all existing landfills in Croatia shall comply with the requirements of the Directive by 31 December 2018 with the exception of the requirements laid down in Annex I, point 1.

Croatia shall ensure a gradual reduction of waste landfilled in existing non-compliant landfills in accordance with the following annual maximum quantities:

- by 31 December 2013: 1 710 000 tonnes
- by 31 December 2014: 1 410 000 tonnes
- by 31 December 2015: 1 210 000 tonnes
- by 31 December 2016: 1 010 000 tonnes
- by 31 December 2017: 800 000 tonnes

Croatia shall provide the Commission by 31 December of each year starting with the year of accession a report concerning the gradual implementation of the Directive and compliance with intermediate targets.

IV. WATER QUALITY

1. 31991 L 0271: Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).

By way of derogation from Articles 3, 4, 5, 6 and 7, the requirements for collecting systems and treatment of urban waste water shall apply in Croatia as from 1 January 2024, in accordance with the following intermediate targets:

(a) By 31 December 2018, compliance with the Directive shall be achieved in agglomerations with a population equivalent of more than 15 000, except for the following coastal agglomerations:

Bibinje - Sukošan,
Biograd,
Jelsa - Vrboska,
Makarska,
Mali Lošinj,
Malinska - Njivice,
Nin,
Pirovac - Tisno - Jezera,
Pula - sjever,
Vela Luka,
Vir.

(b) By 31 December 2020, compliance with the Directive shall be achieved in agglomerations with a population equivalent of more than 10 000 whose waste water is discharged into sensitive areas, as well as for treatment plants which are situated in the relevant catchment areas of the Danube and other sensitive areas and that contribute to the pollution of these areas, and in the 11 coastal agglomerations listed in point (a) above.

(c) By 31 December 2023, compliance with the Directive shall be achieved in agglomerations with a population equivalent of more than 2 000.

2. 31998 L 0083: Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p.32).

By way of derogation, the microbiological parameters and indicator parameters laid down, respectively, in Annex I – Parts A and C shall apply to the following water supply zones in Croatia as from 1 January 2019:

Water Supply Zone	Area No.	Population	Nuts code
DA BJELOVAR	107	51 921	HR02
DA DARUVAR	125	25 608	HR02
DA ĐURĐEVAC	204	30 079	HR01
DA GORSKI KOTAR	306	26 430	HR03
DA HRVATSKO ZAGORJE	101	143 093	HR01
DA ISTOČNA SLAVONIJA - SLAVONSKI BROD	129	124 349	HR02
DA ISTRA	301	97 046	HR03
DA JASTREBARSKO-KLINČA SELA	114	23 213	HR01
DA KARLOVAC-DUGA RESA	116	91 511	HR02
DA KNIN	404	17 187	HR03
DA KOPRIVNICA	203	58 050	HR01
DA KRIŽEVCI	103	36 338	HR01
DA LAPAC	311	1 880	HR03
DA LIČKA JESENICA	118	13 893	HR02
DA NAŠICE	210	37 109	HR02
DA NERETVA-PELJEŠAC-KORČULA-LASTOVO-MLJET	407	58 246	HR03
DA OGULIN	117	25 192	HR02
DA OPATIJA-RIJEKA-KRK	304	238 088	HR03
DA OTOČAC	309	15 434	HR03
DA OZALJ	113	11 458	HR02
DA PETRINJA-SISAK	121	84 528	HR02
DA PISAROVINA	115	3 910	HR01
DA PITOMAČA	205	10 465	HR02

DA POŽEŠTINE	128	70 302	HR02
DA SVETI IVAN ZELINA	102	17 790	HR01
DA UDBINA-KORENICA	310	6 747	HR03
DA VARAŽDIN	201	184 769	HR01
DA VELIKA GORICA	503	75 506	HR01
DA ZAGREB	501	831 047	HR01
DA ZAPREŠIĆ	502	50 379	HR01
DA ZRMANJA-ZADAR	401	158 122	HR03
DA ŽRNOVNICA	307	20 160	HR03

V. INTEGRATED POLLUTION PREVENTION AND CONTROL

1. 31999 L 0013: Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (OJ L 85, 29.3.1999, p. 1).

(a) By way of derogation from Article 5 and Annexes IIA and IIB, the emission limit values of volatile organic compounds due to the use of organic solvents in certain activities and installations shall apply to the following installations in Croatia only as from the dates mentioned below:

(i) As from 1 January 2014:

1. ČATEKS, dioničko društvo za proizvodnju tkanine, umjetne kože, kućanskog rublja i proizvoda za šport i rekreaciju (ČATEKS d.d.), Čakovec, Ulica Zrinsko-Frankopanska 25
2. Drvna industrija KLANA d.d. (DI KLANA d.d.), Klana, Klana 264.

(ii) As from 1 January 2015:

1. HEMPEL društvo s ograničenom odgovornošću Prerađivačka kemijska industrija (HEMPEL d.o.o.), Umag, Novigradska ulica 32
2. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Zadar (Zadar facility, location: Zadar, Murvica bb)
3. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Umag (Umag facility, location: Umag, Ungarija bb).

(iii) As from 1 January 2016:

1. PALMA društvo s ograničenom odgovornošću za proizvodnju pogrebnih potrepština (PALMA d.o.o.), Jastrebarsko, Donja Reka 24
2. FERRO-PREIS društvo s ograničenom odgovornošću za proizvodnju ljevanih, kovanih i prešanih metalnih proizvoda (FERRO-PREIS d.o.o.), Čakovec, Dr. Tome Bratkovića 2
3. AD PLASTIK dioničko društvo za proizvodnju dijelova i pribora za motorna vozila i proizvoda iz plastičnih masa (AD PLASTIK d.d.), Solin, Matoševa ulica 8 - location: Zagreb, Jankomir 5
4. REMONT ŽELJEZNIČKIH VOZILA BJELOVAR društvo s ograničenom odgovornošću (RŽV d.o.o.), Bjelovar, Trg Kralja Tomislava 2
5. FEROKOTAO d.o.o. za proizvodnju transformatorskih kotlova i ostalih metalnih konstrukcija (FEROKOTAO d.o.o.), Kolodvorska bb, Donji Kraljevec
6. SAME DEUTZ-FAHR Žetelice, društvo s ograničenom odgovornošću za proizvodnju i usluge (SAME DEUTZ-FAHR Žetelice d.o.o.), Županja, Industrijska 5
7. CMC Sisak d.o.o. za proizvodnju i usluge (CMC Sisak d.o.o.), Sisak, Braće Kavurića 12
8. METALSKA INDUSTRIJA VARAŽDIN dioničko društvo (MIV d.d.), Varaždin, Fabijanska ulica 33

9. CHROMOS BOJE I LAKOVI, dioničko društvo za proizvodnju boja i lakova (CHROMOS BOJE I LAKOVI, d.d.), Zagreb, Radnička cesta 173/d
10. CHROMOS-SVJETLOST, Tvornica boja i lakova, društvo s ograničenom odgovornošću (CHROMOS-SVJETLOST d.o.o.), Lužani, Mijata Stojanovića 13
11. MURAPLAST društvo s ograničenom odgovornošću za proizvodnju i preradu plastičnih masa (MURAPLAST d.o.o.), Kotoriba, Industrijska zona bb
12. ISTRAPLASTIKA dioničko društvo za proizvodnju ambalaže (ISTRAPLASTIKA d.d.), Pazin, Dubravica 2/a
13. GRUDINA društvo s ograničenom odgovornošću za proizvodnju i usluge (GRUDINA d.o.o.), Županja, Aleja Matice Hrvatske 21
14. SLAVICA - KEMIJSKA ČISTIONICA, vlasnik Slavica Hinek, Beli Manastir, J. J. Strossmayera 17
15. MIDA d.o.o. za usluge i ugostiteljstvo (MIDA d.o.o.), Osijek, Ivana Gundulića 206
16. EXPRESS KEMIJSKA ČISTIONA, vlasnik Ivanka Drčec, Križevci, Ulica Petra Preradovića 14
17. Kemijska čistionica "BISER", vlasnik Gojko Miletić, Dubrovnik, Nikole Tesle 20
18. Kemijska čistionica "ELEGANT", vlasnik Frane Miletić, Dubrovnik, Andrije Hebranga 106
19. KOLAR obrt za kemijsko čišćenje odjeće, vlasnik Svjetlana Kolar, Žakanje, Kamanje 70/a
20. MM d.o.o. za trgovinu i usluge (MM d.o.o.), Draganić, Lug 112
21. KEMIJSKA ČISTIONA "AGATA", vlasnik Branko Szabo, Virovitica, S. Radića 66
22. Obrt za kemijsko čišćenje odjeća "KEKY", vlasnik Jovita Malek-Milovanović, Pula, Dubrovačke bratovštine 29
23. LORNA d.o.o. za pranje i kemijsko čišćenje tekstila i krznenih proizvoda (LORNA d.o.o.), Pula, Valdebečki put 3
24. KEMIJSKA ČISTIONICA I KOPIRANJE KLJUČEVA "ŠUPER", vlasnik Ivan Šuper, Virovitica, J.J. Strossmayera 5
25. KEMIJSKO ČIŠĆENJE ŠTEFANEC kemijsko čišćenje tekstila i krznenih proizvoda, vlasnik Nadica Štefanec, Koprivnica, Ledinska 1a
26. ARIES društvo s ograničenom odgovornošću za proizvodnju glazbala i usluge (ARIES d.o.o.), Varaždin, Creska 3

27. OBRT ZA PRANJE I ČIŠĆENJE TEKSTILA I ODJEĆE ĐORĐEVIĆ, vlasnik Javorka Đorđević, Makarska, Ante Starčevića 2
28. OBRT ZA USLUGE PRANJA I KEMIJSKOG ČIŠĆENJA "KORDIĆ", vlasnik Pero Kordić, Makarska, Kipara Rendića 2
29. Kemijsko čišćenje tekstila i krznenih proizvoda ČISTIONICA GALEB, vlasnik Stipan Radović, Zadar, Varoška 6
30. KEMIJSKA ČISTIONICA, vlasnik Krešimir Borovec, Varaždin, Juraja Habdelića 2
31. KEMIJSKA ČISTIONICA "VBM", vlasnik Biserka Posavec, Maruševec, Biljevec 47
32. OBRT ZA KEMIJSKO ČIŠĆENJE I PRANJE RUBLJA "PLITVICE", vlasnik Momirka Ninić, Pula, Rizzijeva 34
33. "ANA" KEMIJSKA ČISTIONA, vlasnik Saša Dadić, Pula, Zagrebačka 18
34. Kemijska čistionica, vlasnik Gordana Bralić, Trogir, Put Demunta 16
35. "ECONOMATIC" - PRAONICA RUBLJA, vlasnik Marino Bassanese, Umag, Savudrijska cesta 9
36. SERVIS ZA ČIŠĆENJE "SJAJ", vlasnik Danijela Brković, Virovitica, Golo Brdo 2A.

(b) By way of derogation from Article 5(3)(b), the obligation for the operator to demonstrate to the satisfaction of the competent authority that the best available techniques are being used for coating processes in shipbuilding with regard to the following installations in Croatia shall apply as from 1 January 2016:

1. BRODOTROGIR d.d., Trogir, Put Brodograditelja 16
2. NCP-NAUTIČKI CENTAR PRGIN-REMONTNO BRODOGRADILIŠTE ŠIBENIK d.o.o. za remont i proizvodnju brodova (NCP - REMONTNO BRODOGRADILIŠTE ŠIBENIK d.o.o.), Šibenik, Obala Jerka Šižgorića 1
3. BRODOGRADILIŠTE VIKTOR LENAC dioničko društvo (BRODOGRADILIŠTE VIKTOR LENAC d.d.), Rijeka, Martinšćica bb
4. 3. MAJ BRODOGRADILIŠTE d.d., Rijeka, Liburnijska 3
5. BRODOSPLIT-BRODOGRADILIŠTE društvo s ograničenom odgovornošću (BRODOSPLIT-BRODOGRADILIŠTE d.o.o.), Split, Put Supavla 21
6. ULJANIK Brodogradilište, d.d., Pula, Flaciusova 1.

2. 32001 L 0080: Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants (OJ L 309, 27.11.2001, p. 1).

(a) By way of derogation from Article 4(1) and (3), the emission limit values for sulphur dioxide, nitrogen oxides and dust shall apply to the following plants in Croatia as from 1 January 2018:

1. BELIŠĆE d.d., Belišće: steam boiler K3 +K4 (240 MW)
2. DIOKI d.d., Zagreb: steam boiler SG 6401C (86 MW)
3. HEP-Proizvodnja d.o.o., Zagreb, TE Plomin 1: steam boiler (338 MW)
4. TE PLOMIN d.o.o., Plomin, TE Plomin 2: steam boiler (544 MW)
5. HEP-Proizvodnja d.o.o., Zagreb, TE Rijeka: steam boiler (800 MW)
6. HEP-Proizvodnja d.o.o., Zagreb, TE Sisak - block 1: steam boilers 1A+1B (548 MW)
7. HEP-Proizvodnja d.o.o., Zagreb, TE Sisak - block 2: steam boilers 2A+2B (548 MW)
8. HEP-Proizvodnja d.o.o., Zagreb, TE-TO Zagreb: consisting of block C steam boiler K3, hot water boilers VK 3, VK 4, VK 5, VK 6 and steam boiler PK 3 (total: 828 MW)
9. HEP-Proizvodnja d.o.o., Zagreb, EL-TO Zagreb: consisting of block 30 MW with steam boilers K4 (K8) and K5 (K9), block 12 MW with steam boiler K3 (K6), hot water boilers WK 1 and WK 3, and steam boiler K2 (K7) (total: 510 MW)
10. HEP-Proizvodnja d.o.o, Zagreb, TE-TO Osijek: steam boilers K1+K2 (total: 196 MW).

3. 32008 L 0001: Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, 29.1.2008, p. 8).

By way of derogation from Article 5(1), the requirements for the granting of permits for existing installations shall apply to the following installations in Croatia only as from the date indicated for each installation, insofar as the obligation to operate these installations in accordance with emission limit values, equivalent parameters or technical measures, based on the best available techniques according to Article 2, point 12, is concerned:

(a) As from 1 January 2014:

1. NAŠICECEMENT Tvornica cementa, dioničko društvo (NAŠICECEMENT d.d. Našice), Našice, Tajnovac 1, IPPC activity 3.1.
2. LIPIK GLAS za proizvodnju stakla društvo s ograničenom odgovornošću (LIPIK GLAS d.o.o.), Lipik, Staklanska b.b., IPPC activity 3.2.
3. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 18 (Farm No.18, location: Čakovec, Totovec), IPPC activity 6.6.a.
4. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Forkuševci (Farm Forkuševci), IPPC activity 6.6.c.
5. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma V. Branjevina (Farm V. Branjevina), IPPC activity 6.6.c.
6. Drvna industrija KLANA d.d. (DI KLANA d.d.), Klana, Klana 264, IPPC activity 6.7.
7. ČATEKS, dioničko društvo za proizvodnju tkanine, umjetne kože, kućanskog rublja i proizvoda za šport i rekreaciju (ČATEKS d.d.), Čakovec, Ulica Zrinsko-Frankopanska 25, IPPC activity 6.7.

(b) As from 1 January 2015:

1. CIMOS LJEVAONICA ROČ d.o.o. proizvodnja aluminijskih odljevaka (CIMOS LJEVAONICA ROČ d.o.o.), Roč, Stanica Roč 21, IPPC activity 2.5.b.
2. P. P. C. BUZET društvo s ograničenom odgovornošću za proizvodnju, trgovinu i usluge (P. P. C. BUZET d.o.o.), Buzet, Most 24, IPPC activity 2.5.b.
3. Vetropack Straža tvornica stakla d.d. Hum na Sutli (Vetropack Straža d.d. Hum na Sutli), Hum na Sutli, Hum na Sutli 203, IPPC activity 3.2.
4. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb - pogon mesa (meat facility), IPPC activity 6.4.a.
5. SLADORANA TVORNICA ŠEĆERA dioničko društvo (SLADORANA d.d.), Županja, Šećerana 63, IPPC activity 6.4.b.

6. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 19 (Farm No. 19, location: Donji Martijanec, Vrbanovec), IPPC activity 6.6.a.
7. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Slaščak (Farm Slaščak), IPPC activity 6.6.b.
8. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 - farma Magadenovac (Farm Magadenovac), IPPC activity 6.6.c.
9. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Umag (Umag facility, location: Umag, Ungarija bb), IPPC activity 6.7.
10. ALUFLEXPACK, proizvodno, trgovačko, export-import društvo s ograničenom odgovornošću (ALUFLEXPACK, d.o.o.), Zadar, Murvica bb - pogon Zadar (Zadar facility, location: Zadar, Murvica bb), IPPC activity 6.7.
11. HEMPEL društvo s ograničenom odgovornošću Prerađivačka kemijska industrija (HEMPEL d.o.o.), Umag, Novigradska ulica 32, IPPC activity 6.7.
12. BELIŠĆE dioničko društvo za proizvodnju papira, kartonske ambalaže, strojeva, primarnu i finalnu preradu drva i suhu destilaciju drva (BELIŠĆE d.d.), Belišće, Trg Ante Starčevića 1 - except Steam boilers K3 and K4 (transitional period until 31 December 2017, see below), IPPC activity 6.1.b.
13. MAZIVA-ZAGREB d.o.o. za proizvodnju i trgovinu mazivima i srodnim proizvodima (MAZIVA-ZAGREB d.o.o.), Zagreb, Radnička cesta 175, IPPC activity 1.2.

(c) As from 1 July 2015:

1. GAVRILOVIĆ Prva hrvatska tvornica salame, sušena mesa i masti M. Gavrilovića potomci, d.o.o. (GAVRILOVIĆ d.o.o.), Petrinja, Gavrilovićev trg 1 - pogon klaonice: papkari, rezanje i prerada mesa i proizvodnja prerađevina od peradi i papkara, te skladištenje mesa (facility for animal slaughter: hoof animals, cutting and processing of meat and production of processed products from poultry and hoof animals, and storage of meat), IPPC activity 6.4.a.

(d) As from 1 January 2016:

1. FERRO-PREIS društvo s ograničenom odgovornošću za proizvodnju ljevanih, kovanih i prešanih metalnih proizvoda (FERRO-PREIS d.o.o.), Čakovec, Dr. Tome Bratkovića 2, IPPC activity 2.4.
2. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon Sv. Kajo (Sv. Kajo facility), IPPC activity 3.1.
3. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon Sv. Juraj (Sv. Juraj facility), IPPC activity 3.1.
4. CEMEX Hrvatska dioničko društvo za proizvodnju i prodaju cementa i drugih građevinskih materijala (CEMEX Hrvatska d.d.), Kaštel Sućurac, Cesta dr. Franje Tuđmana bb - pogon 10. kolovoza (10. kolovoza facility), IPPC activity 3.1.
5. KIO KERAMIKA d.o.o. za proizvodnju keramičkih pločica - "u stečaju" (KIO KERAMIKA d.o.o. - "u stečaju"), Orahovica, V. Nazora bb - pogon Orahovica (Orahovica facility, location: Orahovica, V. Nazora bb), IPPC activity 3.5.
6. KIO KERAMIKA d.o.o. za proizvodnju keramičkih pločica - "u stečaju" (KIO KERAMIKA d.o.o. - "u stečaju"), Orahovica, V. Nazora bb - pogon Rujevac (Rujevac facility, location: Dvor, Rujevac bb), IPPC activity 3.5.
7. PLIVA HRVATSKA d.o.o. za razvoj, proizvodnju i prodaju lijekova i farmaceutskih proizvoda (PLIVA HRVATSKA d.o.o.), Zagreb, Prilaz baruna Filipovića 25 - pogon Savski Marof (Savski Marof facility, location: Prigorje Brdovečko, Prudnička 98), IPPC activity 4.5.
8. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - mesna industrija (meat industry, location: Sv. Petar u Šumi), IPPC activity 6.4 a and b.
9. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 20 (Farm No. 20, location: Petrijanec-Nova Ves), IPPC activity 6.6.a.

10. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Sv. Petar u Šumi 8 (Farm Sv. Petar u Šumi 8, location: Sveti Petar u Šumi), IPPC activity 6.6.a.
11. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Sv. Petar u Šumi 9 (Farm Sv. Petar u Šumi 9, location: Sveti Petar u Šumi), IPPC activity 6.6.a.
12. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Barban (Farm Barban, location: Barban), IPPC activity 6.6.a.
13. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Muntrilj (Farm Muntrilj, location: Muntrilj), IPPC activity 6.6.a.
14. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Šikuti (Farm Šikuti, location: Svetvinčenat), IPPC activity 6.6.a.
15. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Žminj 2 (Farm Žminj 2, location: Žminj), IPPC activity 6.6.a.
16. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Surani 2 (Farm Surani 2, location: Tinjani, Surani), IPPC activity 6.6.a.
17. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Pilati (Farm Pilati, location: Lovrin, Pilati), IPPC activity 6.6.a.
18. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Škropeti 2 (Farm Škropeti 2, location: Škropeti), IPPC activity 6.6.a.
19. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Katun 2 (Farm Katun 2, location: Trviz, Katun Trviski), IPPC activity 6.6.a.

20. PURIS, poljoprivredna, prehrambena, trgovačka i ugostiteljska djelatnost, dioničko društvo (PURIS d.d.), Pazin, Hrvatskog narodnog preporoda 2 - farma Srbinjak (Farm Srbinjak, location: Jakovici, Srbinjak), IPPC activity 6.6.a.
21. AD PLASTIK dioničko društvo za proizvodnju dijelova i pribora za motorna vozila i proizvoda iz plastičnih masa (AD PLASTIK d.d.), Solin, Matoševa ulica 8 - location: Zagreb, Jankomir 5, IPPC activity 6.7.
22. BRODOSPLIT-BRODOGRADILIŠTE društvo s ograničenom odgovornošću (BRODOSPLIT-BRODOGRADILIŠTE d.o.o.), Split, Put Supavla 21, IPPC activity 6.7.
23. CHROMOS BOJE I LAKOVI, dioničko društvo za proizvodnju boja i lakova (CHROMOS BOJE I LAKOVI, d.d.), Zagreb, Radnička cesta 173/d, IPPC activity 6.7.
24. MURAPLAST društvo s ograničenom odgovornošću za proizvodnju i preradu plastičnih masa (MURAPLAST d.o.o.), Kotoriba, Industrijska zona bb, IPPC activity 6.7.
25. 3. MAJ BRODOGRADILIŠTE d.d., Rijeka, Liburnijska 3, IPPC activity 6.7.
26. CHROMOS-SVJETLOST, Tvornica boja i lakova, društvo s ograničenom odgovornošću (CHROMOS-SVJETLOST d.o.o.), Lužani, Mijata Stojanovića 13, IPPC activity 6.7.
27. BRODOTROGIR d.d., Trogir, Put Brodograditelja 16, IPPC activity 6.7.
28. ULJANIK Brodogradilište, d.d., Pula, Flaciusova 1, IPPC activity 6.7.

(e) As from 1 January 2017:

1. METALSKA INDUSTRIJA VARAŽDIN dioničko društvo (MIV d.d.), Varaždin, Fabijanska ulica 33, IPPC activity 2.4.
2. KANDIT PREMIJER d.o.o. za proizvodnju, promet i usluge (KANDIT PREMIJER d.o.o.), Osijek, Frankopanska 99, IPPC activity 6.4.b.
3. KOKA peradarsko prehrambena industrija dioničko društvo (KOKA d.d.), Varaždin, Jalkovečka ulica bb – farma br. 21 (Farm No. 21, location: Čakovec, Totovec), IPPC activity 6.6.a.
4. ŽITO d.o.o. za proizvodnju i trgovinu (ŽITO d.o.o.), Osijek, Đakovština 3 – farma Lužani (Farm Lužani), IPPC activity 6.6.b.

(f) As from 1 January 2018:

1. BELIŠĆE dioničko društvo za proizvodnju papira, kartonske ambalaže, strojeva, primarnu i finalnu preradu drva i suhu destilaciju drva (BELIŠĆE d.d.), Belišće, Trg Ante Starčevića 1 – parni kotao K3, parni kotao K4 (Steam boiler K3, Steam boiler K4), IPPC activity 1.1 (this only concerns steam boilers K3 and K4).
2. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 – KTE Jertovec (Jertovec Combined-Cycle Power Plant, location: Konjšćina, Jertovec, Jertovec 151), IPPC activity 1.1.
3. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Plomin 1 (Thermal Power Plant Plomin 1, location: Plomin, Plomin bb), IPPC activity 1.1.
4. TE PLOMIN društvo s ograničenom odgovornošću za proizvodnju električne energije (TE PLOMIN d.o.o.), Plomin, Plomin bb - TE Plomin 2 (Thermal Power Plant Plomin 2, location: Plomin, Plomin bb), IPPC activity 1.1.
5. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - EL-TO Zagreb (Zagreb Power Plant - Heating Station, location: Zagreb, Zagorska 1), IPPC activity 1.1.
6. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE-TO Zagreb (Zagreb Thermal Power Plant - Heating Station, location: Zagreb, Kuševačka 10 a), IPPC activity 1.1.
7. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Sisak (Sisak Thermal Power Plant, location: Sisak, Čret bb), IPPC activity 1.1.
8. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE-TO Osijek (Osijek Thermal Power Plant - Heating Station, location: Osijek, Martina Divalta 203), IPPC activity 1.1.
9. HEP-Proizvodnja d.o.o. za proizvodnju električne i toplinske energije (HEP-Proizvodnja d.o.o.), Zagreb, Ulica grada Vukovara 37 - TE Rijeka (Rijeka Thermal Power Plant, location: Kostrena, Urinj bb), IPPC activity 1.1.

10. DIOKI Organska petrokemija dioničko društvo (DIOKI d.d.), Zagreb, Čulinečka cesta 252, IPPC activity 1.1.
11. INA-INDUSTRIJA NAFTE, d.d. (INA, d.d.), Zagreb, Avenija V. Holjevca 10 – Rafinerija nafte Rijeka - Urinj (Rijeka Oil Refinery - Urinj, location: Kostrena, Urinj), IPPC activity 1.2.
12. INA-INDUSTRIJA NAFTE, d.d. (INA, d.d.), Zagreb, Avenija V. Holjevca 10 – Rafinerija nafte Sisak (Sisak Oil Refinery, location: Sisak, Ante Kovačića 1), IPPC activity 1.2.
13. ŽELJEZARA SPLIT poduzeće za proizvodnju i preradu čelika d.d. "u stečaju" (ŽELJEZARA SPLIT d.d. "u stečaju"), Kaštel Sućurac, Cesta dr. F. Tuđmana bb, IPPC activity 2.2.
14. PETROKEMIJA, d.d. tvornica gnojiva (PETROKEMIJA, d.d.), Kutina, Aleja Vukovar 4, IPPC activity 4.2.b.

VI. CHEMICALS

32006 R 1907: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(a) By way of derogation from Article 23(1) and (2) and Article 28 defining the deadline for the registration and pre-registration of the substances mentioned therein, manufacturers, importers and producers of articles established in Croatia shall be granted an adaptation period of six months after the date of accession for pre-registration of phase-in substances. The dates for the first and second registration deadline set out in Article 23(1) and (2) shall be 12 months after the date of accession.

(b) Articles 6, 7, 9, 17, 18 and 33 shall not apply in Croatia for a period of six months from the date of accession.

(c) By way of derogation from the transitional arrangements specified for any substance included in Annex XIV, if the latest application date falls before the date of accession or less than six months after that date, applicants established in Croatia shall be granted an adaptation period of six months from the date of accession by the end of which applications for authorisations must be received.

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Appendix to Annex V

List(*) as provided by Croatia in one language of medicinal products for which a marketing authorisation issued under Croatian law prior to the date of accession shall remain valid until it is renewed in compliance with the *acquis* or until 30 June 2017, whichever is earlier.

Mention on this list does not prejudge whether or not the medicinal product in question has a marketing authorization in compliance with the *acquis*.

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(*) See OJ C xxx [E], xx.xx.xxxx, p. xxx. [Text as set out in AC 30/11].

ANNEX VI

Rural development (referred to in Article 35(2) of the Act of Accession)

I. RURAL DEVELOPMENT MEASURE FOR CROATIA

32005 R 1698: Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 277, 21.10.2005, p. 1 and OJ L 286M, 4.11.2010, p. 26).

Council Regulation (EC) 1698/2005 shall not apply to Croatia for the whole programming period 2007-2013.

II. TEMPORARY ADDITIONAL RURAL DEVELOPMENT MEASURES FOR CROATIA

A. **Support for semi-subsistence farms undergoing restructuring**

In the rural development legislative framework for programming period 2014-2020, as regards Croatia, a special support for semi-subsistence agricultural holdings shall be granted, pursuant to the principles laid down in Article 34 of Council Regulation (EC) 1698/2005, to farmers in respect of applications approved by 31 December 2017, provided that no similar general measures and/or support is foreseen in the new rural development regulation for programming period 2014-2020.

B. **Producer groups**

In the rural development legislative framework for programming period 2014-2020, as regards Croatia, a special support to facilitate the setting up and administrative operation of producer groups shall be granted, pursuant to the principles laid down in Article 35 of Council Regulation (EC) 1698/2005, to producer groups which are officially recognised by Croatia's competent authority by 31 December 2017, provided that no similar general measures and/or support is foreseen in the new rural development regulation for programming period 2014-2020.

C. **Leader**

In the rural development legislative framework for programming period 2014-2020, as regards Croatia, the minimum EAFRD contribution to the rural development programme for Leader shall be set on average at a level which is at least half of the percentage of the budget that shall be applicable to the other Member States, if such a requirement is set.

D. **Complements to direct payments**

1. Support may be granted to farmers eligible for complementary national direct payments or aids under Article 132 of Council Regulation (EC) No 73/2009[1].

2. The support granted to a farmer in respect of the years 2014, 2015 and 2016 shall not exceed the difference between:

   (a) the level of direct payments applicable in Croatia for the year concerned in accordance with Article 121 of Council Regulation (EC) No 73/2009, and

   (b) 45 % of the level of direct payments applicable in the Union as constituted on 30 April 2004 in the relevant year.

3. The Union contribution to support granted under this subsection D in Croatia in respect of the years 2014, 2015 and 2016 shall not exceed 20 % of its respective total annual EAFRD allocation.

4. The Union contribution rate for the complements to direct payments shall not exceed 80 %.

[1] Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 (OJ L 30, 31.1.2009, p. 16).

E. **Instrument for pre-accession – Rural development**

1. Croatia may continue to contract or enter into commitments under the IPARD programme under Commission Regulation (EC) No 718/2007 of 12 June 2007 implementing Council Regulation (EC) No 1085/2006 establishing an instrument for pre-accession assistance (IPA) until it begins to contract or enter into commitments under the relevant rural development Regulation[1]. Croatia shall inform the Commission of the date on which it begins contracting or entering into commitments under the relevant rural development Regulation.

2. The Commission shall adopt the necessary measures to this end in accordance with the procedure referred to in Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. To that effect, the Commission shall be assisted by the IPA Committee referred to in Article 14(1) of Council Regulation (EC) No 1085/2006.

F. **IPARD ex-post evaluation**

In the rural development legislative framework for programming period 2014-2020, as regards the implementation of the IPARD programme for Croatia, expenditure relating to the ex-post evaluation of the IPARD programme provided for in Article 191 of Commission Regulation (EC) No 718/2007 may be eligible under technical assistance.

[1] OJ L 170, 29.6.2007, p. 1.

G. **Modernisation of agricultural holdings**

In the rural development legislative framework for programming period 2014-2020, as regards Croatia, the maximum intensity of an aid for the modernisation of agricultural holdings shall be 75% of the amount of eligible investment for the implementation of Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources, within a maximum period of four years from the date of accession pursuant to Articles 3(2) and 5(1) of that Directive[1].

H. **Respect of standards**

In the rural development legislative framework for programming period 2014-2020, as regards Croatia, the statutory management requirements referred to in Annex II to Council Regulation (EC) No 73/2009 applicable in that programming period shall be respected according to the following timetable: requirements referred to in Point A of Annex II shall apply from 1 January 2014; requirements referred to in Point B of Annex II shall apply from 1 January 2016; and requirements referred to in Point C of Annex II shall apply from 1 January 2018.

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[1] OJ L 375, 31.12.1991, p. 1.

ANNEX VII

Specific commitments undertaken by the Republic of Croatia in its accession negotiations (referred to in Article 36(1), second subparagraph, of the Act of Accession)

1. To continue to ensure effective implementation of its Judicial Reform Strategy and Action Plan.

2. To continue to strengthen the independence, accountability, impartiality and professionalism of the judiciary.

3. To continue to improve the efficiency of the judiciary.

4. To continue to improve the handling of domestic war crimes cases.

5. To continue to ensure a sustained track record of substantial results based on efficient, effective and unbiased investigation, prosecution and court rulings in organised crime and corruption cases at all levels including high level corruption, and in vulnerable sectors such as public procurement.

6. To continue to improve its track record of strengthened prevention measures in the fight against corruption and conflict of interest.

7. To continue to strengthen the protection of minorities, including through effective implementation of the Constitutional Act on the Rights of National Minorities (CARNM).

8. To continue to address outstanding refugee return issues.

9. To continue to improve the protection of human rights.

10. To continue to cooperate fully with the International Criminal Tribunal for the former Yugoslavia.

ANNEX VIII

Commitments undertaken by the Republic of Croatia on the restructuring of the Croatian shipbuilding industry (referred to in Article 36(1), third subparagraph, of the Act of Accession)

The shipbuilding companies to be restructured (hereinafter referred to as "the companies") are the following:

- Brodograđevna industrija 3 MAJ dioničko društvo, Rijeka (hereinafter referred to as "3. MAJ")
- BRODOTROGIR d.d., Trogir (hereinafter referred to as "Brodotrogir")
- BRODOGRAĐEVNA INDUSTRIJA SPLIT, dioničko društvo, Split (hereinafter referred to as "Brodosplit")
- BRODOSPLIT-BRODOGRADILIŠTE SPECIJALNIH OBJEKATA društvo s ograničenom odgovornošću, Split (hereinafter referred to as "BSO")
- BRODOGRADILIŠTE KRALJEVICA dioničko društvo za izgradnju i popravak brodova, Kraljevica (hereinafter referred to as "Kraljevica").

Croatia agreed to carry out the restructuring of these companies through their privatisation on the basis of a competitive tendering process. Restructuring plans for these companies have been submitted by the bidders and accepted by the Croatian Competition Agency and the Commission. The restructuring plans will be incorporated in the respective privatisation contracts to be concluded between Croatia and the buyers of the companies.

The restructuring plans submitted for each of these companies specify the following key conditions to be respected in the restructuring process:

- All State aid received by these companies since 1 March 2006 must be counted as restructuring aid. The companies shall provide a contribution to the restructuring plan from their own resources which must be real, free of State aid and which represents at least 40 % of the total restructuring costs.

– The overall production capacity of the companies shall be reduced compared to the levels of 1 June 2011 from 471 324 CGT to 372 346 CGT. The companies shall reduce their production capacities no later than twelve months after the signing of the privatisation contract. Capacity reduction shall be implemented through the permanent closure of slipways, through the designation of slipways for exclusive military production within the meaning of Article 346 of the TFEU and/or through surface area reduction. The CGTs are the units of measurement of output calculated according to the applicable OECD rules.

– The total annual production of the companies shall be limited to 323 600 CGT for a ten year period, starting on 1 January 2011. The companies' output will be limited to the following levels[1]:

  – 3 MAJ: 109 570 CGT
  – Brodotrogir: 54 955 CGT
  – Brodosplit and BSO: 132 078 CGT
  – Kraljevica: 26 997 CGT

  The companies may agree to review their individual production limits. On the basis of binding agreements, they can expressly establish which portion of their individual production quota (expressed in CGTs) they cede to each other. The overall yearly production limit of 323,600 CGT shall be respected.

– The restructuring plans also specify a number of other measures which each company will implement to ensure a return to long term viability.

[1] The annual production of a given company is calculated as follows. The start of production of a ship is the planned date of steel cutting and the end of production is the date of expected delivery of the ship as set out in the contract with the buyer (or the anticipated date of delivery of the incomplete ship when the construction of a ship is shared between two companies). The number of CGTs corresponding to a ship is linearly allocated to the calendar years covering the production period. The total output of a company in a given year is calculated by adding the number of CGTs produced over that year.

Any subsequent change to these plans shall comply with the key conditions to be respected in the restructuring process listed above and shall be submitted to the Commission for acceptance.

The companies shall not receive any new rescue or restructuring aid until at least ten years have elapsed since the date of signing of the privatisation contract. Upon Croatia's accession, the Commission shall order Croatia to recover any rescue or restructuring aid granted in breach of this provision, with compound interest.

The restructuring plans that have been accepted by the Croatian Competition Agency and by Commission will be incorporated in the respective privatisation contracts to be concluded between Croatia and buyers of the companies. The privatisation contracts shall be submitted to the Commission for acceptance and shall be signed before Croatia's accession.

The Commission shall closely monitor the implementation of the restructuring plans and the respect of the conditions set out in this Annex regarding the level of State aid, the own contribution, the capacity reductions, the production limitation and the measures taken to ensure a return to viability.

This monitoring shall be carried out each year of the restructuring period. Croatia shall cooperate fully with all the arrangements for monitoring. In particular:

– Croatia shall supply the Commission with six-monthly reports concerning the restructuring of the benefiting companies, no later than 15 January and 15 July each year until the end of the restructuring period.

– The reports shall contain all the information necessary to monitor the restructuring process, the own contribution, the reduction of capacity, the production limitation and the measures taken to ensure a return to viability.

– Croatia shall submit reports on the annual output of the companies under restructuring no later than 15 July each year, until the end of 2020.

– Croatia shall oblige the companies to disclose all relevant data which might, under other circumstances, be considered as confidential. The Commission shall ensure that the company-specific confidential information is not disclosed.

The Commission may at any time decide to mandate an independent expert to evaluate the monitoring results, undertake any research necessary and report to the Commission. Croatia will provide full cooperation to the independent expert appointed by the Commission and ensure that he has full access to all information he will need to carry out the tasks entrusted to him by the Commission.

Upon Croatia's accession, the Commission shall order Croatia to recover all rescue or restructuring aid granted since 1 March 2006 to a particular company, with compound interest if :

– the privatisation contract for this company has not yet been signed or does not fully incorporate the conditions set out in the restructuring plan accepted by the Croatian Competition Agency and by the Commission, or

– the company has not provided a real, State aid free contribution from its own resources which represents at least 40 % of the restructuring costs, or

– the reduction of the overall production capacity has not been implemented within twelve months after the signing of the privatisation contract. In that case, the recovery of the aid shall only be required from those companies that have not achieved the following individual reductions of capacity:

  - 3 MAJ: by 46 543 CGT
  - Brodotrogir: by 15 101 CGT
  - Brodosplit and BSO: by 29 611 CGT
  - Kraljevica: by 9 636 CGT

– the overall production limitation for the shipyards (i.e. 323 600 CGT) has been exceeded in any individual calendar year between 2011 and 2020. In that case, the recovery of the aid shall be required from those companies that have exceeded their individual production limits (if applicable, as amended by a legally binding agreement with another shipbuilding company).

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ANNEX IX

Commitments undertaken by the Republic of Croatia on the restructuring of the steel sector (referred to in Article 36(1), third subparagraph, of the Act of Accession)

By letter dated 23 May 2011, Croatia informed the Commission that it received recognition of debt from the steel producer CMC Sisak d.o.o., corresponding to the restructuring aid, received by this company over the period from 1 March 2002 until 28 February 2007, plus compound interests[1]. The State aid received, without compound interests, amounts to HRK 19 117 572,36.

Upon Croatia's accession, in case the total amount of this aid plus compound interests has not been reimbursed by CMC Sisak d.o.o., the Commission shall order Croatia to recover any rescue and restructuring aid granted to this company since 1 March 2006, with compound interests.

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[1] To be calculated according to Articles 9-11 of Commission Regulation (EC) No 794/2004 of 21 April 2004 implementing Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty (OJ L 140, 30.04.2004, p. 1), as last amended by Commission Regulation (EC) No 1125/2009 of 23 November 2009.

PROTOCOL

on certain arrangements concerning a possible one-off transfer of assigned amount units issued under the Kyoto Protocol to the Republic of Croatia, as well as the related compensation

THE HIGH CONTRACTING PARTIES,

NOTING that in view of the specific historical circumstances that have affected Croatia, it has been agreed to express a readiness to provide assistance to Croatia through a one-off transfer of Assigned Amount Units issued under the Kyoto Protocol,

NOTING that any such transfer would only be made on a single occasion, would not set a precedent and would reflect the unique and exceptional nature of Croatia's situation,

STRESSING that any such transfer would have to be compensated for by Croatia through an adjustment of its obligations under Decision No 406/2009/EC so as to ensure environmental integrity by avoiding an increase in the total amount of allowed emissions of the Union and Croatia until 2020,

HAVE AGREED ON THE FOLLOWING PROVISIONS:

PART I

TRANSFER

Article 1

This Part shall apply to measures relating to a possible one-off transfer of a quantity of Assigned Amount Units issued under the Kyoto Protocol (AAUs) to Croatia.

Article 2

No transfer shall take place unless Croatia has withdrawn its appeal against the decision of the enforcement branch of the Compliance Committee of the Kyoto Protocol in accordance with any relevant rules and time-limits governing the withdrawal of appeals, before the start of the UNFCCC Conference in Durban (28 November - 9 December 2011).

Any transfer shall be conditional upon the determination by the UNFCCC Expert Review Team, after the true-up period, that Croatia has fallen short of its commitments under Article 3 of the Kyoto Protocol.

No transfer shall take place unless Croatia has made all reasonable efforts to comply with its commitments under Article 3 of the Kyoto Protocol, including the full use of removal units from land use, land-use change and forestry.

Article 3

Any decision on the transfer of AAUs shall be adopted in accordance with the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011[1]. The Commission shall be assisted by the Climate Change Committee established by Article 9 of Decision No 280/2004/EC[2]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011. No such decision shall be adopted where no opinion is delivered.

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[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

[2] Decision No 280/2004/EC of the European Parliament and of the Council of 11 February 2004 concerning a mechanism for monitoring Community greenhouse gas emissions and for implementing the Kyoto Protocol (OJ L 49, 19.2.2004, p. 1).

The AAUs to be transferred shall be drawn from the quantity of AAUs referred to in Article 2 of Commission Decision 2006/944/EC[1].

Any transfer shall not exceed a total quantity of seven million AAUs.

PART II
COMPENSATION

Article 4

This Part shall apply to the compensation to be provided by Croatia in the event of a transfer of AAUs in accordance with the provisions of Part I.

Article 5

1. Croatia shall compensate for any AAUs transferred to it through an adjustment, pursuant to this article, of its obligations under Decision No 406/2009/EC[2].

   In particular, the equivalent amount in tonnes of carbon dioxide equivalent of any AAUs transferred shall, pursuant to this article, be subtracted from Croatia's annual emission allocations once they have been determined pursuant to Article 3(2) of Decision 406/2009/EC.

2. The Commission shall publish the figures for Croatia's annual emission allocations resulting from the subtraction made in accordance with paragraph 1.

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[1] Commission Decision 2006/944/EC of 14 December 2006 determining the respective emission levels allocated to the Community and each of its Member States under the Kyoto Protocol pursuant to Council Decision 2002/358/EC (OJ L 358, 16.12.2006, p. 87), as amended by Commission Decision 2010/778/EU of 15 December 2010 (OJ L 332, 16.12.2010, p. 41).

[2] Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020 (OJ L 140, 5.6.2009, p. 136).

FINAL ACT

I. TEXT OF THE FINAL ACT

1. The Plenipotentiaries of:

HIS MAJESTY THE KING OF THE BELGIANS,

THE PRESIDENT OF THE REPUBLIC OF BULGARIA,

THE PRESIDENT OF THE CZECH REPUBLIC,

HER MAJESTY THE QUEEN OF DENMARK,

THE PRESIDENT OF THE FEDERAL REPUBLIC OF GERMANY,

THE PRESIDENT OF THE REPUBLIC OF ESTONIA,

THE PRESIDENT OF IRELAND,

THE PRESIDENT OF THE HELLENIC REPUBLIC,

HIS MAJESTY THE KING OF SPAIN,

THE PRESIDENT OF THE FRENCH REPUBLIC,

[ENTRY FOR CROATIA TO BE INSERTED AT A LATER STAGE],

THE PRESIDENT OF THE ITALIAN REPUBLIC,

THE PRESIDENT OF THE REPUBLIC OF CYPRUS,

THE PRESIDENT OF THE REPUBLIC OF LATVIA,

THE PRESIDENT OF THE REPUBLIC OF LITHUANIA,

HIS ROYAL HIGHNESS THE GRAND DUKE OF LUXEMBOURG,

THE PRESIDENT OF THE REPUBLIC OF HUNGARY,

THE PRESIDENT OF MALTA,

HER MAJESTY THE QUEEN OF THE NETHERLANDS,

THE FEDERAL PRESIDENT OF THE REPUBLIC OF AUSTRIA,

THE PRESIDENT OF THE REPUBLIC OF POLAND,

THE PRESIDENT OF THE PORTUGUESE REPUBLIC,

THE PRESIDENT OF ROMANIA,

THE PRESIDENT OF THE REPUBLIC OF SLOVENIA,

THE PRESIDENT OF THE SLOVAK REPUBLIC,

THE PRESIDENT OF THE REPUBLIC OF FINLAND,

THE GOVERNMENT OF THE KINGDOM OF SWEDEN,

HER MAJESTY THE QUEEN OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

Assembled at [city to be inserted] on the [date to be inserted] on the occasion of the signature of the Treaty between the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, Romania, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland (Member States of the European Union) and the Republic of Croatia concerning the accession of the Republic of Croatia to the European Union.

Have placed on record the fact that the following texts have been drawn up and adopted within the Conference between the Member States of the European Union and the Republic of Croatia concerning the accession of the Republic of Croatia to the European Union:

I. the Treaty between the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, Romania, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland (Member States of the European Union) and the Republic of Croatia, concerning the accession of the Republic of Croatia to the European Union (hereinafter "the Treaty of Accession");

II. the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community (hereinafter "the Act of Accession");

III. the texts listed below which are annexed to the Act of Accession:

A. Annex I: List of conventions and protocols to which the Republic of Croatia accedes upon accession (referred to in Article 3(4) of the Act of Accession),

Annex II: List of provisions of the Schengen *acquis* as integrated into the framework of the European Union and the acts building upon it or otherwise related to it, to be binding on and applicable in the Republic of Croatia as from accession (referred to in Article 4(1) of the Act of Accession),

Annex III: List referred to in Article 15 of the Act of Accession: adaptations to acts adopted by the institutions,

Annex IV: List referred to in Article 16 of the Act of Accession: other permanent provisions,

Annex V: List referred to in Article 18 of the Act of Accession: transitional measures,

Annex VI: Rural development (referred to in Article 35(2) of the Act of Accession),

Annex VII: Specific commitments undertaken by the Republic of Croatia in its accession negotiations (referred to in Article 36(1), second subparagraph, of the Act of Accession),

Annex VIII: Commitments undertaken by the Republic of Croatia on the restructuring of the Croatian shipbuilding industry (referred to in Article 36(1), third subparagraph, of the Act of Accession),

Annex IX: Commitments undertaken by the Republic of Croatia on the restructuring of the steel sector (referred to in Article 36(1), third subparagraph, of the Act of Accession);

B. Protocol on certain arrangements concerning a possible one-off transfer of assigned amount units issued under the Kyoto Protocol to the Republic of Croatia, as well as the related compensation;

C. the texts of the Treaty on European Union, the Treaty on the Functioning of the European Union and of the Treaty establishing the European Atomic Energy Community, and the Treaties amending or supplementing them, including the Treaty concerning the accession of the Kingdom of Denmark, Ireland and the United Kingdom of Great Britain and Northern Ireland, the Treaty concerning the accession of the Hellenic Republic, the Treaty concerning the accession of the Kingdom of Spain and the Portuguese Republic, the Treaty concerning the accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden, the Treaty concerning the accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the Treaty concerning the accession of the Republic of Bulgaria and Romania in the Croatian language.

2. The High Contracting Parties have reached political agreement on a set of adaptations to acts adopted by the institutions required by reason of accession and invite the Council and the Commission to adopt these adaptations before accession in accordance with Article 50 of the Act of Accession, as referred to in Article 3(4) of the Treaty of Accession, completed and updated where necessary to take account of the evolution of the law of the Union.

3. The High Contracting Parties undertake to communicate to the Commission and to each other all necessary information required for the application of the Act of Accession.
Where necessary, this information shall be provided in such good time before the date of accession as to enable the full application of the Act of Accession from the date of accession, in particular as regards the functioning of the internal market. In this context early notification under Article 47 of the Act of Accession of the measures adopted by the Republic of Croatia is of primary importance. The Commission may inform the Republic of Croatia of the time by which it considers it appropriate to receive or transmit specific information. By this day of signature, the Contracting Parties were provided with a list setting out the information obligations in the veterinary domain.

4. The Plenipotentiaries have taken note of the following Declarations which have been made and are annexed to this Final Act:

[A.] Joint Declaration by the present Member States

[1.] Joint Declaration on the full application of the provisions of the Schengen *acquis*

[B.] Joint Declaration by various present Member States

[1.] Joint Declaration by the Federal Republic of Germany and the Republic of Austria on the free movement of workers: Croatia

[C.] Joint Declaration by the present Member States and the Republic of Croatia

[1.] Joint Declaration on the European Development Fund

[D.] Declaration by the Republic of Croatia

[1.] Declaration by the Republic of Croatia concerning the transitional arrangement for the liberalisation of the Croatian agricultural land market

5. The Plenipotentiaries have taken note of the Exchange of Letters between the European Union and the Republic of Croatia on an information and consultation procedure for the adoption of certain decisions and other measures to be taken during the period preceding accession and which is attached to this Final Act.

["Done at….on"…:to be inserted in all the official languages, including Croatian]

Pour Sa Majesté le Roi des Belges
Voor Zijne Majesteit de Koning der Belgen
Für Seine Majestät den König der Belgier

Cette signature engage également la Communauté française, la Communauté flamande, la Communauté germanophone, la Région wallonne, la Région flamande et la Région de Bruxelles-Capitale.

Deze handtekening verbindt eveneens de Vlaamse Gemeenschap, de Franse Gemeenschap, de Duitstalige Gemeenschap, het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest.

Diese Unterschrift bindet zugleich die Deutschsprachige Gemeinschaft, die Flämische Gemeinschaft, die Französische Gemeinschaft, die Wallonische Region, die Flämische Region und die Region Brüssel-Hauptstadt.

За Република България

Za prezidenta České republiky

For Hendes Majestæt Danmarks Dronning

Für den Präsidenten der Bundesrepublik Deutschland

Eesti Vabariigi Presidendi nimel

Thar ceann Uachtarán na hÉireann

For the President of Ireland

Για τον Πρόεδρο της Ελληνικής Δημοκρατίας

Por Su Majestad el Rey de España

Pour le Président de la République française

[Insert translation into Croatian: Entry for Croatia to be inserted at a later stage]

Per il Presidente della Repubblica italiana

Για τον Πρόεδρο της Κυπριακής Δημοκρατίας

Latvijas Republikas Valsts prezidentas vārdā

Lietuvos Respublikos Prezidento vardu

Pour Son Altesse Royale le Grand-Duc de Luxembourg

A Magyar Köztársaság Elnöke részéről

Għall-President ta' Malta

Voor Hare Majesteit de Koningin der Nederlanden

Für den Bundespräsidenten der Republik Österreich

Za Prezydenta Rzeczypospolitej Polskiej

Pelo Presidente da República Portuguesa

Pentru Preşedintele României

Za predsednika Republike Slovenije

Za prezidenta Slovenskej republiky

Suomen Tasavallan Presidentin puolesta

För Republiken Finlands President

För Konungariket Sveriges regering

For Her Majesty the Queen of the United Kingdom of Great Britain and Northern Ireland

II. **DECLARATIONS**

[A.] JOINT DECLARATION BY THE PRESENT MEMBER STATES

[1.] **Joint Declaration on the full application of the provisions of the Schengen *acquis***

It is understood that the agreed procedures for the future full application by Croatia of all provisions of the Schengen *acquis* – as they will be included in the Treaty concerning Croatia's accession to the Union – are without prejudice to and have no implications for the decision to be taken by the Council for the full application of the provisions of the Schengen *acquis* in Bulgaria and Romania.

The decision of the Council on the full application of the provisions of the Schengen *acquis* in Bulgaria and Romania shall be taken on the basis of the procedure laid down in that respect in the 2005 Treaty concerning the accession of Bulgaria and Romania to the EU and in line with the Council Conclusions of 9 June 2011 on the completion of the process of evaluation of the state of preparedness of Bulgaria and Romania to implement all provisions of the Schengen *acquis*.

The agreed procedures for the future full application by Croatia of all provisions of the Schengen *acquis* - as they will be included in the Treaty concerning Croatia's accession to the Union - do not create a legal obligation in any other context than that of Croatia's Accession Treaty.

[B.] JOINT DECLARATION BY VARIOUS PRESENT MEMBER STATES

[1.] **Joint Declaration by the Federal Republic of Germany and the Republic of Austria on the free movement of workers: Croatia**

The wording of point 12 of the transitional measures on the free movement of workers under Directive 96/71/EC in Annex V to the Act of Accession is understood by the Federal Republic of Germany and the Republic of Austria in agreement with the Commission as meaning that 'certain regions' may, where appropriate, also comprise the entire national territory.

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[C.] JOINT DECLARATION BY THE PRESENT MEMBER STATES AND THE REPUBLIC OF CROATIA

[1.] **Joint Declaration on the European Development Fund**

The Republic of Croatia will accede to the European Development Fund (EDF) as of the entry into force of the new Multiannual Financial Framework of Cooperation following its accession to the Union and will contribute to it as from the 1 January of the second calendar year following the date of its accession.

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[D.] DECLARATION BY THE REPUBLIC OF CROATIA

[1.] **Declaration by the Republic of Croatia concerning the transitional arrangement for the liberalisation of the Croatian agricultural land market**

Having regard to the transitional arrangement with respect to the acquisition of agricultural land in the Republic of Croatia by natural and legal persons from the EU/EEA, as provided for in Annex V of the Act of Accession,

Having regard to the provision which stipulates that the Commission, at the request of the Republic of Croatia, shall decide upon the extension of the seven-year transitional period for additional 3 years, provided that there is sufficient evidence that, upon expiry of the seven-year transitional period, there will be serious disturbances or a threat of serious disturbances on the agricultural land market of the Republic of Croatia,

The Republic of Croatia declares that, should the above-mentioned extension of the transitional period be granted, it will endeavour to carry out the necessary steps to liberalise the acquisition of agricultural land in the specified areas before expiry of the fixed three-year period.

III. **EXCHANGE OF LETTERS**

between the European Union and the Republic of Croatia on an information and consultation procedure for the adoption of certain decisions and other measures to be taken during the period preceding accession

Letter No 1

Sir,

I have the honour to refer to the question concerning an information and consultation procedure for the adoption of certain decisions and other measures to be taken during the period preceding the accession of your country to the European Union which was raised in the framework of the accession negotiations.

I hereby confirm that the European Union is able to agree to such a procedure, in the terms set out in the Annex to this letter, which could be applied in respect of the Republic of Croatia as from the date on which the Accession Conference declares that the accession negotiations have been finally concluded.

I should be obliged if you could confirm that your Government is in agreement with the contents of this letter.

Yours faithfully,

Letter No 2

Sir,

I have the honour to acknowledge receipt of your letter which reads as follows:

'I have the honour to refer to the question concerning an information and consultation procedure for the adoption of certain decisions and other measures to be taken during the period preceding the accession of your country to the European Union which was raised in the framework of the accession negotiations.

I hereby confirm that the European Union is able to agree to such a procedure, in the terms set out in the Annex to this letter, which could be applied in respect of the Republic of Croatia as from the date on which the Accession Conference declares that the accession negotiations have been finally concluded.

I should be obliged if you could confirm that your Government is in agreement with the contents of this letter.'

I have the honour to confirm that my Government is in agreement with the contents of this letter.

Yours faithfully,

ANNEX

Information and consultation procedure for the adoption of certain decisions and other measures to be taken during the period preceding accession

I.

1. In order to ensure that the Republic of Croatia, hereinafter referred to as 'Croatia', is kept adequately informed, any proposal, communication, recommendation or initiative which is intended to lead to the adoption of legal acts of the European Parliament and Council, the Council, or the European Council shall be brought to the knowledge of Croatia after being transmitted to the Council or the European Council.

2. Consultations shall take place pursuant to a reasoned request by Croatia, which shall set out expressly therein its interests as a future member of the Union and its observations.

3. Administrative decisions shall not, as a general rule, give rise to consultations.

4. Consultations shall take place within an Interim Committee composed of representatives of the Union and of Croatia. Save for a reasoned objection from the Union or Croatia, consultations may also take place in the form of the exchange of messages by electronic means, in particular in the common foreign and security policy.

5. On the Union side, the members of the Interim Committee shall be the members of the Permanent Representatives Committee or persons designated by them for this purpose. Where appropriate, the members may be the Members of the Political and Security Committee. The Commission shall be adequately represented.

6. The Interim Committee shall be assisted by a Secretariat, which shall be that of the Conference, continued for this purpose.

7. Consultations shall take place as soon as the preparatory work carried out at Union level with a view to the adoption of the acts mentioned in point 1 above has produced common guidelines enabling such consultations to be usefully arranged.

8. If serious difficulties remain after consultations, the matter may be raised at ministerial level at the request of Croatia.

9. The above provisions shall apply *mutatis mutandis* to the decisions of the Board of Governors of the European Investment Bank.

10. The procedure laid down in the above paragraphs shall also apply to any decision to be taken by Croatia which might affect the commitments resulting from its position as a future member of the Union.

II.

11. The Union and Croatia shall take the necessary measures to ensure that its accession to the agreements or conventions and protocols referred to in Articles 3(4), 6(2) and 6(5) of the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaties on which the European Union is founded, hereinafter referred to as 'the Act of Accession', coincides so far as possible with the entry into force of the Treaty of Accession.

12. With regard to the negotiations with the co-contracting parties of the protocols referred to in Article 6(2), second subparagraph, of the Act of Accession, the representatives of Croatia shall be associated with the work as observers, side by side with the representatives of the present Member States.

13. Certain non-preferential agreements concluded by the Union, which remain in force after the date of accession, may be the subject of adaptations or adjustments in order to take account of the enlargement of the Union. These adaptations or adjustments will be negotiated by the Union in association with the representatives of Croatia in accordance with the procedure referred to in the preceding paragraph.

III.

14. The institutions shall, in due course, draw up the texts referred to in Article 52 of the Act of Accession. To that end, Croatia shall provide the institutions with translations of those texts in a timely manner.

COUNCIL OF THE EUROPEAN UNION

GENERAL SECRETARIAT

Brussels, 13 September 2011

AC 30/11

LIMITE

FINAL EUROPEAN UNION AND CANDIDATE COUNTRY AGREED TEXT ON THE ACCESSION TREATY

Subject:	Accession Treaty: Appendix to Annex V Candidate country: Croatia

1. Texts in square brackets [ ] are for information. These could include:
   - the reference text in English of the adaptation inserted in the relevant candidate country language, where necessary,
   - data which still needs to be confirmed,
   - reminders for a later date.

2. The draft provisions included in this text are those that are required in relation to the specific *acquis* screened and negotiated under this chapter, within the framework of the list of chapter headings defined by the EU at the beginning of the negotiations with Croatia.

NAME OF THE MEDICINAL PRODUCT	HARMACEUTICAL FORM	MANUFACTURER	NATURE AND CONTENTS OF CONTAINER	Domestic	Imported	Proprietary	Generic UDMP	nCADREAC	CP	MRP	OTC
1M potassium-chloride (7.45%) concentrate 50 mL	concentrate for intravenous after reconstitution	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb,	50 mL of solution in a glass injection bottle with a chlorobutyl stopper protected	YES			YES				
1M sodium hydrogencarbonate (8.4%) solution for intravenous infusion, 100 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in a glass infusion bottle with rubber stopper protected by Al cap, 20 bottles with plastic holders	YES			YES				
A.T. 10 solution	oral solution	Merck KGaA, Frankfurter Straße 250,	15 mL of solution in an amber glass bottle with		YES	YES					
Abaktal 400 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d.,	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Abaktal 400 mg/5 mL solution for injection	solution for injection	Lek farmacevtska družba d.d.,	10 ampoules each containing 5 mL of solution, supplied in		YES		YES				
Accupro 10 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe,	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Accupro 20 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe,	31 (3x10) tablets in a blister, supplied in a box		YES	YES					
Accupro 5 mg tablets	film coated tablets	Gödecke GmbH, dio Pfizer grupe,	32 (3x10) tablets in a blister, supplied in a box		YES	YES					
Aclasta 5 mg solution for infusion	solution for infusion	Novartis Pharma Stein AG,	100 mL solution in a plastic bottle with rubber stopper,		YES	YES			YES		
Act HIB, vaccine against Haemophilus influenzae type B	lyophilisate and diluent for preparation of injection solution	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Bottle with 1 dose of lyophilised vaccine and 1 glass syringe with solvent for		YES						
Actilyse lyophilisate for injection 50 mg	lyophilisate and diluent for preparation of solution for injection	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer Strasse 65, Biberach an der Riss, Germany	50 mg of lyophilisate in a bottle, 50 mL of solvent (water for injection) in a bottle and a transfer needle, supplied in a box		YES	YES					
Activelle	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets in a plastic calendar dial pack (dispenser with marked days of the week), supplied in a box		YES	YES					
Actonel 30 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Actonel 35 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	4 (1x4) tablets in a blister, supplied in a box		YES	YES					
Actonel 5 mg tablets	film coated tablets	Procter & Gamble Pharmaceuticals Germany GmbH, Weiterstadt, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Actrapid HM 100	solution for injection (for s.c., i.m. and i.v. use)	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	10 mL of solution in a glass bottle, supplied in a box		YES	YES					
Actrapid Penfill	solution for subcutaneous injection	Novo Nordisk A/S, Novo Alle, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of solution in a blister, supplied in a box		YES	YES					

Adartrel 0.25 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	12 (1x12) tablets in PVC/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
Adartrel 0.5 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (2x14) tablets in a PVC/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
Adartrel 2 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (2x14) tablets in a PVC/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
Adriblastina PFS 10 mg injection (2 mg/mL)	solution for injection	Pfizer Italia S.r.l., Milano, Italy	5 mL of solution for injection in a glass bottle, supplied in a box		YES		YES				
Adriblastina PFS 50 mg injection (2 mg/mL)	solution for injection	Pfizer Italia S.r.l., Milano, Italy	25 mL of solution for injection in a glass bottle, supplied in a box		YES		YES				
Advantan cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Advantan ointment	ointment	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Aerius syrup of 0.5 mg/mL	syrup	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	60 mL of syrup in an amber glass bottle and a measuring spoon, supplied in a box		YES	YES					
Aerius 5 mg film coated tablets	film coated tablets	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	10 (1x10) tablets in a blister, supplied in a box		YES	YES					
Afloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 grams of cream in an aluminum tube with a plastic cap, supplied in a box	YES			YES				
Afloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	40 g of cream in an aluminium tube with a plastic stopper, supplied in a box	YES			YES				
Afloderm ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 grams of ointment in an aluminum tube with a plastic cap, supplied in a box	YES			YES				
Afluria suspension for injection in pre-filled syringe, influenza vaccine (fragmented inactivated)	suspension for injections	CSL Limited, 45 Poplar Road, Parkville, Melbourne, Victoria 3052, Australija	Box with 1 pre-filled syringe (glass, type I) with a needle, with 1 dose of vaccine (0.5 mL of suspension)		YES						
Aggrastat concentrate of solution for infusion	concentrate of solution for infusion	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	50 mL of solution concentrate in a glass bottle, supplied in a box		YES	YES				YES	
Aggrenox 200/25 mg modified release capsules	modified release capsules, hard	Boehringer Ingelheim Pharma GmbH&Co.KG, Biberach an der Riss, Germany	60 capsules in a white plastic (PP) container with a plastic (PE) temper-evident stopper with a desiccant, supplied in a box		YES	YES					
Aglurab 1000	film coated tablets	Weifa AS, Oslo, Norway	60 tablets in a plastic (HDPE) bottle with a plastic stopper (there is a bag in a bottle or a capsule in a stopper containing silicagel to attenuate the tablet odor)		YES		YES				
Aglurab 850	film coated tablets	Weifa AS, Oslo, Norway	36 tablets in a plastic (HDPE) bottle with a desiccant		YES		YES				

Agrippal vaccine against influenza (surface antigen, inactivated)	suspension for intramuscular or subcutaneous administration	Chiron S.r.l, Siena, Italy	Pre-filled syringe with a needle (containing a single 0.5-mL vaccine dose in the form of suspension)		YES							
Agrippal suspension for injections in pre-filled syringe, influenza vaccine (surface antigens), inactivated	suspension for injections in a pre-filled syringe	Novartis Vaccines & Diagnostics S.r.l., Siena, Italy	A pre-filled syringe (glass type I) containing 0.5 mL of suspension, equipped with a needle (23G, 1"; or 25G, 1"; or 25G, 5/8";) and a rubber plunger stopper, supplied in a box		YES							
Akineton injection	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 ampoules with 1 mL of solution for injection, supplied in a carton box		YES		YES					
Akineton tablets	tablets	Laboratorio Farmaceutico S.I.T. Srl, Via Cavour 70, Mede (PV), Italy	50 tablets (5x10) in a PVC/Al blister, supplied in a box		YES		YES					
Aknet	dermal solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 mL of solution in an amber glass bottle with a dropper and a plastic stopper, supplied in a box	YES			YES					
Aktivin H capsule	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/PVDC/Al blister, supplied in a box	YES							YES	
Aktivin H capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 capsules in a polypropylene bag, supplied in a box	YES							YES	
Alamcin 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, Skopje, FYROM in cooperation with BILIM PHARMACEUTICALS A.S., Maslak Istanbul, Turkey	Amber glass bottle with powder for preparation of 100 mL of suspension with a polyethylene stopper and a plastic spoon, supplied in a box		YES		YES					
Albothyl solution	solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	25 mL of solution in an amber glass bottle with black plastic cap, supplied in a box		YES		YES					
Albothyl pessaries	pessaries	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	6 pessaries in a white non-transparent plastic foil (PVC/PE), supplied in a box		YES		YES					
Human albumin 20% solution for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution, supplied in a box	YES								
Human albumin 20% solution for i.v. use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution, supplied in a box	YES								
Human albumin 20% solution for intravenous use (Albumini humani solutio), 200g/l	solution for infusion	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution, supplied in a box		YES							
Human albumin 20% solution for intravenous use (Albumini humani solutio), 200g/l blood	solution for infusion	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution, supplied in a box		YES							
Albumin (human) 5% solution for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 250 mL of solution, supplied in a box	YES								
Aldactone 100 mg capsules	capsules	Roche Farma S.A., Madrid, Spain	20 (2x10) capsules in PVC/Al blister, supplied in a box		YES	YES						

Aldactone 25 mg coated tablets	coated tablets	Roche Farma S.A., Madrid, Spain	50 (5x10) coated tablets in a PVC/Al blister, supplied in a box		YES	YES					
Aldactone 50 mg coated tablets	coated tablets	Roche Farma S.A., Madrid, Spain	20 (2x10) coated tablets in PVC/Al blister, supplied in a box		YES	YES					
Aldizem 60 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	34 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Aldizem 90 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	35 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Aldurazyme 100 U/mL concentrate for solution for infusion	concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with 5 mL of solution concentrate, supplied in a box		YES	YES		YES	YES		
Aledox 70 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	4 (1x4) tablets in a PA/Al/PVC//Al blister, supplied in a box	YES			YES				
Alendor 70	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	4 (1x4) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Alendor tablets 5 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES			YES				
Alendor tablets10 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES			YES				
Alfuzosin Pliva tablets 10 mg	film coated tablets with prolonged-release	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	33 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Alfuzosin Pliva tablets 5 mg	prolonged-release film-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10) tablets in a blister (PVC/Al) , supplied in a box	YES			YES				
Alimta 500 mg powder for infusion solution concentrate	powder for concentrate for infusion solution	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	Glass bottle, supplied in a box		YES	YES			YES		
Alkagin 2.5 g/5 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 (5x10) ampoules each with 5 mL of solution in a protective container, supplied in a box		YES		YES				
Alkagin 500 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Almacin 500 mg capsules	capsules	Alkaloid AD - Skopje, Skopje, FYROM in cooperation with BILIM PHARMACEUTICALS A.S., Maslak Istanbul, Turkey	16 capsules in a A/PVC blister, supplied in a box		YES		YES				
Alomax 2% dermal solution	dermal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 mL of solution in a white plastic bottle with a plastic stopper, a metering plastic pump and a spray attachment, in a protective bag, supplied in a box	YES			YES				YES

Alomax 5% dermal solution	dermal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 mL of solution in a white plastic bottle with a plastic stopper, a metering plastic pump and a spray attachment, in a protective bag, supplied in a box	YES			YES				YES
Alomide 1 mg/mL eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle with a dropper, supplied in a carton box		YES	YES					
Alopurinol 100 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 tablets in a plastic bottle, supplied in a box	YES			YES				
Aloxi, solution for injection	solution for injection	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	One glass vial with 5 mL of solution, supplied in a box		YES	YES			YES		
Alphagan eye drops	eye drops	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES					
Alvesco 160 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	Al container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES				YES	
Alvesco 40 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	Al container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES				YES	
Alvesco 80 Inhaler	pressurized inhalant, solution	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	Al container with a metering valve, mouthpiece and stopper, 60 inhalations		YES	YES				YES	
Amaryl 1.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
Amaryl 2.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
Amaryl 3.0	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
Amicor 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	41 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Amicor 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	42 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Amicor 5	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (1x20) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Amicor H 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (1x20) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Amicor H 10	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	43 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Amicor H 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	44 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				

Aminfluorid dental gel	dental gel	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Tube with 25 g of gel, supplied in a box	YES			YES				YES
Aminfluorid dental solution	dental solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 mL of solution in a polyethylene bag with a dropper and a screw cap, supplied in a box	YES			YES				YES
Aminomix 2 Novum	solution for infusion (for parenteral nutrition)	Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany	One plastic bag with two compartments (for solutions A and B), peel seam and two attachments connected to the compartments (with solutions for drug delivery and infusion) in an external protective bag inserted with bag with agent		YES		YES				
Aminomix 2 Novum	solution for infusion (for parenteral nutrition)	Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany	One plastic bag with two compartments (for solutions A and B), peel seam and two attachments connected to the compartments (with solutions for drug delivery and infusion) in an external protective bag inserted with bag with agent		YES		YES				
Aminophyllinum Lek 100 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/Al), supplied in a carton box		YES		YES				
Aminophyllinum Lek 250 mg/10 mL solution for injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) ampoules with 10 mL of solution for injection, supplied in a box		YES		YES				
Aminophyllinum Lek 350 mg prolonged-release tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister (PVC/Al) , supplied in a carton box		YES		YES				
Aminoplasmal - 10% E	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box		YES		YES				
Aminoplasmal - 5% E	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box		YES		YES				
Aminoplasmal Hepa - 10%	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a glass bottle, 10 bottles in a box		YES		YES				
Aminoven 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	One glass bottle for infusion with 500 mL of solution		YES		YES			YES	
Aminoven 5%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	One glass bottle for infusion with 500 mL of solution		YES		YES			YES	
Aminoven Infant 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 100 mL of solution, supplied in a carton box		YES		YES				
Aminoven Infant 10%	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 250 mL of solution, supplied in a carton box		YES		YES				
Amiodaron 200 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica,	Box with 30 (2x15) tablets in a blister	YES			YES				

		Republic of Croatia									
AmLodipin Cipla 10 mg	tablets	Cipla Ltd., Verna Industrial Estate, Verna Goa, India	30 (3x10) tablets in a brown PVC/Al blister, supplied in a box		YES		YES				
AmLodipin Cipla 5 mg	tablets	Cipla Ltd., Verna Industrial Estate, Verna Goa, India	30 (3x10) tablets in a brown PVC/Al blister, supplied in a box		YES		YES				
AmLopin 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
AmLopin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
AmLopin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Amoksicilin 375 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 capsules in a bottle, supplied in a box	YES			YES				
Amoksicilin 500 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 capsules in a blister, supplied in a box	YES			YES				
Amoksicilin powder for oral suspension 250 mg/5 mL	powder for oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Bottle with powder for preparation of 100 mL of suspension, supplied in a box	YES			YES				
Amonex 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES				
Amonex 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES				
Amoxil capsules 500 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	16 (2x8) tablets in a blister, supplied in a box	YES			YES				
Amoxil syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with powder, supplied in a box	YES			YES				
Amphocil 100 mg	powder for preparation of solution for infusion	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	Turbid glass bottle (with 100 mg of dry matter) with a cap and Al ring, supplied in a box		YES		YES				
Amphocil 50 mg	powder for preparation of solution for infusion	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	Turbid glass bottle (with 50 mg of dry matter) with a cap and Al ring, supplied in a box		YES		YES				
Amphotericin B, powder for preparation of injections	powder for preparation of injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	One glass vial with powder for injection preparation, supplied in a box	YES			YES				
Ampril HD tablets 5 mg/25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Ampril HL tablets 2.5 mg/12.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto,	32 (3x10) tablets in a OPA/Al/PVC//Al blister,		YES		YES	YES		YES	

		Republic of Slovenia	supplied in a box								
Ampril 1.25 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	33 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Ampril 10 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	34 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Ampril 2.5 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	35 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Ampril 5 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	36 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Amyzol 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 (4X25) tablets in a blister, supplied in a box		YES		YES				
Amyzol 25 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, supplied in a box		YES		YES				
ANAFRANIL coated tablets	coated tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Novartis Pharma Services Inc., Basel, Switzerland	31 (3x10) coated tablets in a PVC/Al blister, supplied in a box	YES			YES				
Analgin injections	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of solution for injection in an amber glass ampoule, 50 ampoules in a box	YES			YES				
Analgin tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/Al), supplied in a box	YES			YES				
Andol	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10 tablets in Al/PVC/PVDC blister, supplied in a box	YES			YES				YES
Andol 100	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (2x10 tablets in Al/PVC/PVDC blister, supplied in a box	YES			YES				YES
Andol C	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 tablets in a vial (cap with silicagel and protective ring)	YES			YES				
Androcur-10 tablets	tablets	Schering GmbH und Co. Produktions KG, Doebereinerstrasse 20, Weimar, Germany	45 (3x15) tablets in a blister, supplied in a box		YES	YES					
Androcur-50 tablets	tablets	Delpharm Lille S.A.S., Z.I. De Roubaix Est, Rue de Toufflers, Lys Lez Lannoy, France	50 (5x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Androgel 50 mg, gel in bags	gel	Besins International Belgique, Drogenbos, Belgium	5 g of gel in a bag (PET/Al/PE), 30 bags in a carton box		YES	YES				YES	
Anexate	solution for injection or infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 mL of solution in a glass ampoule, 10 ampoules in a box		YES	YES					

Angal lozenges	lozenges	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) lozenges in PVC/Al blister, supplied in a box		YES		YES				YES
Angal S oral spray	oromucosal spray	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 mL of solution in an amber glass bottle with a screw cap and automatic sprayer/spraying attachment, supplied in a box		YES		YES				YES
Angeliq film tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	aluminum		YES	YES				YES	
Ansilan 10 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	25 capsules in a glass bottle, supplied in a box		YES		YES				
Ansilan mite 5 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) capsules in a PVC/Al blister, supplied in a box		YES		YES				
Antithrombin III Immuno 1000 IU	lyophilized powder and diluent for preparation of solution for injection or infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Vial with 1000 IU antithrombin III, vial with diluent, portable needle, filter needle, vent needle, disposable needle, infusion kit , disposable syringe, supplied in a box		YES						
Antithrombin III Immuno 500 IU	lyophilized powder or diluent for preparation of solution for injection or infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Vial with 500 IU antithrombin III, vial with diluent, portable needle, filter needle, vent needle, disposable needle, infusion kit , disposable syringe, supplied in a box		YES						
Antitoxin (equine) against European viper venom	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 bottle containing 10 mL of preparation (1 dose), with a sterile needle and a disposable syringe	YES							
Apidra 100 IU/mL (10 mL glass vial)	solution for injection (for s.c. use)	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	One glass vial with 10 mL of solution, supplied in a box		YES	YES			YES		
Apidra 100 IU/mL (3mL glass cartridge for use with OptiClik injector)	solution for subcutaneous injection	Sanofi - Aventis Deutschland GmbH, Frankfurt am Main, Germany	5 glass cartridges (for OptiClik) with 3 mL of solution, supplied in a box		YES	YES			YES		
Apidra 100 IU/mL (3.0 mL glass cartridge)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 glass cartridges with 3 mL of solution, supplied in a box		YES	YES			YES		
Apidra 100 IU/mL OptiSet (injector with glass cartridge of 3 mL)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 pens (injectors) with a glass cartridge containing 3 mL of solution, supplied in a box		YES	YES			YES		
Aprovel 150 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/Al), supplied in a box		YES	YES			YES		
Aprovel 300 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/Al), supplied in a box		YES	YES			YES		

Aprovel 75 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PC/PVDC/Al), supplied in a box		YES	YES			YES		
Aqua pro injectione	diluent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of water for injection in a glass infusion bottle	YES			YES				
Aqua pro injectione	solvent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	1000 mL of Water for Injection in a glass infusion bottle	YES			YES				
Aqua pro injectione	solvent for preparation of parenteral solutions	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of Water for Injection in a glass infusion bottle	YES			YES				
Aranesp 10 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 100 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.5 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 100 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 15 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.375 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 150 mcg solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.3 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 150 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 20 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.5 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 20 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 30 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 300 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.6 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 300 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.6 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 40 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.4 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		

Aranesp 40 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 50 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.5 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 500 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 1.0 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 500 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 1.0 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 60 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.3 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 60 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.3 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 80 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	A plastic syringe with fitted glass syringe containing 0.4 mL of solution in a protective container, supplied in a box		YES	YES		YES	YES		
Aranesp 80 micrograms of solution for injection in a pre-filled syringe	solution for injection	Amgen Europe B.V., Minervum 7061, Breda, the Netherlands	One disposable glass syringe with needle containing 0.4 mL of solution, in a protective container, supplied in a box		YES	YES		YES	YES		
Arava 10 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	Box with 30 tablets in a plastic bottle		YES	YES					
Arava 100 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	3 tablets in an aluminum blister, supplied in a box		YES	YES					
Arava 20 mg tablets	film coated tablets	Aventis Intercontinental, Route de Choisy au Bac, Compiegne, Cedex, France	Box with 30 tablets in a plastic bottle		YES	YES					
Arcoxia 120 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	7 (1x7) film coated tablets in an Al/Al blister, supplied in a box		YES	YES		YES		YES	
Arcoxia 60 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	14 (2x7) film coated tablets in a A/Al blister, supplied in a box		YES	YES		YES		YES	
Arcoxia 90 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	14 (2x7) film coated tablets in a A/Al blister, supplied in a box		YES	YES		YES		YES	
Aredia 15 mg	powder and diluent for solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	4 colourless glass bottles with powder and 4 ampoules with 5 mL of solvent (water for injection), supplied in a box		YES	YES					
Aredia 30 mg	powder and diluent for solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse,	2 clear glass bottles containing powder and 2 ampoules with 10 mL of		YES	YES					

		Stein, Switzerland	diluent (Water for Injection), supplied in a box								
Arficin 150 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 capsules in a brown plastic bottle, supplied in a box	YES			YES				
Arficin 150 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Plastic bottle with 100 capsules, supplied in a box	YES			YES				
Arficin 300 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 capsules in a white plastic bottle, supplied in a box	YES			YES				
Arilin rapid	pessaries	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	2 pessaries in an Al/Al strip, supplied in a box		YES		YES				
Arimidex	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/al), supplied in a box		YES	YES					
Arixtra 2.5 mg/0.5 mL solution for injection (pre-filled syringe)	solution for s.c. and i.v. Injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	10 glass syringes with 0.5 mL of solution, supplied in a box		YES	YES		YES	YES		
Arixtra 7.5 mg/0.6 mL solution for injection (pre-filled syringe)	solution for s.c. and i.v. Injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	10 pre-filled glass syringes with 0.6 mL of solution, supplied in a box		YES	YES		YES	YES		
Artein 20 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	21 (2x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Arvind 100 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES			YES				
Arvind 200 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES			YES				
Arvind 25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES			YES				
Arvind 50 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x10) tablets in a blister, supplied in a box	YES			YES				
Asacol 400 mg gastric-resistant tablets	gastric-resistant tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia in cooperation with Tillotts Pharma AG, Ziefen, Switzerland	100 (10x10) gastro-resistant tablets PVC/Al blisters, supplied in a box		YES		YES				
Asacol 800 mg gastric-resistant tablets	gastric-resistant tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia in cooperation with Tillotts Pharma AG, Ziefen, Switzerland	50 (5x10) gastro-resistant tablets in a PVC/Al blister, supplied in a box		YES		YES				
Asentra 100 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto,	28 (4x7) tablets in a blister, supplied in a box		YES		YES				

		Republic of Slovenia									
Asentra 50 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister, supplied in a box		YES		YES				
Aspirin 100 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) tablets in a blister, supplied in a box		YES		YES				YES
Aspirin 500 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) tablets in a blister, supplied in a box		YES		YES				YES
Aspirin direct	chewing tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (5x2) tablets in a strip, supplied in a box		YES		YES				YES
Aspirin plus C	effervescent tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (5x2) effervescent tablets in a strip, supplied in a box		YES		YES				YES
Aspirin protect 100 mg gastric-resistant tablets	gastric-resistant tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Aspirin protect 300 mg gastric-resistant tablets	gastric-resistant tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Astax tablets 10 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/Al) blister, supplied in a box	YES			YES				
Astax tablets 20 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/Al) blister, supplied in a box	YES			YES				
Astax tablets 40 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/TE/PVDC/Al) blister, supplied in a box	YES			YES				
Atacand 16 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umea, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	
Atacand 32 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umea, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	
Atacand 4 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umea, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	
Atacand 8 mg tablets	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umea, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	
Atacand Plus	tablets	AstraZeneca AB, Södertälje, Sweden, AstraZeneca AB, Umea, Sweden and AstraZeneca GmbH, Plankstadt, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	

ATenativ 1000 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 50 mL of lyophilisate and a bottle with 20 mL of solvent		YES						
ATenativ 1500 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 100 mL of lyophilisate and a bottle with 30 mL of solvent		YES						
ATenativ 500 IU	lyophilisate and diluent for intravenous solution	Octapharma AB, Stockholm, Sweden	Glass bottle with 50 mL of lyophilisate and a bottle with 10 mL of solvent		YES						
Atenolol Pliva 100 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister (PVC/PVDC/Al), supplied in a box	YES			YES				
Atenolol Pliva 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/PVdC/A1 blister, supplied in a box	YES			YES				
ATG-Fresenius	concentrate for infusion solution	Fresenius Biotech GmbH, Am Haag 6-7, Gräfelfing, Germany	One glass bottle with 5 mL of concentrate, supplied in a box		YES						
Athyrazol	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	34 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Atoris tablets 10 mg	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia ili Krka-Farma d.o.o., Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Atoris 10 mg tablets	film coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Atoris 20 mg tablets	film coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Atoris tablets 20 mg	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia ili Krka-Farma d.o.o., Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Atoris tablets 40 mg	film coated tablets	Krka d.d., Novo mesto, Republic of Slovenia or KRKA - FARMA d.o.o., DPC Jastrebarsko, Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister (OPA/Al/PVC-Al), supplied in a box	YES			YES				
Atorvox tablets 10 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Atorvox tablets 20 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Atorvox tablets 40 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	31 (3x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Atropini sulfas 0.5 mg/mL injection	solution for s.c., i.m. and i.v. Injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 colourless glass ampoules each with 1 mL of solution, supplied in a box	YES			YES				

Atropini sulfas 1 mg/mL injection	solution for s.c., i.m. and i.v. Injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 colourless glass ampoules each with 1 mL of solution, supplied in a box	YES			YES				
Atrovent 0.025% inhalation solution	inhalation solution	Instituto de Angeli S.r.l., Regello (Firenca), Italy	20 mL of solution in an amber glass bottle with a plastic (PE) dropper and a plastic (PP) cap, supplied in a box		YES	YES					
Atrovent N inhalation aerosol	aerosol	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	200 inhalation doses in a metal container with metering valve and plastic mouthpiece, supplied in a box		YES	YES					
Augmentin injection 1.2 g	powder for solution for injection or infusion	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	5 glass bottles each with a dose of drug, supplied in a box		YES	YES					
Augmentin injection 2.2 g	powder for solution for injection or infusion	SmithKline Beecham S.A., Heppignies, Belgium	One glass vial containing one dose of medicinal product, supplied in a box		YES	YES					
Augmentin syrup 457mg/5 mL	powder for preparation of oral suspension	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	Powder for preparation of 70 mL of suspension (by the addition of 64 mL of water) in a glass bottle (with aluminium stopper), supplied in a box		YES	YES					
Augmentin tablets 1 g	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	14 (2x7) film coated tablets in a PVC/PVDC//Al blister inserted in a protective aluminum bags (with desiccant), supplied in a box		YES	YES					
Aulin 100 mg granules	granules	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	6 bags each with 2 g of granules for preparation of oral suspension, supplied in a box		YES	YES					
Aulin 100 mg tablets	tablets	Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland	6 (1x6) tablets in a blister (white non-transparent PVC/Al), supplied in a box		YES	YES					
Auropan film coated tablets 3 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 film coated tablets in an amber glass bottle, supplied in a box		YES		YES				
Aurorix	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	38 (3x10) tablets in a PVC/Al blister, supplied in a box		YES	YES					
Avandamet 2 mg/1000 mg tablets	film coated tablets	GlaxoWellcome S.A., Avenida de Extremadura 3, 9400 Aranda de Duero, Burgos, Spain	56 (4x14) film coated tablets in a PVC/PVDC//Al blister, supplied in a carton box		YES	YES		YES	YES		
Avandamet 4 mg/1000 mg tablets	film coated tablets	GlaxoWellcome S.A., Avenida de Extremadura 3, 9400 Aranda de Duero, Burgos, Spain	56 (4x14) film coated tablets in a PVC/PVDC//Al blister, supplied in a carton box		YES	YES		YES	YES		
Avandia 2 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	56 (4x14) tablets in a blister, supplied in a box		YES	YES		YES	YES		
Avandia 4 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES		

Avandia 8 mg film-tablets	film coated tablets	Glaxo Wellcome Production, Mayenne, France	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES	YES		
Avastin 25 mg/mL concentrate for infusion solution	concentrate of solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	16 mL of infusion solution concentrate in a glass bottle, supplied in a box		YES	YES		YES	YES		
Avastin 25 mg/mL concentrate for infusion solution	concentrate for infusion solution	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	4 mL of concentrate for solution for infusion in a glass bottle, supplied in a box		YES	YES		YES	YES		
Avelox 400 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	5 (1x5) film coated tablets in a blister (PP/Al), supplied in a box		YES	YES				YES	
Avelox 400 mg/250 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	One glass bottle with 250 mL of infusion solution, supplied in a box		YES	YES					
AVODART 0.5 mg soft capsules	soft capsules	RP Scherer S.A., Beinheim, France (for GlaxoSmithKline)	30 (3x10) capsules in a blister (PVC/PVdC/Al), supplied in a box		YES	YES				YES	
AVONEX 30 µg powder and diluent for injection	powder and diluent for solution for injection	BIOGEN Idec BV, 2132 WX Hoofddorp, the Netherlands	Box with 4 bottles with BIO SET reconstitution kit, 4 syringes with solvent and 4 needles (BIO SET kit)		YES	YES			YES		
Azilect 1 mg tablets	tablets	Teva Pharmaceuticals Europe B.V., the Netherlands	7 (1x7) tablets in a blister (Al/Al), supplied in a box		YES	YES		YES	YES		
Azilect 1 mg tablets	tablets	Teva Pharmaceuticals Europe B.V., the Netherlands	30 tablets in a plastic (HDPE) bottle (desiccant in a plastic PP stopper), supplied in a box		YES	YES		YES	YES		
AZIMED capsules 250 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) capsules in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
AZIMED tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	3 (1x3) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Azitromicin Lek 250 mg film coated tablets	film coated tablets	Sandoz S.R.L., TG. Mures, Mures District, Rumunjska	6 (1x6) film coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES		YES				
Azitromicin Lek 500 mg film coated tablets	film coated tablets	Sandoz S.R.L., TG. Mures, Mures District, Rumunjska	3 (1x3) film-coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES		YES				
Azopt eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Box with 5 mL of suspension in a plastic bottle with a dropper		YES	YES					
Baclofen 10 mg	tablets	Polpharma S.A., Poland	50 tablets in a polypropylene bottle, supplied in a box		YES		YES				
Baclofen 25 mg	tablets	Polpharma S.A., Poland	50 tablets in a polypropylene bottle, supplied in a box		YES		YES				
Balance 1.5 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 1.5 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	

Balance 1.5% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 1.5% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 2.3 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 2.3 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 2.3% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 2.3% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 4.25 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 4.25 % glucose, 1.25 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 4.25% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2500 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Balance 4.25% glucose, 1.75 mmol/l calcium	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 unit packs ("Stay Safe Balance system") each with 2000 mL of solution for peritoneal dialysis in a protective plastic bag, supplied in a carton box		YES		YES			YES	
Baralgin M	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Bazetham capsules 0.4 mg	modified release capsules, hard	Pliva Croatia Ltd., Ulica grada Vukovara 49,	30 (3x10) capsules in an orange blister	YES			YES				

		Zagreb, Republic of Croatia	(PVC/PE/PVDC/Al), supplied in a box								
BCG VACCINE SSI, vaccine against tuberculosis - BCG SSI, 0.75 mg	lyophilisate and solvent for preparation of suspension for injection	Statens Serum Institut, Artillerivej, Copenhagen S, Denmark	Box with 10 glass bottles each with 10 doses of lyophilised vaccine (0.75 mg) and a box with 10 glass bottles each with 1 mL of solvent Sauton SSI		YES						
BCG VACCINE SSI, tuberculosis vaccine - BCG SSI, 1.5 mg	lyophilisate and solvent for preparation of suspension for injection	Statens Serum Institut, Artillerivej, Copenhagen S, Denmark	Box with 10 glass bottles each containing 20 doses of lyophilised vaccine (1.5 mg) and a box with 10 glass bottles each containing 2 mL of solvent Sauton SSI		YES						
B-COMPLEX granules	granules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	70 g of granules in a (PEPT/Al/PE) bag		YES		YES				YES
B-COMPLEX coated tablets	coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (2x15) capsules in a PVC-Al blister, supplied in a box		YES		YES				YES
Bekunis herbal tea	herbal tea	Roha Arzneimittel GmbH, Bremen, Germany	80 g of tea in a round carton box closed with aluminium foil and a plastic lid		YES						YES
Bekunis coated tablets	coated tablets	Roha Arzneimittel GmbH, Bremen, Germany	45 coated tablets in a plastic tube with a plastic stopper, supplied in a box		YES						YES
Belara	film coated tablets	Grünenthal GmbH, Stolberg, Germany	21 (1x21) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES				YES	
Bellune 35	coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	63 (3x21) tablets in a transparent blister (PVC/Al) calendar dial pack, supplied in a box	YES			YES				
Beloderm cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES				
Beloderm ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES				
Belodin	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 7 tablets (blister)	YES			YES				
Belodin 10mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Belogent cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES				
Belogent ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 g of cream in a tube, supplied in a box	YES			YES				
Belomet 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES				YES
Belomet 200 mg/2 mL injection	solution for injection for intramuscular and intravenous use	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) ampoules each containing 2 mL of solution for injection, supplied in a box	YES			YES				

Belosalic lotion	lotion	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 mL of lotion in a plastic bottle, supplied in a box	YES			YES				
Belosalic ointment	ointment	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 g of ointment in a tube, supplied in a box	YES			YES				
Belosept solution	oromucosal solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	200 mL of solution in an amber glass bottle with aluminum cap and a 10 mL graduated plastic cup, supplied in a box	YES			YES				YES
Benil 0.5 ‰ nasal drops	nasal drops	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10-mL of solution in a glass bottle with plastic dropper attachment, supplied in a box		YES		YES				YES
Benil nasal drops 1.0 ‰	nasal drops	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10-mL of solution in a glass bottle with plastic dropper attachment, supplied in a box		YES		YES				YES
Benzyl benzoate, Jadran	skin emulsion	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of emulsion in an amber glass bottle with a plastic cap, supplied in a box	YES			YES				
Beriate P 500	lyophilized preparation and diluent	Aventis Boehring GmbH, Emil-von-Behring Strasse 76, Marburg, Germany	Bottle with a lyophilized drug and a bottle with water for injection in a carton box also containing a leaflet, dissolution kit, and a filter needle		YES						
Betadine 1 % solution	gargling solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	100 mL of solution in a brown plastic bottle, supplied in a box		YES		YES				YES
Betadine 10 % ointment	ointment	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	20 grams of cream in an aluminum tube, supplied in a box		YES		YES				
Betadine 10 % solution	solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	100 mL of solution in a brown plastic bottle, supplied in a box		YES		YES				YES
Betadine 200 mg pessaries	pessaries	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	14 (2x7) pessaries in a PVC/PE foil, supplied in a box		YES		YES				
Betadine 7.5 % solution	solution for cleansing and disinfection of skin	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Mundipharma AG, Basel, Switzerland	1000 mL of solution in a white polyethylene bottle		YES		YES				YES
Betaferon	lyophilisate and diluent for prepartion of solution for injection	Boehringer Ingelheim Pharma KG, Biberach an der Riss, Germany and Chiron Corporation, Emeryville, US for Schering AG, Berlin, Germany	15 3-mL bottles with lyophilisate and 15 3-mL bottles with 2 mL of diluent		YES	YES			YES		
Betaferon injection	lyophilisate and diluent for preparation of solution for injection	Boehringer Ingelheim Pharma KG, Biberach, Germany and Chiron Corporation, Emeryville, US for	15 lyophilisate bottles and 15 syringes with 1.2 mL of diluent (0.54% sodium chloride solution)		YES	YES			YES		

		Schering AG, Berlin, Germany									
Betaglid 1 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES			YES				
Betaglid 2 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	33 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES			YES				
Betaglid 3 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	34 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES			YES				
Betaklav duo tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (5x2) tablets in a AL/PE//AL strip, supplied in a box		YES		YES				
Betaklav powder for solution for infusion 2.2	powder for solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100-mL glass bottle containing 2.2 g of powder for solution for infusion, supplied in a box		YES		YES				
Betaklav powder for solution for injection 1.2	powder for solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20-mL glass bottle containing 1.2 g of powder for solution for injection, supplied in a box		YES		YES				
Betaserc 16 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	60 (3x20) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Betaserc 24 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	20 (1x20) tablets in a PVC/PVDC blister, supplied in a box		YES	YES					
Betaserc 8 mg	tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands i Solvay Pharmaceuticals, Lieu dit Maillard, Chatillon sur Chalaronne, France	100 (4x25) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Betazon cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube, supplied in a box	YES			YES				
Betazon ointment	ointment	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube, supplied in a box	YES			YES				
Betoptic 0.5 % eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle, supplied in a box		YES	YES					
Betrion	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminium tube	YES			YES				
BiCNU injection 100 mg	powder and diluent for preparation of solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	Vial with powder and vial with 3 mL of diluent, supplied in a box		YES	YES					

Bilobil forte capsules 80 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC-Al), supplied in a box		YES						YES
Bilobil capsules	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister, supplied in a box		YES						YES
Bisobel 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al), supplied in a box	YES			YES				
Bisobel 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al), supplied in a box	YES			YES				
Bisolex F tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in an orange blister (PVC/Al), supplied in a box	YES			YES				YES
Bisolex solution	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 mL of solution in an amber glass bottle with a dropper and a plastic 6 mL measuring cup, supplied in a box	YES			YES				YES
Bisolex syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of solution in an amber glass bottle with an aluminum cap and a 5 mL plastic measuring spoon, supplied in a box	YES			YES				YES
Bisolex tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in an orange blister (PVC/Al), supplied in a box	YES			YES				YES
Bisolvon 2 mg/mL solution	oral and inhalation solution	Instituto de Angeli, Regello (FI), Italy	40 mL of solution in an amber glass bottle with a plastic dropper and a measuring graduated (1-6 mL) cup, supplied in a box		YES		YES				YES
Bisolvon syrup 4 mg/5 mL	syrup	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	250-mL of syrup in an amber glass bottle, a plastic dispenser glass with 2.5 and 5 mL printed graduation lines or plastic dispenser spoon with 2.5 an 5 mL graduation marks, supplied in a box		YES		YES				YES
Bisolvon 8 mg tablets	tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	20 (2x10) tablets in a white blister (PVC/PVDC//Al), supplied in a box		YES		YES				YES
Bisopromerck 10	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Bisopromerck 5	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Bivacyn eye and nasal drops	eye and nasal drops	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One amber glass bottle with powder, one glass bottle with 10 mL of diluent, and a plastic dropper attachment (in a protective package), supplied in a box		YES		YES				
Bivacyn ointment	ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of ointment in an aluminium tube, supplied in a box		YES		YES				

Bivacyn eye ointment	eye ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	3.5 g of ointment in an aluminum tube, supplied in a box		YES		YES				
Bivacyn dermal powder	dermal powder	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 g of powder in a plastic bottle, supplied in a box		YES		YES				
Bivacyn dermatological spray, powder	dermatological spray, powder	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	150 mL of spray (in a Powder form) in an aluminum container with nebulizer, supplied in a box		YES		YES				
BLEOCIN - S	powder for solution for injection	Euro Nippon Kayaku GmbH, Frankfurt am Main, Germany	10-mL clear glass bottle containing powder, supplied in a box		YES	YES					
Bloxan 100 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Bondronat 2 mg concentrate for solution for infusion	concentrate for infusion solution	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	One glass vial with 2-mL of concentrate, supplied in a box		YES	YES		YES	YES		
Bondronat 50 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	28 (4x7) tablets in a blister (A1/Al), supplied in a box		YES	YES		YES	YES		
Bondronat 6 mg concentrate for solution for infusion	concentrate for solution for infusion	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	One glass vial with 6 mL of concentrate, supplied in a box		YES	YES		YES	YES		
Bonefos 400 mg capsules	capsules	Schering Oy, Turku, Finland	100 capsules in a plastic (HDPE) bottle, supplied in a box		YES	YES					
Bonefos 60 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Schering Oy, Turku, Finland	5 glass ampoules with 5 mL of solution concentrate, supplied in a box		YES	YES					
Bonefos 60 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Schering Oy, Turku, Finland	5 glass ampoules with 5 mL of solution concentrate, supplied in a box		YES	YES					
Bonefos 800 mg tablets	film coated tablets	Schering Oy, Turku, Finland	60 tablets in a PVC/Al blister, supplied in a box		YES	YES					
Bonna 35 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	4 (1x4) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Bonna 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a PVC/PE/PVDC//Al blister, supplied in a box	YES			YES				
Bonviva 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One film coated tablet in a blister (Al/Al), supplied in a box		YES	YES		YES	YES		
Bonviva 3 mg solution for injection in a pre-filled syringe	solution for injection (in pre-filled syringe)	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	Pre-filled syringe containing 3 mL of solution, supplied in a box		YES	YES		YES	YES		
Botox	lyophilisate for preparation of injection for intramuscular use	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road,	Glass bottle of 10 mL containing 1.4 mg of lyophilisate, supplied in a box		YES	YES					

		Westport, Co Mayo, Republic of Ireland									
Brinerdin coated tablets	coated tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	50 (5x10) tablets in a blister, supplied in a box		YES		YES				
Brivuzost	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	7 tablets in a blister (PVC/Al), supplied in a carton box		YES	YES				YES	
Bromergon 2.5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 tablets in an amber glass bottle, supplied in a box		YES		YES				
Brufen 400 film coated tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	30 (3x10) tablets in a PVC/Al or PVC/PVDC/Al blister, supplied in a box		YES	YES					
Brufen 600 film coated tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	30 (3x10) tablets in a PVC/Al or PVC/PVDC/Al blister, supplied in a box		YES	YES					
Bubil shampoo	shampoo	AD JAKA 80 Radoviš, Radoviš, FYROM	60 mL of shampoo in an amber glass bottle with an aluminium stopper, supplied in a box		YES		YES				
Buscol dragee	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 (2x10) sugar-coated tablets in a blister	YES			YES				
Buscopan 10 mg coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	20 (1x20) tablets in PVC/Al blister, supplied in a box		YES		YES				YES
Byol 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), in an aluminium bag, supplied in a carton box		YES		YES				
Byol 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, in an aluminium bag, supplied in a box		YES		YES				
Byol 5 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), in an aluminium bag, supplied in a carton box		YES		YES				
Byol 5 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3X10) tablets in a blister, in an aluminium bag, supplied in a box		YES		YES				
Ca-C 500 Sandoz	effervescent tablets	Krka d.d., Novo Mesto, Republic of Slovenia for Novartis Consumer Health S.A., Nyon, Switzerland	10 effervescent tablets in an Al-foil in a vial, supplied in a box		YES		YES				YES
Caduet 10 mg/10 mg tablets	film coated tablets	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldalle 1, Freiburg, Germany	30 (3x10) film coated tablets in a blister (polyamide/aluminum/PVC), supplied in a carton box		YES	YES		YES		YES	
Caduet 5 mg/10 mg tablets	film coated tablets	Pfizer GmbH Arzneimittelwerk	31 (3x10) film coated tablets in a blister		YES	YES		YES		YES	

		Gödecke, Mooswaldalle 1, Freiburg, Germany	(polyamide/aluminum/PVC), supplied in a carton box								
Caffetin Cold	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a PVC/TE/PVdc-Al blister, supplied in a box		YES		YES				YES
Caffetin tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	12 (2x6) tablets in Al/PE strip, supplied in a box		YES		YES				YES
"Droga" herbal laxative	herbal laxative tea	Droga Kolinska d.d., Ljubljana, Republic of Slovenia	1.8 g of herbal tea in a filter bag wrapped in paper envelope, 20 filter bags in a box		YES						YES
Calcium Sandoz 10 % injection	solution for injection for intramuscular and intravenous use	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	10 mL of solution in a glass ampoule, 5 ampoules in a carton box		YES	YES					
Calciumvita C effervescent tablets	effervescent tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 effervescent tablets wrapped in an Al-foil in a vial, supplied in a box		YES		YES				YES
Calgel gum gel	gum gel	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	10 g of gel in aluminum tube, supplied in a box		YES		YES				YES
Calixta 15 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Calixta 30 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Calixta 45 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
CAMPTO 100 mg/5 mL	concentrate for preparation of solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	Amber glass bottle containing 5 mL of solution, supplied in a box		YES	YES					
CAMPTO 40 mg/2 mL	concentrate for preparation of solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	Amber glass bottle containing 2 mL of solution, supplied in a box		YES	YES					
CANCIDAS 50 mg powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	10-mL glass bottle with powder, supplied in a box		YES	YES			YES		
CANCIDAS 70 mg powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	10-mL glass bottle with powder supplied ina box		YES	YES			YES		
Canesten 1 vaginal tablet 0.5 g	vaginal tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	One vaginal tablet in a PA/Al/PVC/Al blister pack and one applicator, supplied in a box		YES	YES					
Canesten 1 vaginal tablet 0.5 g/Canesten cream	vaginal tablets and cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	One vaginal tablet in a PA/Al/PVC/Al blister pack, 20 g of cream in an aluminum tube and applicator, supplied in a box		YES	YES					
Canesten 3 vaginal cream	vaginal cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 grams of cream and 3 applicators, supplied in a box		YES	YES					

Canesten 3 vaginal tablets 0.2 g	vaginal tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	3 (1x3) vaginal tablets in a blister (PA/Al/PVC/Al) and one applicator, supplied in a box		YES	YES					
Canesten 3 vaginal tablets 0.2 g / Canesten cream	vaginal tablet and cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	3 vaginal tablets in a blister (PA/Al/PVC/Al), 20 g cream in aluminum tube and an applicator, supplied in a box		YES	YES					
Canesten cream	cream	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 grams of cream in an aluminum tube, supplied in a box		YES	YES					
Canesten solution	solution (for external use)	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 mL of solution in a plastic bottle with dropper attachment, supplied in a box		YES	YES					
Canesten dermal powder	dermal powder	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 g of powder in a plastic bottle, supplied in a box		YES	YES					
Canesten dermatological spray, solution	dermatological spray, solution	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box		YES	YES					
Canifug 1% solution	dermal solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	30 mL of solution in an amber glass bottle with a spray applicator supplied in a box		YES		YES				
CAPD/DPCA 17 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box		YES		YES				
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 17 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 18 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe		YES		YES				

			cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box								
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 18 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 19 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box		YES		YES				
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2500 mL of solution and an empty collection bag, inserted in a protective plastic bag, supplied in a box		YES		YES			YES	
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with casing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 19 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2500 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter		YES		YES				

			connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")								
CAPD/DPCA 2 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box		YES		YES				
CAPD/DPCA 2 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag, supplied in a box		YES		YES				
CAPD/DPCA 2 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 3 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box"		YES		YES				
CAPD/DPCA 3 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")		YES		YES				
CAPD/DPCA 3 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag, supplied in a box		YES		YES				
CAPD/DPCA 4 sleep safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	One plastic bag with 5000 mL of solution, a feeding tube, a connector (with protective cap) to the dialysis machine ("sleep safe cycler") and drug administration attachment, two plastic bags with 5000 mL of solution, supplied in a box"		YES		YES				
CAPD/DPCA 4 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany	4 plastic bags with 2000 mL of solution, inserted in a protective plastic bag		YES		YES				
CAPD/DPCA 4 stay safe	solution for peritoneal dialysis	Fresenius Medical Care Deutschland GmbH, St. Wendel,	One plastic bag with 2000 mL of solution, an feeding tube, a disc connector with		YES		YES				

		Germany	housing and solution drain regulator, a catheter connector (with protective cap), a collecting bag with drain tube and attachments ("Injection Unit")								
Carbomed granules	granules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 g of granules in an amber glass bottle, supplied in a box	YES			YES				YES
Carbomed tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				YES
CARBOPLATIN EBEWE 150 mg/15 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	15 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a box		YES		YES				
CARBOPLATIN EBEWE 50 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a box		YES		YES				
Carboplatin Pliva 150	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	15 mL of concentrate in a glass bottle (amber orclear, with rubber stopper and aluminum cap with plastic lid), supplied in a box	YES			YES				
Carboplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of concentrate in a glass bottle (amber or colourless, with a rubber stopper and an Al cap with a plastic lid), supplied in a box	YES			YES				
Cardiopirin 100 mg gastric-resistant tablets	gastric-resistant tablets	Lannacher Heilmittel GmbH, Lannach, Austria	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Cardiopirin 50 mg gastric-resistant tablets	gastric-resistant tablets	Lannacher Heilmittel GmbH, Lannach, Austria	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
CARMOL drops	drops, solutiojn	Dr. A.&L. Schmidgall, Vienna, Austria	40 mL of solution in a glass bottle with a plastic dropper and a plastic stopper, supplied in a box		YES		YES				YES
Carvelol 12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
Carvelol 25 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
Carvelol 3.125 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in transparent PVC/PVDC/Al blister, supplied in a box		YES		YES				
Carvelol 6.25 mg tablets	tablets	Belupo, lijekovi i kozmetika, d.d., Koprivnica in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	28 tablets in a blister, supplied in a box	YES			YES				
CARVETREND tablets 12.5 mg	each tablet contains 12.5 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of	28 (2x14) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				

		Croatia									
CARVETREND tablets 25 mg	each tablet contains 25 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (1x28) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
CARVETREND tablets 3.125 mg	each tablet contains 3.125 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
CARVETREND tablets 6.25 mg	each tablet contains 6.25 mg of carvedilolum	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Casodex tablets 150 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany and AstraZeneca UK Limited, Macclesfield, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Casodex tablets 50 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Cheshire, Great Britain	28 (2x14) tablets in a blister (PVC/Alu foil), supplied in a carton box		YES	YES					
Cedax capsules 400 mg	capsules	SIFI S.p.A., Aci S. Antonio, Catania, Italy	5 capsules in a strip, supplied in a box		YES	YES					
Cedax powder for preparation of oral suspension 180 mg/5 mL	powder for preparation of oral suspension	SIFI S.p.A., Aci S. Antonio, Catania, Italy	15 grams of powder for preparation of 60 mL oral suspension		YES	YES					
Cefaleksin 500 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 (1x16) capsules in a PVC/Al blister, supplied in a box	YES			YES				
Cefaleksin 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Amber glass bottle with an aluminium screw cap	YES			YES				
Cefalexin Alkaloid 250 mg /5 mL powder for oral suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	Amber glass bottle with powder for preparation of 100 mL of suspension with an aluminium stopper and a plastic measuring soon, supplied in a box		YES		YES				
Cefalexin Alkaloid 500 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	16 (2x8) capsules in a PVC/Al blister, supplied in a carton box		YES		YES				
Cefalin capsules 500 mg	capsules	Pliva Krakow, Krakow, Poland	16 capsules (2x8) in a PVC/Al blister, supplied in a box		YES		YES				
Cefalin syrup 250 mg/5 mL	powder for preparation of oral suspension	Pliva Krakow, Krakow, Poland	Amber glass bottle of 100 mL with a plastic stopper and ROPP cap		YES		YES				
Cefalin tablets 1 g	film coated tablets	Pliva Krakow, Krakow, Poland	16 tablets (2x8) in a PVC/Al blister, supplied in a box		YES		YES				
Cefixim suspension	powder for preparation of oral suspension	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	53 g of powder for preparation of 100 mL of suspension in an amber glass bottle, supplied in a box		YES		YES				
Cefixim tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a box		YES		YES				
Cefotaksim injection 1 g	powder for preparation of injection solution	Farmal d.d., Ludbreg, Branitelja domovinskog	One glass vial with 1.0 g of powder, supplied in a box	YES			YES				

		rata 8, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Verovškova 57, Republic of Slovenia									
Cefotaksim injection 2 g	powder for preparation of solution for injection	Farmal d.d., Ludbreg, Branitelja domovinskog rata 8, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Verovškova 57, Republic of Slovenia	One glass vial with 2.0 g of powder, supplied in a box	YES			YES				
Cefzil 250 mg/5 mL powder for oral suspension	powder for preparation of oral suspension	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	30 g of powder for oral suspension in a 60 mL plastic (HDPE) bottle with a plastic measuring spoon, supplied in a box	YES			YES				
Cefzil 500 mg film-tablets	film coated tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	10 (2x5) film coated tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Celebrex capsules 200 mg	capsules	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE613YA, Great Britain	10 capsules in a blister, supplied in a box		YES	YES					
CellCept 250 mg capsules	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (10x10) capsules in a PVC/Al blister, supplied in a box		YES	YES		YES	YES		
CellCept 500 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 (5x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
Cerezyme 200 U powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with powder for infusion solution concentrate supplied, in a carton box		YES	YES			YES		
Cerezyme 400 U powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial with powder for infusion solution concentrate supplied, in a carton box		YES	YES			YES		
Cerson 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Certican 0.1 mg tablets for oral suspension	tablets for oral susupension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	
Certican 0.25 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	

Certican 0.25 mg tablets for oral suspension	tablets for oral susupension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	
Certican 0.5 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	
Certican 0.75 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	
Certican 1.0 mg tablets	tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	60 (6x10) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES				YES	
CETROTIDE 0.25 mg	powder and diluent for solution for injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Vial with powder and syringe with diluent, supplied in a box		YES	YES					
CETROTIDE 3 mg	powder and diluent for solution for injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Vial with powder and syringe with diluent, supplied in a box		YES	YES					
Champix tablets 0.5 mg/1 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	Eleven 0.5 mL tablets in a blister (Aclar/PVC//Al) + fourteen1-mg tablets in a blister (Aclar/PVC//Al), supplied in a carton box		YES	YES		YES	YES		
Champix tablets 1 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (Aclar/PVC//Al) in a carton wrapping		YES	YES		YES	YES		
Chirocaine 2.5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chirocaine 5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chirocaine 7.5 mg/mL solution for injection	solution for injection/concentrate for preparation of infusion solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	10 polypropylene ampoules Each containing 10 mL of solution for injection, supplied in a box		YES	YES					
Chloramphenicol Krka eye ointment	eye ointment	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 g of ointment in a tube, supplied in a box		YES		YES				
Cialis 10 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	4 tablets in a blister (PVC/PE/Aclar/Al), supplied in a carton box		YES	YES			YES		
Cialis 20 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	2 tablets in a blister (PVC/PE/Aclar/Al), supplied in a carton box		YES	YES			YES		
Cialis 20 mg tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	4 tablets in a blister (PVC/PE/Aclar/Al), supplied in a carton box		YES	YES			YES		
Ciflox 250 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Ciflox 500 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				

Ciflox 750 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Cilazil 2.5mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilazil 5mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilazil plus	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES					
Cilazil tablets 1 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film tablets in a blister, supplied in a box	YES			YES					
Cilest tablets	tablets	Cilag AG, Schaffhausen, Switzerland	21 (1x21) tablets in a blister (PVC/A1), supplied in a box		YES	YES						
CIMOLAN capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) capsules in a blister (PVC/Al), supplied in a box	YES			YES				YES	
CIMOLAN P syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic measuring spoon, supplied in a box	YES			YES				YES	
CIMOLAN syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic measuring spoon, supplied in a box	YES			YES				YES	
Cinarizin forte 75mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 50 tablets (blister, 5x10 tablets)		YES		YES					
CINNABSIN	tablets	Deutsche Homöopathie - Union, DHU - Arzneimittel GmbH & Co.KG, Karlsruhe, Germany	100 (5x20) tablets in PVC/Al blister, supplied in a box		YES						YES	
Cipralex 10 mg film-tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Cipralex 5 mg film-tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Cipralex, 10mg film-tablets	film tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	Box with 28 tablets (blister, 2x14 tbl.)		YES	YES						
Cipralex, 5mg film-tablets	film tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	Box with 28 tablets (blister, 2x14 tbl.)		YES	YES						
Ciprinol film coated tablets 250 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES					

Ciprinol film coated tablets 500 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES					
Ciprinol 100 mg/10 mL solution concentrate for infusion	solution concentrate for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 mL of infusion solution concentrate in a glass ampoule, 5 ampoules on a plastic tray, supplied in a box		YES		YES					
Ciprinol solution for infusion 100 mg/50 mL	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	50 mL of solution for infusion in a glass bottle (with a rubber stopper, aluminium ring and a plastic flip off stopper), supplied in a carton box		YES		YES					
Ciprinol 200 mg/100 mL solution for infusion	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 mL of infusion solution in a glass bottle (with rubber stopper and aluminum ring), supplied in a carton box		YES		YES					
Ciprinol solution for infusion 400 mg/200 mL	solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	200 mL of solution for infusion in a glass bottle (with rubber stopper, aluminum ring and plastic cap/flip off), supplied in a carton box		YES		YES					
Ciprobay 200 mg/100 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	100 mL of infusion solution in a plastic bottle, supplied in a box		YES	YES						
Ciprobay 250 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (1x10) film coted tablets in a PP/Al blister, supplied in a box		YES	YES						
Ciprobay 400 mg/200 mL solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	200 mL of solution for infusion in a glass bottle, supplied in a box		YES	YES						
Ciprobay 500 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	10 (1x10) film coted tablets in a PP/Al) blister, supplied in a box		YES	YES						
Cipromed tablets 250mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES					
Cipromed tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES					
Cipromed tablets 750mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES					
Cisplatin Pliva 10	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with 20 mL of concentrate (with a rubber stopper, and an aluminium cap with a plastic lid), 10 bottles in a box	YES			YES					
Cisplatin Pliva 10	solution concentrate for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 amber glass vials each containing 20 mL of solution, u supplied in a box	YES			YES					
Cisplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of solution in an amber glass bottle, supplied in a box	YES			YES					
Cisplatin Pliva 50	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with 100 mL of concentrate (with a rubber stopper, and aluminium cap with a plastic lid), supplied in a box	YES			YES					
Citalon 10 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES		YES			YES		

		3, Ismaning, Germany									
Citalon 20 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring 3, Ismaning, Germany	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES		YES			YES	
Citalon 40 mg film coated tablets	film coated tablets	Sandoz Pharmaceuticals GmbH, Carl-Zeiss-Ring 3, Ismaning, Germany	28 (2x14) tablets in a PVC/PVDC/Alu blister, supplied in a carton box		YES		YES			YES	
Citeral 100 mg/10 mL concentrate for solution for infusion	concentrate for infusion solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	5 ampoules with 10 mL of solution, supplied in a carton box		YES		YES				
Citeral 250 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Citeral 500 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of vaccine (5 mL of suspension)	YES							
Absorbed diphtheria and tetanus vaccine for children (above the age of 7) and adults, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 20 doses of vaccine (10 mL of suspension)	YES							
Absorbed diphtheria and tetanus vaccine, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							
Absorbed diphtheria and tetanus vaccine 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of vaccine (5 mL of suspension)	YES							
Absorbed diphtheria, tetanus and pertussis vaccine, 10 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of vaccine (5 mL of suspension)	YES							
Absorbed diphtheria, tetanus and pertussis vaccine, 1 dose	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of vaccine (0.5 mL of suspension)	YES							
Absorbed diphtheria, tetanus and pertussis vaccine, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 20 doses of vaccine (10 mL of suspension)	YES							
Meningococcal group A and group C polysaccharide vaccine, lyophilized, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Amber glass lyophilisation bottle, volume of 3.5 mL with 0.5 mL of lyophilisate for one dose of vaccine + ampoule with the volume of 2 mL with 0.5 mL of solvent for one dose of vaccine	YES							
Meningococcal A and C polysaccharide vaccine, lyophilized, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Amber glass lyophilisation bottle, volume of 5.5 mL with 0.5 mL of lyophilisate for ten doses of vaccine + ampoule with 5 mL of solvent for ten	YES							

			doses of vaccine								
Live, lyophilized morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle with 1 dose of lyophilised vaccine (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against measles and rubella, sterile water for injection	YES							
Live, lyophilzed morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against measles and rubella, sterile water for injection	YES							
Live, lyophilzed morbilli and rubella vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS, 5 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for vaccine against measles and rubella, sterile water for injection	YES							
Live, lyophilized vaccine against morbilli, rubella, parotitis, Edmonston-Zagreb, HDS, RA 27/3, HDS i L-Zagreb, PF, 1 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 1 dose of lyophilised vaccine (for 0.5 mL of reconstituted vaccine) and 1 ampoule with 0.5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES							
Live, lyophilzed morbilli, rubella and parotitis vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS; L-Zagreb, PF, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES							
Live, lyophilzed morbilli, rubella and parotitis vaccine, Edmonston-Zagreb, HDS; RA 27/3, HDS; L-Zagreb, PF, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 5 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for vaccine against measles, rubella and parotitis, sterile water for injection	YES							
Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with singe dose of lyophilized vaccine (for 0.5 mL of reconstituted vaccine) and one ampoule with 0.5 mL of diluent, sterile Water for Injection, supplied in a carton box	YES							
Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	50 glass bottles with 5 doses of lyophilised vaccine (for 2.5 mL of reconstituted vaccine), supplied in a carton box, and 50 ampoules with 2.5 mL of solvent, sterile water for injection, supplied in a carton box	YES							

Live, lyophilized morbilli vaccine, Edmonston-Zagreb, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	50 glass bottles with 10 doses of lyophilised vaccine (for 5 mL of reconstituted solvent), supplied in a carton box, and 50 ampoules with 5 mL of solvent, sterile water for injection, supplied in a carton box	YES							
Live, lyophilized parotitis vaccine, L-Zagreb, PF, 1 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with a glass bottle with 1 dose of lyophilised vaccine against parotitis (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against parotitis, sterile water for injection	YES							
Live, lyophilized parotitis vaccine, L-Zagreb, PF, 10 doza	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine against parotitis (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against parotitis, sterile water for injection	YES							
Live, lyophilized rubella vaccine RA 27/3, HDS, 1 dose	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 1 dose of lyophilised vaccine against rubella (for 0.5 mL of reconstituted vaccine) + 1 ampoule with 0.5 mL of solvent for vaccine against rubella, sterile water for injection	YES							
Live, lyophilized rubella vaccine, RA 27/3, HDS, 10 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 10 doses of lyophilised vaccine against rubella (for 5 mL of reconstituted vaccine) + 50 ampoules with 5 mL of solvent for vaccine against rubella, sterile water for injection	YES							
Live, lyophilized rubella vaccine, RA 27/3, HDS, 5 doses	lyophilisate and diluent for suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 glass bottles with 5 doses of lyophilised vaccine against rubella (for 2.5 mL of reconstituted vaccine) + 50 ampoules with 2.5 mL of solvent for vaccine against rubella, sterile water for injection	YES							
Anti-tetanus vaccine, absorbed, 1 dose	suspension for injections	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass ampoule containing 1 dose of tetanus vaccine (0.5 mL of suspension)	YES							
Anti-tetanus vaccine, absorbed, 1 dose	suspension for injections	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle containing 10 doses of tetanus vaccine (5 mL of suspension)	YES							
Absorbed tetanus vaccine, 20 doses	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 glass bottle with 20 doses of tetanus vaccine (5 mL of suspension)	YES							
Claccium Folinat Ebewe 100 mg/10 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 amber glass ampoules with 10 mL of solution, supplied in a box		YES		YES				
Claccium Folinat Ebewe 30 mg/3 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG,	5 amber glass ampoules with 3 mL of solution, supplied in		YES		YES				

		Mondseestrasse 11, Unterach, Austria	a box								
Claccium Folinat Ebewe 50 mg/5 mL	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 amber glass ampoules with 5 mL of solution, supplied in a box		YES		YES				
Clarexid tablets 250 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 tablets in PVC/Al blister, supplied in a box	YES			YES				
Clarexid tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 tablets in PVC/Al blister, supplied in a box	YES			YES				
Clarinase 5 mg/120 mg prolonged-release tablets	prolonged release tablets	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	10 tablets in a PVC/PE/PCTFE//Al or PVC/PCTFE//Al blister, supplied in a box		YES	YES					YES
Claritine syrup 1mg/mL	syrup	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	120 mL of solution in an amber glass bottle, supplied in a box		YES	YES					
Claritine tablets 10 mg	tablets	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	10 (1x10) tablets in a PVC/PVDC//Al OR PVC/PCTFE//AL blister, supplied in a box		YES	YES					YES
Clarosip 125 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES				YES	
Clarosip 187.5 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES				YES	
Clarosip 250 mg	granules for oral suspension	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	White polypropylene tube with granules for oral suspension, closed with propylene cap on the top and regulator (porous structure) for the control of suspension flow at the bottom, in protective aluminum bag		YES	YES				YES	
Clexane 10.000 IU anti-Xa/1.0 mL injections	solution for injection (for s.c. and i.v. use in haemodyalisis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 1.0 mL of solution) in a blister, supplied in a box		YES	YES					
Clexane 2000 IU anti-xa/0.2 mL injection	solution for injection (for s.c. and i.v. use in haemodyalisis)	Aventis Intercontinental, Maisons Alfort, France; Aventis Pharma Le Trait, Le Trait, France	2 glass syringes with needles (each containing 0.2 mL of solution) in a blister, supplied in a box		YES	YES					
Clexane 4000 IU anti-xa/0.4 mL injection	solution for injection (for s.c. and i.v. use in haemodyalisis)	Aventis Intercontinental, Maisons Alfort, France; Aventis Pharma Le Trait, Le Trait, France	2 glass syringes with needles (each containing 0.4 mL of solution) in a blister, supplied in a box		YES	YES					

Clexane 6000 IU anti-Xa/0.6 mL injection	solution for injection (for s.c. and i.v. use in haemodyalisis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 0.6 mL of solution) in a blister, supplied in a box		YES	YES					
Clexane 8000 IU anti-Xa/0.8 mL injection	solution for injection (for s.c. and i.v. use in haemodyalisis)	Aventis Intercontinental, France i Aventis Pharma Le Trait, France	2 glass syringes with needles (each containing 0.8 mL of solution) in a blister, supplied in a box		YES	YES					
Climen	coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	Coated tablets		YES	YES					
Clivarin 1432	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.25 mLL of solution, in a protective container, supplied in a carton box		YES	YES					
Clivarin 1750	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (5x2) syringes with needles each containing 0.25 mL of solution in a blister, supplied in a box		YES	YES					
Clivarin 3436	solution for subcutaneous injection	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.6 mLL of solution, in a protective container, supplied in a carton box		YES	YES					
Clivarin 5153	solution for injection (for s.c. use)	Abbott GmbH & Co. KG, Ludwigshafen, Germany	10 (2x5) glass syringes (with needle) each containing 0.9 mLL of solution, in a protective container, supplied in a box		YES	YES					
Clopixol acuphase 50 mg/mL solution for injection	solution for intramuscular injection	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	5 ampoules each with 1 mL of solution, supplied in a box		YES	YES					
Clopixol depot 200 mg/mL solution for injection	solution for injection for intramuscular use	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	10 ampoules each containing 1 mL of solution, supplied in a box		YES	YES					
Clopixol 10 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 tablets in a polypropylene container with a specially designed stopper with a leaflet		YES	YES					
Clopixol 25 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 tablets in a polypropylene container with a specially designed stopper with a leaflet		YES	YES					
Coaprovel 150 mg/12.5 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES	YES			YES		
Coaprovel 300 mg/12.5 mg	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES	YES			YES		
Coaxil	coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (1x30) tablets in a PVC/Alu blister , supplied in a carton box		YES	YES					
Coaxil	coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (2x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Codeini phosphatis Alkaloid	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12,	10 (1x10) tablets in a Al/PE//PE/Al strip, supplied in a box		YES		YES				

		Skopje, FYROM										
CO-Diovan film-tablets 160/12.5 mg	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES		
CO-Diovan film-tablets 160/25 mg	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES		
CO-Diovan film-tablets 80/12.5 mg	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES		
Coldrex HotRem Blackcurrant	powder for preparation of oral solution	SmithKline Beecham S.A., Madrid, Spain	5 bags with 5 g of powder, supplied in a box		YES	YES					YES	
Coldrex Junior	film coated tablets	Famar S.A., Atena, Greece	16 (2x8) tablets in a blister, supplied in a box		YES	YES					YES	
COLDREX JUNIOR syrup	oral solution	Wrafton Laboratories Ltd., Wrafton, Braunton, North Devon, Great Britain	160 mL of oral solution in an amber glass bottle with a platic (PP) temper-proof closure and 20-ml measuring glass, supplied in a box		YES	YES					YES	
Coldrex MaxGrip Lemon	powder for preparation of oral solution	SmithKline Beecham S.A., Madrid, Spain	5 bags with 6.4 g of powder, supplied in a box		YES	YES					YES	
Coldrex tablets	tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 tablets in a blister, supplied in a box		YES	YES					YES	
Combivir tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain i GlxoSmithKline Pharmaceuticals S.A., Poznan, Poland	60 (6x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES						
COMTAN 200 mg film-tablets	film coated tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	30 film coated tablets in an amber glass bottle with a plastic (HDPP) stopper, supplied in a box		YES	YES						
Concerta 18 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES		YES		
Concerta 36 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES		YES		
Concerta 54 mg	prolonged-release tablets	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES		YES		
Concor 10	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Concor 5	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	30 (3x10) tablets in a blister, supplied in a box		YES	YES						
Concor Cor 1.25 mg	film tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	Box with 20 tablets (blister, 2x10 tbl.)		YES	YES						
Concor Cor 2.5 mg	film tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	Box with 30 tablets (blister, 3x10 tbl.)		YES	YES						

Contractubex gel	gel	Merz Pharma GmbH & Co KGaA, Frankfurt am Main, Germany	10 g of gel in aluminum tube, supplied in a box		YES		YES				YES
Contral	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Controloc 20 mg tablets	gastric-resistant tablets	Altana Pharma Oranienburg GmBH, Oranienburg, Germany	28 (2X14) gastric-resistant tablets in a blister (OPA/Al/PE//Al), supplied in a box		YES	YES					
Controloc 40 mg tablets	gastric-resistant tablets	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	14 (1x14) gastric-resistant tablets in a blister (OPA/Al/PE//Al), supplied in a box		YES	YES					
Controloc intravenous	powder for solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	One glasss vial with lyophilisate, supplied in a box		YES	YES					
Copaxone 20 mg, powder and diluent for solution for injection	powder and diluent for solution for injection	Teva Pharmaceutical Industries Ltd., Kfar Saba, Izrael	28 (4x7) amber glass bottles with powder and 28 (4x7) ampoules with diluent for solution for injection, supplied in a box		YES	YES		YES		YES	
Copaxone 20 mg/mL solution for injection	solution for injection, pre-filled syringe	Teva Pharmaceuticals Europe B.V., Mijadrecht, The Nederlands	Pre-filled syringe with 1 mL of solution for injection with a needle, in a blister, 28 (4x7) pre-filled syringes supplied in a box		YES	YES					
Copegus 200 mg	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	42 film coated tablets in a polyethylene bag, supplied in a box		YES	YES		YES		YES	
Cordarone 150 mg/3 mL injection	solution for injection	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	6 ampoules each with 3 mL of solution for injection, supplied in a box		YES	YES					
Cordarone 200 mg tablets	film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	30 (3x10) tablets in a blister (PVC/Alu-foil) supplied in a box		YES	YES					
Cordipin XL tablets 40 mg	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10 tablets in PVC/PVD/Al blister, supplied in a box		YES		YES				
Cordipin XL tablets 40 mg	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a PVC/PVD/Al blister , supplied in a box		YES		YES				
Corlentor 5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiebiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszava, Poland	28 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		
Corlentor 7.5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey	28 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		

		Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiebiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszava, Poland									
CORTEF tablets 10 mg	tablets	Pantheon YM Inc., Toronto, Canada i Pfizer Manufacturing Belgium, Puurs, Belgium	100 tablets in an amber glass bottle, supplied in a box		YES	YES					
Coryol tablets 12.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Coryol tablets 25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Coryol tablets 3.125 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Coryol tablets 6.25 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Cosopt eye drops	eye drops, solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	5 mL of solution in a plastic container OCUMETER PLUS, supplied in a box		YES	YES					
Cozaar 100 mg filmom oblo□ete tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Cozaar 50 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Crestor 10 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES		YES	
Crestor 20 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	29 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES		YES	
Crestor 40 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (4x7) film coated tablets of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES		YES	
Crestor 5 mg	film coated tablets	AstraZeneca GmbH, Plankstadt, Germany; AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	30 (2x14) film coated tablets in a blister of aluminum laminate and aluminum foil, supplied in a carton box		YES	YES		YES		YES	
CRINONE 8% vaginal gel	vaginal gel	M.Y. Healthcare Packaging Limited,	1.45 g of gel in an applicator for single use, inserted in a		YES	YES					

		Bedfordshire, Great Britain	protective bag (paper/Al/PE), 15 bags in a box								
CRIXIVAN 100 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	180 capsules in a polyethylene (HDPE) container		YES	YES			YES		
Crixivan 200 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	360 capsules in a polyethylene (HDPE) container		YES	YES			YES		
CRIXIVAN 333 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	135 capsules in a polyethylene (HDPE) container		YES	YES			YES		
Crixivan 400 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	180 capsules in a polyethylene (HDPE) container		YES	YES			YES		
Crystacillin	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 bottles with powder, supplied in a box	YES			YES				
Cymbalta 30 mg hard gastric-resistant capsules	gastric-resistant capsules, hard	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) capsules in a blister (PVC/PE/PCTFE//Al), supplied in a box		YES	YES			YES		
Cymbalta 60 mg hard gastric-resistant capsules	gastric-resistant capsules, hard	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) capsules in a blister (PVC/PE/PCTFE//Al), supplied in a box		YES	YES			YES		
Cymevene powder for solution for infusion	powder for solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10-mL glass vial with powder (for multiple use) supplied in a box		YES	YES					
Dabroston 10 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
DACARBAZINE PLIVA 100	lyophilisate for preparation of solution for injection or infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Lyophilisate in an amber glass bottle (with a rubber stopper and an aluminium cap with a plastic lid), 10 bottles in a box	YES			YES				
DACARBAZINE PLIVA 200	lyophilisate for preparation of solution for injection or infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Lyophilisate in an amber glass bottle (with a rubber stopper and an aluminium cap with a plastic lid), 10 bottles in a box	YES			YES				
Daktarin cream	cream	Krka d.d., Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 g of cream in a tube, supplied in a box		YES		YES				
Daktarin oral gel	oral gel	Krka d.d., Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	40 g of gel in a tube with a measuring spoon, supplied in a box		YES		YES				
DALERON C granules for oral solution	granules for oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES		YES				YES

DALERON C JUNIOR granules for oral solution	granules for oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES		YES				YES
Dalsy syrup	syrup	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Brown polyethylene bottle with 100 mL of syrup, supplied in a box		YES	YES					
Dalsy syrup	syrup	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Brown polyethylene bottle with 200 mL of syrup, supplied in a box		YES	YES					
Danoptin 100 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES				
Danoptin 25 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES				
Danoptin tablets 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	31 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES				
Danoptin tablets for oral suspension 5 mg	tablets for oral solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/Aclar/Al blister, supplied in a box	YES			YES				
Danoval capsules 100 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 capsules in a brown plastic bottle with aluminum cap, supplied in a carton box		YES		YES				
Darob	tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) tablets in a blister, supplied in a box		YES	YES					
Darob mite	tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) tablets in a blister, supplied in a box		YES	YES					
Dartelin 400 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
DaTscan 74 MBq/mL solution for injection	solution for injection	Amersham Health BV, Den Dolech 2, Eindhoven, NL 5612 AZ, the Netherlands	10-mL glass vial with 5.0 mL of solution, supplied in a box		YES	YES			YES		
DaTscan 74 MBq/mL solution for injection	solution for injection	Amersham Health BV, Den Dolech 2, Eindhoven, NL 5612 AZ, the Netherlands	10-mL glass vial with 2.5 mL of solution, supplied in a box		YES	YES			YES		
Decapeptyl 0.1 mg	solution for subcutaneous injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	7 syringes each with 1 mL of solution for injection in a blister, supplied in a box		YES	YES					
Decapeptyl CR	micro-capsules for preparation of suspension for subcutaneous or intramuscular injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	One syringe with 172 mg microcapsules, one syringe with 1 mL of suspending agent, one adapter and one needle, supplied in a box		YES	YES					
Decortin 20	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				

Decortin 5	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	24 (2x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Deep Freeze Cold gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	35 g of gel in an alumininum tube with a plastic (HDPE) stopper, supplied in a box		YES		YES				YES
Deep Freeze spray	spray, solution	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	200 mL (135 g) of spray solution in a metal container (with PE tube and PP atmizer) with plastic (PP) cap		YES		YES				YES
Deep heat rub cream	cream	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	15 g of cream in an aluminum tube with plastic (HDPE) cap, supplied in a box		YES		YES				YES
Deep Heat spray	spray, solution	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	150 mL of sprey solution in a metal container (with PE tube and PP nebulizer) with plastic (HDPE) cap		YES		YES				YES
Deep relief gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	100 grams of gel in an aluminum tube, supplied in a box		YES		YES				YES
Dentinox N	drops, oromucosal solution	Dentinox Gesellschaft für pharmazeutische Präparate Lenk & Schuppan, Berlin, Germany	10 g of solution in an amber glass bottle with plastic dropper and cap, supplied in a box		YES						YES
Depakine Chrono 300 mg	film coated modified-release tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	100 tablets (two plastic containers with 50 tablets each) supplied in a box		YES	YES					
Depakine Chrono 500 mg	modified release film coated tablets	Sanofi Winthrop Industrie, 1 rue de la Vierge, 33440 Ambares, France	30 tablets in a plastic container, supplied in a box		YES	YES					
DEPAKINE CHRONOSPHERE 100 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES					
DEPAKINE CHRONOSPHERE 1000 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES					
DEPAKINE CHRONOSPHERE 250 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES					
DEPAKINE CHRONOSPHERE 500 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES					
DEPAKINE CHRONOSPHERE 750 mg	prolonged-release granules	Sanofi Winthrop Industrie, AMILLY, France	30 bags with granules, supplied in a box		YES	YES					
Deprozel tablets 20 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES				

Deprozel tablets 30 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES				
Dercome Clear	suspension for topical application to the skin	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of suspension in a plastic tube, supplied in a box		YES		YES				
Detralex	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (2x15) film coated tablets in a PVC/Al blister, supplied in a box		YES	YES					
Detrunorm coated tablets 15 mg	coated tablets	Apogepha Arzneimittel GmbH, Germany	30 (3x10) coated tablets in a PVC/A1 blister, supplied in a box		YES	YES					
Dexamethason Krka solution for injection	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	25 ampoules (5x5) each containing 1 mL of solution in a blister, supplied in a box		YES		YES				
Dexamethason Krka tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 tablets in a blister, supplied in a box		YES		YES				
Diane-35 sugar-coated tablets	sugar-coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	63 (3x21) tablets in a PVC/Al blister, supplied in a box		YES	YES					
Dianeal PD1 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES		YES				
Dianeal PD1 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES		YES				
Dianeal PD1 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution and 5x1 empty bags (for draining of liquid), in a protective plastic bag; supplied in a carton box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 1.36% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES		YES				

Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 2.27% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4x1 plastic bags with 2500 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	2x1 plastic bags containing 5000 mL of solution in a protective plastic bag, supplied in a box		YES		YES				
Dianeal PD4 solution for peritoneal dialysis with 3.86% glucose and electrolytes	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5x1 plastic bags with 2000 mL of solution with attachments and one empty bag (for draining of liquid), in a protective plastic bag; supplied in a box		YES		YES				
Diaprel	tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (3x20) tablets in a blister, supplied in a box		YES	YES					
Diaprel MR	modified release tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	60 (2x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Diazepam Alkaloid 10 mg/2 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 2 mL of solution, supplied in a box		YES		YES				
Diazepam Alkaloid 2 mg coated tablets	coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 coated tablets in a 15 mL amber glass bottle, supplied in a box		YES		YES				
Diazepam Alkaloid 5 mg coated tablets	coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 coated tablets in a 15 mL amber glass bottle, supplied in a box		YES		YES				
Diazepam Desitin 10 mg rectal solution	rectal solution	Desitin Arzneimittel GmbH, Hamburg, Germany	5 (5x1) plastic containers each with 2.5 mL of solution (with applicator for rectal administration) in a protective bag, supplied in a box		YES		YES				

Diazepam Desitin 5 mg rectal solution	rectal solution	Desitin Arzneimittel GmbH, Hamburg, Germany	5 (5x1) plastic containers each with 2.5 mL of solution (with applicator for rectal administration) in a protective bag, supplied in a box		YES		YES				
Diazepam Jadran 10 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Diazepam Jadran 2 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Diazepam Jadran 5 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 30 (3x10) tablets in a blister	YES			YES				
Diclo Duo capsules 75 mg	modified release capsules, hard	TemmLer Werke GmbH, München, Germany	20 (2x10) capsules in a blister (PVC/PVDC/Al), supplied in a box		YES		YES				
Diclo Duo spray 4%	dermatological spray, solution	Pharbil Waltrop GmbH, Im Wirrigen 25, D-45731 Waltrop, Germany	15-mL amber glass bottle containing 12.5 g solution, with metering pump/ spraying attachment and protective cap, supplied in a carton box		YES		YES	YES		YES	YES
DICLORAPID 75 mg	gastric-resistant capsules, hard	Astellas Pharma GmbH, München, Germany	10 (1x10) capsules in a PVC/PVdC/Al blister, supplied in a box		YES		YES	YES		YES	
Diclorapid 75 mg	gastric-resistant capsules, hard	Astellas Pharma GmbH, München, Germany	20 (2x10) capsules in a PVC/PVDC/Al blister, supplied in a box		YES		YES	YES		YES	
Dicynone 250 mg/2 mL injection	solution for injection for intramuscular use and intravenus infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 (2x5) ampoules each containing 2 mL of solution in a blister, supplied in a box		YES		YES				
DIFETOIN	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 (10x10) tablets in OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
DIFLUCAN 100 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	7 (1x7) capsules in (PVC/Al) blister, supplied in a box		YES	YES					
DIFLUCAN 150 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) capsule in a blister (PVC/Al) supplied in a box		YES	YES					
DIFLUCAN 50 mg capsules	capsules	Pfizer PGM, Poce-sur-Cisse, France	7 (1x7) capsules in (PVC/Al) blister, supplied in a box		YES	YES					
DIFLUCAN solution for infusion	solution for infusion	Pfizer PGM, Poce-sur-Cisse, France	100 mL of solution in a glass bottle for infusion, supplied in a box		YES	YES					
DIFLUCAN powder for suspension 50 mg/7 mL	powder for oral suspension	Pfizer PGM, Poce-sur-Cisse, France	Plastic (HDPE) bottle of 60 mL (with a plastic, temper-evident stopper) with powder for preparation of 35 mL of suspension and a plastic measuring spoon (of 5 mL), supplied in a box		YES	YES					
Diphtheria antitoxin (equine) 10000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 bottle containing 10000 IU of preparation	YES							
Diphtheria antitoxin (equine) 10000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 bottles with 10000 IU of preparation	YES							
Diglical tablets 80 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49,	60 (6x10) tablets in a blister, supplied in a box	YES			YES				

		Zagreb, Republic of Croatia									
Dihalar tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	30 (2x15) tablets in a blister, supplied in a box		YES		YES				
Diklofenak retard 100 mg tablets	prolonged-release tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Diklonat P gel	gel	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 g of gel in an aluminium tube, supplied in a box	YES			YES				YES
Diltiazem Pliva 60 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a carton box	YES			YES				
Diltiazem Pliva 90 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a carton box	YES			YES				
Dimidril tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	32 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Dinamico tablets 100 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES				
Dinamico tablets 25 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES				
Dinamico tablets 50 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One (1x1) tablet in a blister supplied in a box	YES			YES				
Diovan 160 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES	
Diovan 320 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES		YES		YES	
Diovan 40 mg film-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES	
Diovan 80 mg flim-tablets	film coated tablets	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	28 (2x14) tablets in a blister, supplied in a box		YES	YES		YES		YES	
Diprogenta cream	cream	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Diprogenta ointment	ointment	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	Aluminium tube with 15 g of ointment, supplied in a box		YES	YES					
Diprosalic losion	lotion	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium;	30 mL of lotion in a plastic bottle, supplied in a box		YES	YES					

		Schering-Plough France, Herouville-Saint-Clair, France									
Diprosalic ointment	ointment	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Disoprivan 1% propofolum	emulsion for infusion	Fresenius Kabi AB, Stockholm, Sweden and AstraZeneca SpA, Caponago, Italy for AstraZeneca UK Ltd., Macclesfield, Cheshire, Great Britain	Box with 5 ampoules containing 20 mL of emulsion		YES		YES				
Disopyramide JADRAN	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 capsules in an amber glass bottle, supplied in a box	YES			YES				
Diuver 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Diuver 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Dobutamin Admeda 250	solution for infusion	Wuelfing Pharma GmbH, Gronau, Germany	50 mL of solution for infusion in a glass ampoule, 1 ampoule in a box		YES		YES				
DOKSICIKLIN 100 mg capsules	capsules, hard	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	6 capsules in a white plastic (PP) bottle of 50 mL bag with a temper-evident (PP/PE) stopper, supplied in a box	YES			YES				
Dolokain gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of gel in an aluminum tube with plastic cap (in a protective bag), supplied in a carton box	YES			YES				
Dopamin Admeda 200	concentrate of solution for infusion	Wuelfing Pharma GmbH	5 glass ampoules each with 10.3 mL of solution for infusion concentrate, supplied in a box		YES		YES				
Dopamin Admeda 50	concentrate of solution for infusion	Wuelfing Pharma GmbH	5 glass ampoules each with 5.3 mL of solution for infusion concentrate, supplied in a box		YES		YES				
Dormicum 15 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) tablets in a blister, supplied in a box		YES	YES					
Dormicum 15 mg/3 mL injection	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 3 mL of solution, supplied in a box		YES	YES					
Dormicum 5 mg/1 mL injection	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 ampoules each containing 1 mL of solution, supplied in a box		YES	YES					
Dormicum 7.5 mg tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) tablets in a blister, supplied in a box		YES	YES					

Dotarem 0.5 mmol/mL	solution for injection	Guerbet, Roissy CdG Cedex, France	20 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES				YES	
Dotarem 0.5 mmol/mL	solution for injection	Guerbet, Roissy CdG Cedex, France	15 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES				YES	
Doxazin 2 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Doxazin 4 mg	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
DOXORUBICIN EBEWE 10 mg/ 5 mg	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a box		YES		YES				
DOXORUBICIN EBEWE 50 mg/ 25 mg	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a box		YES		YES				
Doxorubicin Pliva injection 10 mg	powder for solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	5-mL bottle containing 10 mg of powder, with bromobutyl stopper and aluminum cap and ring, supplied in a box		YES		YES				
Doxorubicin Pliva injection 50 mg	powder for solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	25-mL bottle containing 50 mg of powder, with bromobutyl stopper and aluminum cap and ring, supplied in a box		YES		YES				
Doxorubicin-Teva 2 mg/mL	solution for injection	Pharmachemie B.V., Haarlem, the Netherlands	Colourless glass bottle (glass type I) with a rubber stopper (chlorobutyl) coated with fluoropolymer film, aluminium ring and polypropylene lid containing 5 mL of solution, supplied in a box		YES		YES	YES		YES	
Doxorubicin-Teva 2 mg/mL	solution for injection	Pharmachemie B.V., Haarlem, the Netherlands	Colourless glass bottle (glass type I) with a rubber stopper (chlorobutyl) coated with fluoropolymer film, aluminium ring and polypropylene lid containing 25 mL of solution, supplied in a box		YES		YES	YES		YES	
Dr. Theiss Mucoplant eucalyptus balm against cold	ointment	Dr. Theiss Naturwaren GmbH, Homburg, Germany	50 g of ointment in an amber glass bottle with a wide neck, supplied in a box		YES						YES
Dramina	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 tablets in a A/PVC blister, supplied in a carton box	YES			YES				YES
Driptane	tablets	Laboratories Fournier S.A., Fontaine les Dijon, France	60 (2x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Dulcolax suppositories	suppositories	Boehringer Ingelheim Italia S.p.A., Firenca, Italy	6 suppositories in aluminium foil, supplied in a box		YES		YES				YES
Dulcolax coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	30 (3x10) coated tablets in a PVC/PVDC-Al blister, supplied in a box		YES		YES				YES
Duodopa intestinal gel	intestinal gel	Solvay Pharmaceuticals GmbH, Justus-von-Liebig-Strasse 33, Neustadt, Germany	100 mL of intestinal gel in a PVC bag with a plastic tube and pump attachement, inside a hard plastic cassette, carton with 7		YES	YES		YES		YES	

			casettes								
Duphaston	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	42 (3x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Duphaston	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	20 (1x20) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
DURACEF 250 mg capsules	capsules	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	12 capsules (2x6) in PVC/PVDC//Al blister, supplied in a box	YES			YES				
DURACEF 500 mg capsules	capsules	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	12 capsules (2x6) in PVC/PVDC//Al blister, supplied in a box	YES			YES				
Duracef powder for oral suspension 250 mg/5 mL	powder for preparation of oral suspension	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	35 g of powder for oral suspension in a 60 mL plastic (HDPE) bottle with a plastic measuring spoon, supplied in a box	YES			YES				
Duracef 1 g dispersible tablets	dispersible tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	10 (2x5) tablets in blisters, supplied in a box	YES			YES				
Durogesic transdermal patch 100 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					
Durogesic transdermal patch 12 µg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					
Durogesic transdermal patch 12 microg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					
Durogesic transdermal patch 25 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					
Durogesic transdermal patch 50 ug/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					
Durogesic transdermal patch 75 µg/h	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 transdermal patches (individually packed in a protective bag), supplied in a box		YES	YES					

Nitric oxidul	medical gas	SOL SpA, Cremona, Italy i SOL SpA, Marcianise, Italy	10 or 40 l of nitrogen oxidule in stainless steel bottles under pressure of 50 bars		YES		YES				
Nitric oxidul	medical gas	Messer Croatia Plin d.o.o., Zaprešić, Industrijska 1, Republic of Croatia	11 or 40 l of nitrogen oxidule in stainless steel bottles under pressure of 50 bars	YES			YES				
Dysport	lyophilisate for solution for injection	IPSEN BIOPHARM LIMITED, Wrexham, Great Britain	2 glass bottles of lyophilisate for preparation of injection, supplied in a box		YES						
Dysport	lyophilisate for preparation of solution for injections	IPSEN BIOPHARM LIMITED, Wrexham, Great Britain	Glass vial with lyophilisate for preparation of injection, supplied in a box		YES						
Ebixa 10 mg tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Ebixa 10 mg/g oral drops	solution for oral drops	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	50 g of solution in an amber glass bottle with a dropper and a plastic stopper, supplied in a box		YES	YES					
Ebrantil 25 iv.	solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	5 ampoules each with 5 mL of solution, supplied in a box		YES	YES					
Ebrantil 30 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES					
Ebrantil 50 iv.	solution for injection	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	5 ampoules each with 10 mL of solution, supplied in a box		YES	YES					
Ebrantil 60 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES					
Ebrantil 90 capsules	prolonged release capsules	Altana Pharma Oranienburg GmbH, Oranienburg, Germany	50 prolonged release capsules in a plastic bottle with a desiccant, supplied in a box		YES	YES					
Edemid forte 500 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Edemid forte 250mg/10mL injection	solution for infusion (concentrate)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 ampoules with 10 mL of solution in a plastic container, supplied in a box		YES		YES				
Edicin 0.5 g injection for intravenous infusion	powder for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One glass vial with powder for injection, supplied in a box		YES		YES				
Edicin 1.0 g injection for intravenous infusion	powder for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	One glass vial with powder for injection, supplied in a box		YES		YES				
EDRONAX tablets 4 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	60 (3x20) tablets in a blister, supplied in a box		YES	YES					
Efectin ER capsules 150 mg	prolonged release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 28 capsules (blister, 2x14 capsules)		YES	YES					

Efectin ER capsules 37.5 mg	prolonged-release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 30 capsules (blister, 3x10 capsules)		YES	YES					
Efectin ER capsules 75 mg	prolonged release capsules	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	Box with 28 capsules (blister, 2x14 capsules)		YES	YES					
Efferalgan 1 g effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	8 effervescent tablets in a plastic tube, supplied in a box		YES		YES				YES
Efferalgan 150 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES				YES
Efferalgan 300 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES				YES
EFFERALGAN 500 mg, effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France i Bristol-Myers Squibb, 979 Avenue des Pyrénés, Le Passage, France	16 (4x4) effervescent tablets in a strip (Al/PE), supplied in a box		YES		YES				YES
Efferalgan 80 mg suppositories	suppositories	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES				YES
Efferalgan solution for children	solution for oral use	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	90 mL of solution in a brown plastic bottle with a temper-evident stopper, supplied in a box		YES		YES				YES
EFFERALGAN plus vitamin C, effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube, supplied in a box		YES		YES				YES
Efflumidex Liquifilm eye drops	eye drops, suspension	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of suspension in a plastic bottle with a dropper, supplied in a box		YES	YES					
EFOX tablets 250 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 (1x10) tablets in a Al/Al blister, supplied in a box	YES			YES				
Efox tablets 500 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 (1x10) tablets in a Al/Al blister, supplied in a box	YES			YES				
Eglonyl 100 mg/2 mL solution for injection	solution for injection	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	30 colourless glass ampoules each containing 2 mL of solution, supplied in a box		YES		YES				
Eglonyl 25 mg/5 mL oral solution	oral solution	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	120 mL of solution in an amber glass botlle with dispenser, supplied in a box		YES		YES				

Eglonyl 50 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 capsules in an amber glass bottle, supplied in a box		YES		YES				
Eglonyl forte tablets	tablets	Alkaloid AD-Skopje, Skopje, FYROM in cooperation with Sanofi-Aventis, France	12 tablets in an amber glass bottle, supplied in a box		YES		YES				
Elaprase 2 mg/mL concentrate for infusion solution	concentrate for infusion solution	Shire Human Genetic Therapies AB, Danderyd, Sweden	5-mL glass bottle with 3-mL of concentrate supplied in a box		YES	YES		YES	YES		
Elaprase 2 mg/mL concentrate for infusion solution	concentrate for solution for infusion	Shire Human Genetic Therapies AB, Danderyd, Sweden	10 5-mL glass bottles with 3 mL of concentrate, supplied in a box		YES	YES		YES	YES		
Elaprase 2 mg/mL concentrate for solution for infusion	concentrate for solution for infusion	Shire Human Genetic Therapies AB, Danderyd, Sweden	4 glass bottles (à 5 mL) with 3 mL of concentrate, supplied in a box		YES	YES		YES	YES		
ELEVIT PRONATAL film coated tablets	film coated tablets	Rottendorf Pharma GmbH, Enningerloh, Germany	30 (3x10) film coated tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES		YES				YES
Elidel 1 % cream 15 g	cream	Novartis Pharma Produktions GmbH, Öflinger Strasse 44, Wehr, Germany	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Elocom cream	cream	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Elocom lotion	lotion	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	20 mL of lotion in a plastic bottle with dropper attachment, supplied in a box		YES	YES					
Elocom ointment	ointment	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Emadine eye drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Bottle-dropper with 5 mL of sterile solution, supplied in a box		YES	YES					
Emend 125 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	One (1x1) capsule in a blister back (Al/Al) supplied in a carton box		YES	YES		YES	YES		
Emend 125 mg hard capsules / Emend 80 mg hard capsules	hard capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	One 125-mg capsule in a blister (Al/Al) and two 80-mg capsules in a blister (A/Al), supplied in a box		YES	YES		YES	YES		
Emend 40 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	One capsule in a blister (Al/Al), supplied in a box		YES	YES		YES	YES		
Emend 80 mg hard capsules	capsules, hard	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	2 (1x2) capsules in a blister (Al/Al), supplied in a box		YES	YES		YES	YES		
Eminens 0.25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	210 tablets in a white plastic (HDPE) bottle with temper-proof closure and desiccant, supplied in a box	YES			YES				
Eminens 0.5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES				
Eminens 1 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica	21 tablets in a white (HDPE) plastic bottle with temper-	YES			YES				

		Danica 5, Koprivnica, Republic of Croatia	proof closure and desiccant, supplied in a box								
Eminens 2 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES				
Eminens 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	21 tablets in a white (HDPE) plastic bottle with temper-proof closure and desiccant, supplied in a box	YES			YES				
Emselex 15 mg	prolonged-release tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES		
Emselex 7.5 mg	prolonged-release tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES			YES		
Enap -H tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Enap HL tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Enap tablets 10 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Enap tablets 20 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Enap tablets 5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Enap-HL 20 tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in a blister, supplied in a box		YES		YES				
Enap-HL 20 tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Enazil 10	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Enazil 20	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
ENAZIL 5	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Enbrel 25 mg powder and diluent for solution for injection	powder and diluent for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder, 4 syringes with needle filled with solvent (water for injection), 4 needles with protection, 3 bottle adapters and 8 alcohol impregnated pads		YES	YES					
Enbrel 25 mg powder and diluent for solution for injection	powder and diluent for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder, 4 syringes with needle filled with solvent (water for injection) and 8 alcohol		YES	YES					

			impregnated pads								
Enbrel 25 mg powder for solution for injection	powder for solution for injection	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P092NG, Great Britain	Box with 4 glass bottles containing 25 mg of lyophilised powder and 8 alcohol impregnated pads		YES	YES					
ENCEPUR for for children, vaccine against viral Middle-European tick-borne meningoencephalitis (inactivated, absorbed)	intramuscular suspension	Chiron Behring GmbH & Co, Marburg, Germany	Box with 1 pre-filled syringe with a needle with 1 dose of vaccine (0.25 mL of suspension)		YES						
ENCEPUR Adult, inactivated absorbed vaccine against viral Central European tick-born meningoencephalitis	intramuscular suspension	Chiron Behring GmbH & Co, Marburg, Germany	Box with 1 pre-filled syringe with a needle with 1 dose of vaccine (0.5 mL of suspension)		YES						
Endoxan coated tablets 50 mg	coated tablets	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	50 (5x10) coated tablets in a blister (PVC/PVDC/Al), supplied in a box		YES	YES					
Endoxan 1 g powder for solution for injection	powder for injection solution (for intravenous use)	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES					
Endoxan 200 mg powder for solution for injection	powder for solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES					
Endoxan powder for injection solution 500 mg	powder for solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	Powder for solution for injection in a glass bottle, supplied in a box		YES	YES					
Engerix-B Dosis Adulta; recombinant hepatitis B vaccine for adults	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with one pre-filled syringe with 1 mL of vaccine, needle and needle protection		YES						
Engerix-B Dosis Adulta; recombinant hepatitis B vaccine for adults	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with 25 glass bottles with 1 mL of vaccine		YES						
Engerix-B Dosis Paediatrica; recombinant hepatitis B vaccine for children	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with 25 glass bottles with 0.5 mL of vaccine		YES						
Engerix-B Dosis Paediatrica; recombinant hepatitis B vaccine for children	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89, Rixensart, Belgium	Box with one pre-filled syringe with 0.5 mL of vaccine, needle and needle protection		YES						
Epiramat tablets 100 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Epiramat tablets 200 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Epiramat tablets 25 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Epiramat tablets 50 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Epirubicin Ebewe 10 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution for infusion concentrate in a glass bottle (with a rubber stopper), supplied in a box		YES		YES				

Epirubicin Ebewe 100 mg/50 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	50 mL of solution for infusion concentrate in a glass bottle (with a rubber stopper), supplied in a box		YES		YES				
Epirubicin Ebewe 50 mg/ 25 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of infusion solution concentrate in a glass bottle (with rubber stopper), supplied in a box		YES		YES				
Epivir tablets 150 mg	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	60 tablets in a polyethylene bottle, supplied in a box		YES	YES					
Epoetal injection 2000 IU/mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One ampoule in a box	YES		YES					
Epoetal injection 4000 IU/mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One ampoule in a box	YES		YES					
Eprex 10 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 bottles with rubber stoppers containing 1.0 mL of solution for injection, in protective packaging, supplied in a box		YES	YES		YES		YES	
Eprex 10 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 1.0 mL of solution, in protective packaging, supplied in a box		YES	YES		YES		YES	
Eprex 2 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.5 mL of solution, in protective packaging, supplied in a box		YES	YES		YES		YES	
Eprex 20 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Pre-filled disposable syringe containing 0.5 mL of solution for injection in a protective container, supplied in a box		YES	YES		YES		YES	
Eprex 3 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.3 mL of solution, in protective packaging, supplied in a box		YES	YES		YES		YES	
Eprex 4 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	6 syringes with a needle (disposable) with 0.4 mL of solution, in protective packaging, supplied in a box		YES	YES		YES		YES	
Eprex 40 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Vial containing 1 mL of solution for injection, with rubber stopper, in a protective container, supplied in a box		YES	YES		YES		YES	
Eprex 40 000 injection	solution for injection	Cilag AG, Schaffhausen, Switzerland	Pre-filled disposable syringe containing 1.0 mL of solution for injection in a protective container, supplied in a box		YES	YES		YES		YES	
Equoral 100 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravska 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES				
Equoral 25 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravska 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES				
Equoral 50 mg	soft capsules	IVAX-Pharmaceuticals s.r.o., Ostravska 29, Opava - Komarov, Czech Republic	50 (5x10) capsules in an Al/Al blister, supplied in a carton box		YES		YES				

Equoral solution	oral solution	IVAX-Pharmaceuticals s.r.o., Ostravska 29, Opava - Komarov, Czech Republic	50 mL of solution in an amber glass bottle in a protective container, 1 plastic syringe of 4 mL, 1 plastic pipe for extraction of bottle content in a protective plastic container and 1 plastic temper-evident screw cap, supplied in a carton box		YES		YES				
ERAZON capsules 10 mg	capsules, hard	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC -Al), supplied in a box	YES			YES				
ERAZON capsules 20 mg	capsules, hard	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	20 (2x10) capsules in a blister (PVC -Al), supplied in a box	YES			YES				
ERAZON suppositories	suppositories	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	10 (2x5) suppositories in a strip, supplied in a box	YES			YES				
Erbitux 2 mg/mL solution for infusion	solution for infusion	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	50 mL of solution in a glass bottle, supplied in a box		YES	YES			YES		
Ergometrin Lek 0.2 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 film coated tablets in an amber glass bottle, supplied in a box		YES		YES				
Ergometrin Lek 0.2 mg/mL solution for injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 ampoules with 1 mL of solution, supplied in a carton box		YES		YES				
Eritromicin 250 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	16 (1x16) capsules in a blister, supplied in a box	YES			YES				
Esberitox N tablets	tablets	Schaper & Brümmer GmbH & Co. KG, Salzgitter, Germany	50 (5x10) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES						YES
Esmeron	solution for injection (for intravenous use)	N.V. Organon, Oss, The Nederlands	10 mL of solution for injection in a glass bottle with rubber stopper, 10 glass bottles in a box		YES	YES					
Esmeron	solution for injection (for intravenous use)	N.V. Organon, Oss, the Netherlands; ORGANON S.A., Usine Saint Charles, France	5 mL of solution for injection in a glass bottle with a rubber stopper, 12 glass bottles in a box		YES	YES					
Espumisan	capsules, soft	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	25 (1x25) capsules in a PVC/Al blister, supplied in a box		YES		YES				YES
Estracomb TTS	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	4 transdermal patches Estraderm TTS 50 and 4 transdermal patches Estragest TTS 250/50 (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES					
Estracyt	capsules	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation	40 capsules in an amber glass bottle, supplied in a box	YES			YES				

		with Pharmacia & Upjohn S.p.A., Milano, Italy									
Estraderm TTS 100	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES					
Estraderm TTS 25	patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES					
Estraderm TTS 50	transdermal patch	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	6 (3x2) transdermal patches (individually packed in a protective Surlyn/Al bag), supplied in a box		YES	YES					
Estrofem 1 mg	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets in a plastic calendar pack (dispenser with marked days of the week), supplied in a box		YES	YES				YES	
Estrofem 2 mg	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets in a plastic calendar dial pack (dispenser with marked days of the week), supplied in a box		YES	YES				YES	
Etambutol 400 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 tablets in an amber glass bottle, supplied in a box	YES			YES				
Etambutol Alkaloid	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	100 tablets in an amber glass bottle, supplied in a box		YES		YES				
ETOPOSIDE EBEWE 100 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 1000 mg/50 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	50 mL of solution concentrate in an amber glass bottle (with a rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 200 mg/10 mL	solution concentrate for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	10 mL of concentrate in an amber glass bottle (with rubber stopper), supplied in a carton box		YES		YES				
ETOPOSIDE EBEWE 50 mg/2.5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	2.5 mL of solution concentrate in an amber glass bottle (with rubber stopper), supplied in a carton box		YES		YES				
EURAX emulsion	emulsion for application on skin	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	50 mL of emulsion in an amber glass bottle with a plastic measuring insert and a plastic stopper, supplied in a box		YES		YES				YES
EURAX cream	cream	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 grams of cream in an aluminum tube with plastic cap, supplied in a box		YES		YES				YES
Euthyrox 100 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Euthyrox 150 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Euthyrox 25 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					

Euthyrox 50 tablets	tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	100 (4X25) tablets in a blister, supplied in a box		YES	YES					
Evista 60 mg film coated tablets	film coated tablets	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	28 (2x14) film coated tablets in a blister (PVC/PE/Aclar//Al), supplied in a box		YES	YES			YES		
Evra transdermal patch	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	9 patches individually packaged in protective sachets (paper/LDPE/Al-foil/LDPE), wrapped à 3 in a transparent plastic bag, supplied in a box		YES	YES					
Evra transdermal patch	transdermal patch	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	3 patches individually packaged in protective bags (paper/LDPE/Al-foil/LDPE) inserted in a common transparent plastic bag, supplied in a box		YES	YES					
Exforge 5 mg/160 mg film coated tablets	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES		YES	YES		
Exforge 5 mg/80 mg film coated tablets	film coated tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (2x14) tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES		YES	YES		
EXJADE 125 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
EXJADE 250 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
EXJADE 500 mg tablets for oral suspension	tablets for oral suspension	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	28 (4x7) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	4 plastic (PVC) Viaflex bags with 2500 mL of solution, a supply/drain pipe (PVC), a connector with a protective cap, an attachment for drug administration, and a collective plastic Viaflex bag (individual packaging in a protective plastic bag), supplied in a box		YES		YES			YES	
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5 plastic (PVC) Viaflex bags with 2000 mL of solution, a supply/drain pipe (PVC), a connector with a safety cap, a dispensing unit and a collective plastic Viaflex bag (individual packaging in a protective plastic bag), supplied in a box		YES		YES			YES	
Extraneal	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	5 plastic (PVC) Viaflex bags with 2000 mL of solution, with a connector with a safety cap and a dispensing unit (individual packaging in a protective plastic bag), supplied in a box		YES		YES			YES	
Ezetrol 10 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39,	28 (2x14) tablets in an Aclar/PVC/Al blister, supplied		YES	YES				YES	

		Postbus 581, Haarlem, the Netherlands	in a box								
Fabrazyme 35 mg	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial containing powder for concentrate, supplied in a box		YES	YES			YES		
Fabrazyme 5 mg	powder for concentrate for solution for infusion	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	One glass vial containing powder for concentrate, supplied in a box		YES	YES			YES		
Faktu suppositories	suppositories	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	10 (2x5) suppositories in a PVC/PE strip, supplied in a box		YES		YES				
Faktu ointment	ointment	Altana Pharma AG, Byk-Gulden Strasse 2, Konstanz, Germany	20 grams of ointment in an aluminum tube and an applicator for rectal use, supplied in a box		YES		YES				
Famosan 20 mg	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 (1x20) tablets in a blister, supplied in a box		YES		YES				
Famosan 40 mg	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Farmorubicin PFS 10 mg injection (2 mg/mL)	solution for intravenus and intravesical use	Pfizer Italia s.r.l., Viale Pasteur 10, Nerviano Plant, Milano, Italy	Box with a bottle with 5 mL of solution		YES		YES				
Farmorubicin PFS 50 mg injection (2 mg/mL)	solution for intravenus and intravesical use	Pfizer Italia s.r.l., Viale Pasteur 10, Nerviano Plant, Milano, Italy	Box with a bottle with 25 mL of solution		YES		YES				
Faslodex 250 mg/5 mL solution for injection	solution for injection (in a pre-filled syringe)	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	One glass syringe with 5 mL of solution, with child resistant closure, in a plastic container, supplied in a box		YES	YES		YES	YES		
Fastum Gel	gel	A. Menarini Manufacturing Logistic and Services S.r.l., Firenca, Italy	20 grams of gel in an aluminum tube with plastic cap, supplied in a box		YES		YES				YES
Favora Eusin drops	drops, solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Amber glass bottle (10 mL) with a plastic screw cap and a dropper, supplied in a box	YES							YES
Favora Fitolax powder	powder	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	200 grams of powder in a PP vessel with PE cap and measuring spoon, supplied in a box	YES							YES
Favora Orasept lozenges	lozenges	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) lozenges in a blister, supplied in a box	YES							YES
Favora Urosal capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (2x25) capsules in a blister, supplied in a box	YES							YES
Feiba TIM 4 immuno 1000 FJ	lyophilisate for preparation of intravenous solutions	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with a bottle with lyophilisate, bottle with 20 mL of water for injection and dissolution and injection kit		YES						
Feiba TIM 4 immuno 500 FJ	lyophilisate for preparation of intravenous solutions	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with a bottle with lyophilisate, bottle with 20 mL of water for injection and dissolution and injection kit		YES						
Femara 2.5 mg film-tablets	film coated tablets	Novartis Pharma Stein AG,	30 (3x10) tablets in a PVC/PE/PVDC/Al blister,		YES	YES				YES	

		Schaffhauserstrasse, Stein, Switzerland	supplied in a box								
Femoston 1/10	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets (14 white and 14 grey) in a blister, supplied in a box		YES	YES					
Femoston 2/10	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets (14 pink and 14 yellow) in a blister, supplied in a box		YES	YES					
Femoston Conti 1/5	film coated tablets	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	28 (1x28) tablets in a blister, supplied in a box		YES	YES					
Fenistil 0.1% oral drops	oral drops (solution)	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 mL of solution in an amber glass bottle with a polyethylene dropper and a polypropylene cap, supplied in a box		YES	YES					
Fenistil gel	gel	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	Al tube with 30 g of gel with a polyethylene cap, supplied in a box		YES	YES					
Fentanil M Lek 100 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
Fentanil M Lek 25 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
Fentanil M Lek 50 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
Fentanil R Lek 100 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
Fentanil R Lek 25 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
Fentanil R Lek 50 transdermal patch	transdermal patch	Hexal AG, Holzkirchen, Germany	One transdermal patch in a protective bag (PE/Al/PE/paper foil), 5 patches in a box		YES		YES				
FENTANYL injection	solution for intravenous injection	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	50 ampoules with 10 mL of solution for injection, supplied in a box		YES	YES					
FENTANYL injection	solution for intravenous injection	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	50 ampoules with 2 mL of solution for injection, supplied in a box		YES	YES					
Ferrum Lek 100 mg chewing tablets	chewing tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) chewable tablets in a strip, supplied in a box		YES		YES				
Ferrum Lek 50 mg/5 mL syrup	syrup	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 mL of syrup in an amber glass bottle and a measuring spoon, supplied in a box		YES		YES				

FERVEX	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 13.100 g of granules, supplied in a box		YES		YES				YES
FERVEX sugar-free	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 4.950 g of granules, supplied in a box		YES		YES				YES
FERVEX for children	granules for oral solution	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrénées, Le Passage, France	8 bags each with 3.0 g of granules, supplied in a box		YES		YES				YES
Fevarin	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	15 (1x15) film coated tablets in PVC/PVDC/Al blister, supplied in a box		YES	YES					
FINCAR 5 mg	film coated tablets	Cipla Ltd, Bangalore, India	28 (2x14) tablets in a blister (PVC/PVDC/Al), supplied in a box		YES		YES				
Flixonase nasal spray	water suspension	Glaxo Wellcome S.A., Aranda de Duero, Burgos, Spain	120 doses of suspension in a glass bottle with plastic dispenser, supplied in a box		YES	YES					
Flixotide 100 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES					
Flixotide 125 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals SA, poznan, Poland; Glaxo Wellcome Production, Evreux, France	Aluminium container with a plastic mouthpiece containing 60 doses		YES	YES					
Flixotide 250 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES					
Flixotide 250 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals SA, Poznan, Poland; Glaxo Wellcome Production, Evreux, France	Aluminium container with a plastic mouthpiece containing 60 doses		YES	YES					
Flixotide 50 Inhaler	inhalation aerosol	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	120 doses (not less than 10.0 g of suspension) in an aluminum container with metering valve in a plastic nebulizer, supplied in a box		YES	YES					
Flixotide 500 Diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Vel. Britanija; Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES					
Flonidan 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57,	10 (1x10) tablets in a blister, suplied in a box		YES		YES				

		Ljubljana, Republic of Slovenia									
Flonidan 5mg/5mL suspension	oral suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	120 mL of solution in an amber glass botlle and plastic spoon, supplied in a box		YES		YES				
Flosteron suspension for injections	suspension for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 ampoules each with 1 mL of suspension, supplied in a box		YES		YES				
Fluacet gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 g of gel in an aluminium tube, supplied in a box	YES			YES				
Fluad MF59C.1 adjuvanted vaccine against influenza in ready-to-use syringe, inactivated (surface antigens)	suspension for injection in pre-filled syringe	Novartis Vaccines & Diagnostics S.r.l., Siena, Italy and Imunološki zavod d.d., Zagreb, Republic of Croatia	Pre-filled syringe with a needle containing 0.5 mL of suspension, supplied in a box	YES							
Fluarix vaccine against influenza, inactivated, fragmented (without preservative)	suspension for injections	Sächsisches Serumwerk Dresden NL der SmithKline Beecham Pharma GmbH & Co. KG, Germany	Box with 1 glass syringe with a needle containing 1 dose of vaccine of 0.5 mL		YES						
Flucinom tablets 250 mg	tablets	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	100 (10x10) tablets in an orange (PVC/Al) blister, supplied in a box		YES	YES					
Fluconax 100 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Fluconax 150 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	One capsule in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
Fluconax 200 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Fluconax 2mg/1mL solution for intravenous infusion	solution for intravenous infusion	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	100 mL of solution in a glass bottle for infusion and a plastic bottle holder, supplied in a box	YES			YES				
Fluconax 50 mg capsules	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	7 (1x7) capsules in (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Fludara	powder for solution for injection or infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	5 glass bottles with powder, supplied in a box		YES	YES					
Fludara oral 10 mg film coated tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	20 (4x5) tablets in a blister (PA/Al/PP//Al) in a 150 mL plastic (HDPE) bottle with a plastic child resistant closure		YES	YES				YES	
Fluimukan 100 mg granules for oral solution	granules for oral solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 bags each containing 5 g of granules, supplied in a box		YES		YES				YES
Fluimukan 200 mg granules for oral solution	granules for oral solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of	20 bags with à 5 grams of granules, supplied in a box		YES		YES				YES

		Slovenia									
FLUIMUN, vaccine against influenza (surface antigen, inactivated)	suspension for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass vial containing 0.5 mL of suspension for injection, plastic syringe, needle for drawing suspension from the bottle (21Gx1"; inch) and one needle for drug administration (23Gx1 inch or 25Gx1 inch or 25Gx5/8 inch), supplied in a box	YES							
FLUONATRIL 0.25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	400 tablets in a plastic (PP) bottle with a stopper, supplied in a box	YES			YES				
FLUONATRIL 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	250 tablets in a plastic (PP) bottle with a cap, supplied in a box	YES			YES				
Fluorouracil Pliva injection 250 mg/5 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials each containing 5 mL of solution, supplied in a box	YES			YES				
Fluorouracil Pliva injection 500 mg/10 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial with 10 mL of solution, supplied in a box	YES			YES				
Fluval capsules 20 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2x7) capsules in a blister (PVC/PVDC//Al), supplied in a box		YES		YES				
Fluzepam capsules 15 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) capsules in a blister, supplied in a box		YES		YES				
Fluzepam capsules 30 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) capsules in a blister, supplied in a box		YES		YES				
Folacin	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 tablets in a PE vial, supplied in a carton box	YES			YES				
Forane	inhalation liquid	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 100 mL of liquid in an amber glass bottle		YES	YES					
Forteo 20 micrograms/80 microliters, solution for injection in a pre-filled pen-injector	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	Pen-injector containing 3 mL of solution (750 µg teriparatide) in a glass cartridge		YES	YES					
Fortral solution for injection 30 mg/1 mL	solution for injection	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Sanofi, France	10 ampoules each containing 1 mL of solution, supplied in a box		YES		YES				
Fortral tablets 50 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Sanofi, France	100 tablets in an amber glass bottle, supplied in a box		YES		YES				
Fortrans powder for oral solution	powder for oral solution	Beaufor Ipsen Industrie, Dreux, France	4 bags (LDPE/Al/paper) each with 73.69 g of powder for oral solution, supplied in a box		YES		YES				
Fortzaar	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	31 (2x14) film coated tablets in a blister, supplied in a carton box		YES	YES					
Fosamax T	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem,	Box with 4 tablets (blister, 1 x 4 tbl.)		YES	YES				YES	

		the Netherlands									
Fosavance tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	4 (1x4) tablets in a blister (Al/Al) in a carton casing (with a leaflet), supplied in a box		YES	YES			YES		
Fraxiparine 2850 IU AXa/0.3 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.3 mL of solution		YES	YES					
Fraxiparine 3800 IU AXa/0.4 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.4 mL of solution		YES	YES					
Fraxiparine 5700 IU AXa/0.6 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.6 mL of solution		YES	YES					
Fraxiparine 7600 IU AXa/0.8 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 0.8 mL of solution		YES	YES					
Fraxiparine 9500 IU AXa/1 mL injection	subcutaneous injection	Glaxo Wellcome Production, Notre Dame de Bondeville, France	Box with 10 syringes with a needle containing 1 mL of solution		YES	YES					
Fromilid 250 tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 tablets (2x7) in A/PVC/PVDC blister, supplied in a box		YES		YES				
Fromilid 500 tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 tablets (2x7) in A/PVC/PVDC blister, supplied in a box		YES		YES				
Fromilid 125 mg/5 mL granules for oral suspension	granules for oral suspension	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	25 grams of granules for the preparation of 60 mL of oral suspension in a glass bottle and a 5 mL plastic syringe for oral dose delivery, supplied in a box		YES		YES				
Fromilid uno prolonged-release tablets 500 mg	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2x7) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES				
Fromilid uno 500 mg tablets with prolonged release	prolonged release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 (1x5) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES				
FSME Immun inject, inactivated vaccine against viral tick-borne meningoencephalitis	intramuscular suspension	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 pre-filled syringe with 1 dose of vaccine (0.5 mL susp), with a needle		YES						
FSME-IMMUN 0.25 mL Junior	suspension for injection	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Pre-filled syringe with needle containing one 0.25 mL of vaccine dose, supplied in a box		YES						
Funzol capsules 100 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	7 (1x7) capsules in (PVC/PVDC/Al) blister, supplied in a box		YES		YES				
Funzol capsules 150 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	One (1x1) capsule in a PVC/PVDC/Al blister supplied in a box		YES		YES				
Funzol capsules 50 mg	capsules	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	7 (1x7) capsules in (PVC/PVDC/Al) blister, supplied in a box		YES		YES				
Fursemid 20 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica	5 ampoules each with 2 mL of solution in a plastic holder,	YES			YES				

		Danica 5, Koprivnica, Republic of Croatia	supplied in a box								
Fursemid 40 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 (1x12) tablets in a blister, supplied in a box	YES			YES				
Fursemid 40 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister, supplied in a box	YES			YES				
Fursemid forte 500 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) tablets in PVC/Al blister , supplied in a box	YES			YES				
Gabalept capsules 100 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) capsules in a blister, supplied in a box	YES			YES				
Gabalept capsules 300 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES			YES				
Gabalept capsules 400 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES			YES				
Gadovist 1.0 mmol/mL injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	7.5 mL of solution in a glass syringe, 5 syringes individually packed in a blister, supplied in a box		YES	YES				YES	
Gadovist 1.0 mmol/mL solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	15 mL of solution in a glass bottle, 10 bottles in a box		YES	YES				YES	
Gammagard S/D 10 g	lyophilisate and solvent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Bottle with lyophilisate, bottle with 192 mL of diluent, sterile set for lyophilisate dissolution, and sterile application kit used with a filter, supplied in a box		YES						
Gammagard S/D 2.5 g	lyophilisate and diluent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Bottle with lyophilisate, bottle with 50 mL of diluent, sterile kit for lyophilisate reconstitution, and one sterile kit for use with filter, supplied in a box		YES						
Gammagard S/D 5 g	lyophilisate and diluent for preparation of solution for intravenous infusion	Baxter S.A, Hyland Immuno, Lessines, Belgium	Botle with lyophilisate, bottle with 96 mL of diluent, sterile kit for lyophilisate reconstitution, and sterile kit for use with filter, supplied in a box		YES						
GANFORT eye drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	3 mL of solution in a 5 mL plastic (LDPE) bottle with dropper attachment and plastic (HDPE) temper-proof closure, 1 bottle in a box		YES	YES			YES		
Garasone eye/nasal drops	eye/nasal drops	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	5 mL of solution in a plastic (10 mL) bottle with a dropper		YES	YES					
GARDASIL, suspension for injections in a pre-filled syringe, vaccine against human papillomavirus [type 6, 11, 16, 18] (recombinant, absorbed)	suspension for injections in a pre-filled syringe	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Pre-filled glass syringe (glass type I) with 0.5 mL of suspension for injection, a needle with protective mechanism, and two needles, supplied in a box		YES	YES		YES	YES		

GARDASIL, suspension for injection, human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, absorbed)	suspension for injection	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Tyle 1 glass ampoule containing 0.5 mL of suspension, supplied in a box		YES	YES		YES	YES		
Gastal tablets peppermint	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES			YES				YES
Gastal tablets spearmint	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES			YES				YES
Gastal tablets, sour cherry	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	24 (4x6) tablets in a blister, supplied in a box	YES			YES				YES
Gastrografin solution	solution	Berlimed S.A., Madrid, Spain	100 mL of solution in an amber glass bottle with plastic cap, supplied in a box		YES	YES					
Gemzar 1 g powder for solution for infusion	powder for solution for infusion	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One glasss vial with lyophilisate, supplied in a box		YES	YES					
Gemzar 200 mg powder for solution for infusion	powder for solution for infusion	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One glasss vial with lyophilisate, supplied in a box		YES	YES					
Genotropin 5.3 mg	powder and diluent for solution for subcutaneous injection	Pfizer Health AB, Stockholm, Sweden	5 two-part glass cartridges with lyophilisate (front part (I) and solvent (rear part (II)) in a plastic container, supplied in a box		YES	YES					
Gentamicin 120 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin 20 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin 40 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin 80 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin injection 120 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES		YES				
Gentamicin injection 120 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin injection 40 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES		YES				
Gentamicin injection 40 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				

Gentamicin injection 80 mg	solution for injection	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	50 amber glass ampoules each with 2 mL of solution, supplied in a box		YES		YES				
Gentamicin injection 80 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin Jadran 120	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin Jadran 40	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Gentamicin Jadran 80	solution for injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Geokorton ointment 20 g	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminium tube with 20 g of ointment, supplied in a box	YES			YES				
Geomycin	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	16 (2x8) capsules in a PVC/Al blister, supplied in a box	YES			YES				
Geonistin	vaginal tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (2x3) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Ginkgo film-tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES							YES
Glibenclamid Genericon 3.5 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	30 (3x10) tablets in a PVC/Al blister , supplied in a box		YES		YES				
Glibenclamid Genericon 3.5 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	120 (12x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Glivec 100 mg film coated tablets	film coated tablets	Novartis Pharma GmbH, Nurnberg, Germany	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
Glivec 100 mg capsules	hard capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (10x12) capsules in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
Glivec 100 mg capsules	capsules	Novartis Pharma A.G., Basel, Switzerland	120 (10x12) capsules in a blister, supplied in a box		YES	YES		YES	YES		
Glivec 400 mg film coated tablets	film coated tablets	Novartis Pharma GmbH, Nurnberg, Germany	30 (3x10) tablets in a PVC/PE/PVDC/Al blister, supplied in a box		YES	YES		YES	YES		
Glivec 50 mg capsules	capsules	Novartis Pharma A.G., Basel, Switzerland	30 (3x10) capsules in a blister, supplied in a box		YES	YES		YES	YES		
Glivec 50 mg capsules	hard capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	30 (3x10) capsules in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
GlucaGen HypoKit	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with lyophilisate and one glass syringe with needle (1 mL of diluent), in a plastic container		YES	YES					

Glucobay 100 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	30 tablets (2x15) in a blister (polypropylene/Al), supplied in a box		YES	YES					
Glucobay 50 mg tablets	tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	32 (2x15) capsules in a PVC/Al blister, supplied in a box		YES	YES					
Glucomerck 1000 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centere de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGcA, Frankfurt Strasse 250, 64293 Darmstadt, Germany	60 (4x15) film coated tablets in a transparent blister (PVC/Al), supplied in a box		YES	YES					
Glucomerck 500 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centere de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGcA, Frankfurt Strasse 250, 64293 Darmstadt, Germany	100 (5x20) film coated tablets in transparent blister (PVC/Al), supplied in a box		YES	YES					
Glucomerck 850 mg film coated tablets	film coated tablets	Merck SANTE s.a.s., Centere de Production de Semoy, 2 Rue du Pressior Vert - 45400 Semoy, France; Merck KGcA, Frankfurt Strasse 250, 64293 Darmstadt, Germany	30 (2x15) film coated tablets in a transparent PVC/Al blister, supplied in a box		YES	YES					
Glucophage 1000 mg film coated tablets	film coated tablets	Merck SANTE s.a.s./Centre de Production de Semoy, France Merck KGaA, Germany	30 (3x10) film coated tablets in a transparent blister (PVC/A1), supplied in a box		YES	YES		YES		YES	
Glucophage 500 mg film coated tablets	film coated tablets	Merck SANTE s.a.s./Centre de Production de Semoy, France Merck KGaA, Germany	50 (5x10) film coated tablets in a transparent blister (PVC/Al), supplied in a box		YES	YES		YES		YES	
Glucophage 850 mg tablets	film coated tablets	Merck Sante s.a.s., Lyon CEDEX 08, France	30 (2x15) tablets in a blister, supplied in a box		YES	YES		YES		YES	
Glucovance 500 mg/ 2.5 mg tablets	film coated tablets	Merck SANTE s.a.s., 2 Rue du Pressoir Vert - 45400 Semoy, France	30 (2x15) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Glucovance 500 mg/ 5 mg tablets	film coated tablets	Merck SANTE s.a.s., 2 Rue du Pressoir Vert - 45400 Semoy, France	30 (2x15) tablets in a PVC/Al blister, supplied in a box		YES	YES					
Gluformin 850 mg tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	35 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box	YES			YES				
Gluformin tablets1g	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (2x15) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Glukosalina I solution , 100mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in an infusion bottle with rubber stopper protected by Al cap and plastic lid, 10 bottles with holders in a carton box	YES			YES				
Glukosalina I solution for intravenous infusion, 250mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in an infusion bottle with rubber stopper and protective Al cap with plastic lid (10 bottles with holders, supplied in a	YES			YES				

			carton box)								
Glukosalina I solution for intravenous infusion, 500mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in an infusion bottle with a rubber stopper and an aluminium cap with a plastic lid (10 bottles with holders, supplied in a carton box)	YES			YES				
Glukosalina III solution for intravenous infusion	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in an infusion bottle with a rubber stopper and an aluminium cap with a plastic lid (10 bottles with holders, supplied in a carton box)	YES			YES				
Glucose 10% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 10% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 10% solution for intravenous infusion, 100 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in a glass bottle	YES			YES				
Glucose 10% solution for intravenous infusion, 250 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle	YES			YES				
Glucose 10% solution for intravenous infusion, 500 mL	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in a glass bottle	YES			YES				
Glucose 10% Pliva solution for infusion	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 PVC bags with 500 mL of solution, supplied in a box	YES			YES				
Glucose 10% Pliva solution for infusion 250 mL	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution in a glass infusion bottle with rubber stopper and combi-cap (10 bottles with polyethylene holder supplied in a box)	YES			YES				
Glucose 10% Pliva solution for infusion 500mL	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES			YES				
Glucose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Viaflo bags with 250 mL of solution for infusion in a protective bag, supplied in a box		YES		YES				
Glucose 5 % Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	10 plastic Viaflo bags with sa 1000 mL of infusion solution, in a protective bag, supplied in a box		YES		YES				
Glukose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A.,	50 plastic Viaflo bags with 50 mL of solution for infusion in a protective bag, supplied in a box		YES		YES				

		Republic of Ireland									
Glucose 5 %, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic bags Viaflo with 100 mL of solution for infusion, in a protective bag, supplied in a box		YES		YES				
Glucose 5 % Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES		YES				
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL of solution in a glass bottle	YES			YES				
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL of solution in a glass bottle	YES			YES				
Glucose 5%	solution for infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle	YES			YES				
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	250-mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Glucose 5% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of infusion solution in a plastic bottle (20 bottles in a box)		YES		YES				
Glucose 5% Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a PVC bag, with a draining attachment (closed with combiflack stopper) and an application attachment, 12 bags in a box	YES			YES				
Glucose 5% Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a glass infusion bottle with a rubber stopper and a protective cap, 10 bottles in a box	YES			YES				
Glurenorm 30 mg tablets	tablets	Boehringer Ingelheim Ellas A.E., Atena, Greece	60 (6x10) tablets in a white blister (PVC/PVDC//Al), supplied in a box		YES	YES					
GONAL-f 1050 IU/1.75 mL	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 2 mL of diluent, supplied in a box		YES	YES			YES		
GONAL-f 300 IU/0.5 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen-syringe with 0.5 mL of solution (in a 3-mL glass cartridge) and 5 needles in a plastic container, supplied in a box		YES	YES			YES		

GONAL-f 450 IU/0.75 mL	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 1 mL of diluent, supplied in a box		YES	YES			YES		
GONAL-f 450 IU/0.75 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen-syringe with 0.75 mL of solution (in a 3-mL glass cartridge) and 7 needles in a plastic container, supplied in a box		YES	YES			YES		
GONAL-f 75 IU	powder and diluent (in a syringe) for solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and syringe with 1 mL of diluent in a plastic container, supplied in a box		YES	YES			YES		
GONAL-f 900 IU/1.5 mL	solution for injection in pen syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	Pen syringe with 1.5 mL of solution (in a 3-mL glass cartridge) and 14 needles in a plastic container, supplied in a box		YES	YES			YES		
Gopten 0.5 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) capsules in a blister, supplied in a box		YES	YES					
Gopten 2 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box		YES	YES					
Gopten 4 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box		YES	YES					
Grippostad C	capsules	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	20 (2x10) capsules in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES
Grippostad Good Night syrup	syrup	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	90 mL of syrup in a glass bottle with a plastic temper-evident stopper (white PP/PE), supplied in a box		YES		YES				YES
Grippostad hot drink	effervescent powder	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 bags (Al/paper/PE) each containing 5.0 g of powder, supplied in a box		YES		YES				YES
Haemate P 500	powder and diluent for solution for injection/infusion	ZLB Behring GmbH, Emil-von-Behring Str. 76, Marburg, Germany	Glass vial with powder, glass vial with 10 mL of Water for Injection, transfer kit, and disposable filter, supplied in a box		YES						
Haldol depo solution for injection 50 mg/1 mL	oily solution for intramuscular injection	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	5 brown ampoules (in a blister) each with 1 mL of solution, supplied in a box		YES		YES				
Haldol 10 mg/1 mL oral drops	oral drops	Krka d.d. , Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 mL of solution in an amber glass bottle, supplied in a box		YES		YES				
Haldol oral drops 2 mg/1 mL	oral drops	Krka d.d. , Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	10 mL of solution in an amber glass bottle, supplied in a box		YES		YES				
Haldol solution for injection 5 mg/1 mL	solution for injection for intramuscular and intravenous use	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	10 (2x5) ampoules each containing 1 mL solution in a blister, supplied in a box		YES		YES				

Haldol 10 mg tablets	tablets	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 tablets in an amber glass bottle, supplied in a box		YES		YES				
Haldol tablets 2 mg	tablets	Krka d.d. , Novo Mesto, R. Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	25 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Halea 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES				
Halea 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES				
Heferol	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 capsules in a bottle, supplied in a box		YES		YES				
Helicobacter test INFAI for infrared spectroscopy	oral powder	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	75 mg of 13 C-urea in a polystyrene container with a closed polyethylene "snap" stopper; equipment for sampling and transfer of samples of expired air (4 glass "vacutainer" test tubes or plastic"vacuette" of 10 mL and 1 flexible straw), inserted in a box		YES	YES			YES		
Helicobacter test INFAI for infrared spectroscopy	powder for preparation of oral solution	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	50 polystyrene jars with polyethylene snap cap containing 75 mg 13C-urea powder for oral solution, with a kit for sampling and transporting of breath samples, 50x2 bags with plastic attachments, and 50x1 bendable plastic straws, supplied in a box		YES	YES			YES		
Helicobacter test INFAI for mass spectrometry	powder for oral solution	INFAI Institut für Biomedizinische Analytik & NMR Imaging GmbH, Bochum, Germany	75 mg of 13 C-urea in a polystyrene container with a closed polyethylene "snap" stopper; equipment for sampling and transfer of samples of expired air (4 glass "vacutainer" test tubes or plastic"vacuette" of 10 mL and 1 flexible straw), inserted in a box		YES	YES			YES		
Hemofil M 250 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini infusion kit, sterile disposable syringe of 10 mL, supplied in a box		YES						
Hemofil M 500 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini		YES						

			infusion kit, sterile disposable syringe of 10 mL, supplied in a box									
Hemofil M 500 IU human coagulation factor VIII, monoclonally purified	lyophilisate and solvent for preparation of intravenous solution (injection/infusion)	Baxter S.A., Hyland Immuno, Lessines, Belgium	Glass bottle with lyophilisate and a glass bottle with 10 m of solvent, sterile double dissolution needle, sterile filter needle, sterile mini infusion kit, sterile disposable syringe of 10 mL, supplied in a box		YES							
Hepan gel	gel	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 50 g of gel in an Al tube	YES			YES				YES	
Hepan cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 50 g of cream in an Al tube	YES			YES				YES	
HEPARIN injection	solution for injection (for s.c. and i.v. use)	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 mL of solution in a glass bottle (with a rubber stopper and an Al cap), 10 bottles in a box	YES			YES					
Heptanon injection	solution for intramuscular and subcutaneous injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 ampoules with 1 mL of solution, supplied in a box	YES			YES					
Heptanon drops	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic dropper attachment, supplied in a box	YES			YES					
Heptanon solution	oral solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of solution in a 125-mL brown plastic bottle with aluminum cap, supplied in a box	YES			YES					
Heptanon tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					
HERCEPTIN 150 mg powder for concentrate for solution for infusion	powder for concentrate for solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass vial with powder, supplied in a box		YES	YES		YES	YES			
Hermes Cevitt lemon	effervescent powder	Hermes Arzneimittel GmbH, München, Germany	20 effervescent tablets in a polypropylene tube		YES		YES				YES	
Hermes Cevitt naranca	effervescent powder	Hermes Arzneimittel GmbH, München, Germany	20 effervescent tablets in a polypropylene tube		YES		YES				YES	
Herplex 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	35 (7x5) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Herplex 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	35 (7x5) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Herplex cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	2 grams of cream in a tube, supplied in a box	YES			YES				YES	
Hiberix vaccine against Haemophilus influenzae type B, glycoconjugated	lyophilisate	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Box with one bottle wtih 1 dose of lyophilised vaccine and 1 syringe with solvent and 2 needles		YES							

Hiramicin	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 (1x5) capsules in a blister, supplied in a box	YES			YES				
Holyplant Purgal tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES							YES
Holyplant Sena tea	herbal tea	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	50 g of tea in a polypropylene transparent bag, supplied in a box	YES							YES
Holyplant Septogal oriblettes	oriblettes	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	30 (3x10) oriblettes in a PVC/Al blister, supplied in a box	YES			YES				YES
Humaject M3 (30/70) 100 IU/mL (3.0 mL)	suspension for subcutanous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES					
Humaject N 100 IU/mL (3.0 mL)	suspension for subcutanous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES					
Humaject R 100 IU/mL (3.0 mL)	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 disposable injectors with glass cartridges each with 3 mL of solution, supplied in a box		YES	YES					
Humalog 100 IU/mL cartridge (3.0 mL)	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 cartridges with 3 mL of solution in a blister, supplied in a box		YES	YES					
Humalog Mix25 100 IU/mL (suspension in cartridge 3.0 mL)	suspension for injection	Lilly France S.A.S., Fegersheim, France i Lilly S.A., Alcobendas-Madrid, Spain	5 glass cartridges with 3.0 mL of suspension to be administered with a pen injector, in protective packaging, supplied in a box		YES	YES			YES		
Humalog Mix25 Pen 100 IU/mL	suspension for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge with 3.0 mL of suspension, supplied in a box		YES	YES			YES		
Humalog Mix50 100 IU/mL (suspension in cartridge 3.0 mL)	suspension for injection	Lilly France S.A.S., Fegersheim, France i Lilly S.A., Alcobendas-Madrid, Spain	5 glass cartridges with 3.0 mL of sspension to be administered with a pen injector, in protective packaging, supplied in a box		YES	YES			YES		
Humalog Mix50 Pen 100 IU/mL	suspension for injections	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3.0 mL of suspension, supplied in a box		YES	YES			YES		
Humalog Pen 100 IU/mL (3 mL)	solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge with 3 mL of solution, supplied in a carton box		YES	YES			YES		
Human albumin 20% immuno 50 mL	solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 bottle containing 50 mL of solution		YES						
HUMAN ALBUMIN 20% OCTAPHARMA 100 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria and Octapharma SA, Lingolsheim, France	One glass vial with 100 mL of solution for infusion, supplied in a box		YES						
Human Albumin 20% Octapharma 100 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 100 mL		YES						

HUMAN ALBUMIN 20% OCTAPHARMA 50 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria and Octapharma SA, Lingolsheim, France	One glass vial containing 50 mL of solution for infusion, supplied in a box		YES							
Human Albumin 20% Octapharma 50 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 50 mL		YES							
Human albumin 5% immuno 250 mL	solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with 1 bottle containing 250 mL of solution		YES							
Human Albumin 5% Octapharma 100 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 100 mL		YES							
HUMAN ALBUMIN 5% OCTAPHARMA 100 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	One glass vial with 100 mL of solution for infusion, supplied in a box		YES							
Human Albumin 5% Octapharma 250 mL	intravenous solution	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	Paper box with 1 glass bottle with human albumin solution à 250 mL		YES							
HUMAN ALBUMIN 5% OCTAPHARMA 250 mL	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	One glass vial with 250 mL of solution for infusion, supplied in a box		YES							
Humatrope 12 mg	lyophilisate for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One cartridge with lyophilisate, a syringe with 3.15 mL of diluent and a diluent feed line, supplied in a box		YES	YES						
Humatrope 6 mg	lyophilisate and diluent for solution for injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	One cartridge with lyophilisate, a syringe with diluent, and a needle with protective plastic cap, supplied in a box		YES	YES						
Humira solution for injection	solution for injection	Abbott Biotehnology Deutschland GmbH, Max-Planck-Ring 2, Wiesbaden, Germany	Pre-filled glass syringe containing 0.8 mL of solution and one alcohol drenched cotton wool roll in a blister		YES	YES						
Humulin M3 (30/70) 100 IU/mL (3.0 mLcartridge)	suspension for subcutanous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of suspension per blister, supplied in a box		YES	YES						
Humulin M3 Pen 100 IU/mL	suspension for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3 mL of suspension, supplied in a carton box		YES	YES				YES		
Humulin N 100 IU/mL (3.0 mL cartridge)	suspension for subcutanous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of suspension per blister, supplied in a box		YES	YES						
Humulin N Pen 100 IU/mL	solution for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 injectors with a glass cartridge each with 3 mL of suspension, supplied in a carton box		YES	YES				YES		
Humulin R 100 IU/mL (cartridge 3.0 mL)	solution for subcutaneous injection	Lilly France S.A.S., Rue du Colonel Lilly, Fegersheim, France	5 (1x5) cartridges with 3 mL of solution per blister, supplied in a box		YES	YES						
HUSTAGIL	oral solution	Dentinox Gesellschaft für pharmazeutische Präparate Lenk & Schuppan, Berlin, Germany	150 mL of solution an amber glass bottle with Alu cap, supplied in a box		YES						YES	

Hycamtin	lyophilisate for preparation of infusion	SmithKline Beecham Pharmaceuticals, West Sussex, Great Britain i GlaxoSmithKline Manufacturing S.p.A., Parma, Italy	5 glass bottles of 5 mL with lyophilisate, supplied in a box		YES	YES					
Hydrocyclin	ointment	Galenika a.d., Beograd - Zemun, Srbija	5 g of ointment in an aluminium tube, supplied in a box		YES		YES				
Hyperici Aktiv granules	granules	Cedevita d.o.o., Zagreb, Republic of Croatia	15 bags (paper/Al/PE) containing 5 g , supplied in a box	YES							YES
HYPNOMIDATE	solution for injection	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	5 ampoules with 10 mL of solution, supplied in a box		YES	YES					
Hyzaar	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	32 (2x14) film coated tablets in a blister, supplied in a carton box		YES	YES					
Ibuprofen 100 mg/5 mL oral suspension	oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of suspension in an amber glass bottle, supplied in a box	YES			YES				
Ibuprofen 400 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Ibuprofen 600 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Ibuprofen 800 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a white polyethylene (PE) bottle, with a PE screw cap, supplied in a box	YES			YES				
Ibuprofen gel	gel	The Mentholatum Company Ltd, 1 Redwood Avenue, Peel Park Campus, East Kilbride, Great Britain	50 g of gel in an aluminium tube with a plastic stopper, supplied in a box		YES		YES				YES
Ibuprofen 200 mg coated tablets	coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Ibuprofen 400 mg coated tablets	coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Ibuprofen retard 800 mg tablets	prolonged release tablets	Farmal d.d., Ludbreg, Republic of Croatia, in cooperation with Valpharma Int. s.a., San Marino	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES				
Imacort cream	cream	Spirig Pharma AG, Egerkingen, Switzerland	20 grams of cream in an aluminum tube, supplied in a box		YES		YES				
Imazol cream-paste	paste	Spirig Pharma AG, Egerkingen, Switzerland	30 g of paste in an aluminium tube		YES		YES				
Imazol Plus	cream	Spirig Pharma AG, Egerkingen, Switzerland	30 g of cream in an aluminium tube, supplied in a box		YES		YES				

Imigran nasal spray of 20 mg	nasal spray	GlaxoSmithKline S.p.A., Parma, Italy	Two plastic measuring devices (for nasal spray) in a blister ,supplied in a box		YES	YES						
Imigran tablets 50 mg	film coated tablets	Glaxo Wellcome Operations, Greenford, Middlesex, Great Britain i GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	2 tablets in aluminum blister (Al/Al), supplied in a carton box		YES	YES						
ImmuCyst, BCG Immunotherapeutic agent	lyophilisate and diluent for intravesical instillation	Sanofi Pasteur Limited, Toronto, Ontario, Canada	One glass vial with BCG 81g (lyophilisate) and one glass bottle with 3 mL of diluent, supplied in a box		YES							
Immunate 1000 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES							
Immunate 250 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES							
Immunate 500 IU	lyophilisate and diluent for preparation of solution for intravenous use	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Bottle with lyophilisate, bottle with 5 mL of diluent, and set for dissolution and injection of medicinal product, supplied in a box		YES							
Immunine 1200 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 10 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES							
Immunine 200 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 5 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES							
Immunine 600 IU	lyophilisate and solvent for preparation of solution for i.v. injection/infusion	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Lyophilisate in a glass bottle, 5 mL of solvent in a glass bottle and dissolution and injection kit, supplied in a box		YES							
IMOVAX POLIO inactivated poliomyelitis vaccine	suspension for intramuscular or subcutaneous injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	0.5-mL of suspension in a glass syring, supplied in a box		YES							
Human rabies immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Bottle with 5 mL of preparation (not less than 500 IU), supplied in a box	YES								
Human rabies immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Bottle with 2 mL of preparation (not less than 200 IU), supplied in a box	YES								
Human hepatitis B immunoglobulin , 250 IU	solution for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 250 IU of immunoglobulin, supplied in a carton box	YES								
Human hepatitis B immunoglobulin, 500 IU	solution for injection	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	One glass vial with 500 IU of immunoglobulin, supplied in a carton box	YES								
Human tetanus immunoglobulin	solution for intramuscular use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box containing 1 ampoule of preparation - 250 IU/ampoule	YES								

Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 50 mL of solution and an infusion kit, supplied in a box	YES							
Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 100 mL of solution and an infusion kit, supplied in a box	YES							
Human immunoglobulin for intravenous use	solution for intravenous use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Glass bottle with 10 mL of solution with a needle and a filter, supplied in a box	YES							
Imuran tablets	film coated tablets	Heumann PCS GmbH, Feucht, Germany	100 (4 x 25) tablets in PVC/Al blister, supplied in a box		YES	YES					
Indamid SR tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a white PVC/Al blister , supplied in a box	YES			YES				
INDAP	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	30 (3x10) capsules in a blister (PVC/Al), supplied in a box		YES		YES				
Indap	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	30 (3x10) capsules in a blister, supplied in a box		YES		YES				
Indapamid SR Pliva tablets	prolonged-release tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a white PVC/Al blister, supplied in a box	YES			YES				
Indometacin 100 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a strip, supplied in a box	YES			YES				
Indometacin 25 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a blister, supplied in a box	YES			YES				
Indometacin 75 mg retard capsules	prolonged-release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/Al blister, supplied in a box	YES			YES				
Inegy 10 mg/10 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister (Al/Al), supplied in a box		YES	YES				YES	
Inegy 10 mg/20 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES				YES	
Inegy 10 mg/40 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES				YES	
Inegy 10 mg/80 mg	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES				YES	
Infanrix diphtheria, tetanus and pertussis (acellular) vaccine, absorbed	intramuscular suspension	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Box with one glass syringe containing 1 dose of vaccine (0.5 mL), needle and needle protection		YES						
Infanrix Hexa	lyophilisate and suspension for parenteral use	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	One glass syringe with 0.5 mL of liquid vaccine component (DTP-HBV-IPV), one glass bottle with Hib lyophilisate and two needles with protective caps, supplied		YES						

			in a box								
INFANRIX-IPV+Hib, Combined Diphtheria, Tetanus, acellular Pertussis,inactivated Polio and Haemophilus influenzae type B conjugate Vaccine	powder and suspension for preparation of suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Box with 1 glass syringe containing 0.5 mL of suspension (component Infanrix IPV), 1 glass bottle with powder (component Hib) and 2 needles with protection		YES						
Influvac (inactivated influenza vaccine, surface antigen)	suspension for injection	Solvay Pharmaceuticals B.V., Veerweg 12, 8121 AA Olst, the Netherlands	Box with 1 pre-filled syringe (glass, type I) with 1 dose of vaccine (0.5 mL of suspension)		YES						
Infusol (solution for infusion)	solution for intravenous infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES			YES				
Inspra 25 mg tablets	film coated tablets	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE613YA, Great Britain	30 (3x10) film coated tablets in a nontransparent PVC/Al blister, supplied in a carton box		YES	YES		YES		YES	
Inspra 50 mg tablets	film coated tablets	Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE613YA, Great Britain	30 (3x10) film coated tablets in a nontransparent PVC/Al blister, supplied in a carton box		YES	YES		YES		YES	
Instillagel 11 mL	gel	Almed GmbH, Motzener Str. 41, Berlin, Germany	10 syringes each containing 11 mL of gel in a blister, supplied in a box		YES		YES				
Instillagel 6 mL	gel	Almed GmbH, Motzener Str. 41, Berlin, Germany	10 syringes each containing 6 mL of gel in a blister, supplied in a box		YES		YES				
Insulatard HM 100	solution for injection (for s.c. use)	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	10 mL of suspension in a glass bottle, supplied in a box		YES	YES					
Insulatard Penfill	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Alle, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES					
Integrilin solution for infusion 0.75 mg/mL	solution for infusion	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium and Glaxo Operations UK Ltd., Great Britain	One glass vial with 10 mL of solution, supplied in a box		YES	YES		YES	YES		
Integrilin solution for injection 2 mg/mL	solution for injection	Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium and Glaxo Operations UK Ltd., Great Britain	One glass vial with 10 mL of solution, supplied in a box		YES	YES		YES	YES		
Intralipid 10%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 500 mL of emulsion, 10 bottles in a carton box		YES		YES				
Intralipid 10%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness		YES		YES				

			control								
Intralipid 10%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 100 mL of emulsion, 10 bottles in a carton box		YES		YES				
Intralipid 10%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES				
Intralipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES				
Intralipid 20%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 500 mL of emulsion, 10 bottles in a carton box		YES		YES				
Intralipid 20%	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria and Fresenius Kabi AB, Uppsala, Sweden	Glass infusion bottle containing 100 mL of emulsion, 10 bottles in a carton box		YES		YES				
Intralipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES				
Intron A 18 million IU solution for injection, multi-dose syringe	solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	One multi-dose syringe with a cartridge containing 1.2 mL of solution otopine, 12 needles and 12 cotton wool riolls, supplied in a box		YES	YES			YES		
Intron A 30 million IU solution for injection, multi-dose syringe	solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	One multi-dose syringe with a cartridge containing 1.2 mL of solution otopine, 12 needles and 12 cotton wool riolls, supplied in a box		YES	YES			YES		
Intron A solution for injection 18 mil.IU, multi-dose injector	solution for subcutaneous administration	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Box with 1 pen injection device with a glass cartridge containing 1.2 mL of solution, 6 Novofine needles and 6 gauze pads		YES	YES			YES		
Intron A solution for injection 30 mil.IU, multidozni injektor	solution for subcutaneous administration	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Box with 1 pen injection device with a glass cartridge containing 1.2 mL of solution, 6 Novofine needles and 6 gauze pads		YES	YES			YES		
Invanz 1 g powder for concentrate for infusion solution	powder for concentrate for infusion solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem,	20-mL glass bottle with powder supplied in a box		YES	YES			YES		

		the Netherlands									
Iopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	30 mL of solution in a glass bottle, supplied in a box		YES	YES					
Iopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	100 mL of solution in a glass bottle , supplied in a box		YES	YES					
Iopamiro 300 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	50 mL of solution in a glass bottle, supplied in a box		YES	YES					
Iopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	100 mL of solution in a glass bottle, supplied in a box		YES	YES					
Iopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	30 mL of solution in a glass bottle, supplied in a box		YES	YES					
Iopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	50 mL of solution in a glass bottle, supplied in a box		YES	YES					
Iopamiro 370 solution for injection	solution for injection	Bracco s.p.a., Via Egidio Folli 50, Milano, Italy Patheon Italia SpA, Via Morolense 87, Ferentino, Italy	200 mL of solution in a glass bottle, supplied in a box		YES	YES					
IRUMED 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PVDC-Al foil), supplied in a box	YES			YES				
Irumed 2.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al folil), supplied in a box	YES			YES				
Irumed 20 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al folil), supplied in a box	YES			YES				
Irumed 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/PVDC-Al folil), supplied in a box	YES			YES				
Iruzid 10/12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES				
Iruzid 20/12.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES				
Iruzid 20/25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	32 (1x30) tablets in a transparent blister (PVC/PVDC-Al foil), supplied in a box	YES			YES				

ISMN Genericon 20 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				
ISMN Genericon 40 mg tablets	tablets	Genericon Pharma Ges.m.b.H, Lannach, Austria	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				
ISMN Jadran 20	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	60 (6x10) tablets in a blister, supplied in a box	YES			YES				
ISMN Jadran 40	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	60 (6x10) tablets in a blister, supplied in a box	YES			YES				
Isoptin 120 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in PVC/Al blister, supplied in a box	YES			YES				
Isoptin 40 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) film coated tablets in a PVC/Al blister, supplied in a box	YES			YES				
Isoptin 80 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Isoptin injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution in a glass ampoule, 50 (5x10) ampoules in a plastic holder, supplied in a box	YES			YES				
ISOPTIN RR tablets	prolonged-release tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Abbott GmbH and Co. KG, Ludwigshafen, Germany	20 (2x10) prolonged-release tablets in PVC/PVDC//Al blister, supplied in a box	YES			YES				
ISOPTO TEARS eyel drops	eye drops	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	15 mL of solution in a platic bottle with dropper attachment, supplied in a box		YES		YES				YES
ITRAC 3 capsules	capsules, hard	Belupo, lijekovi i kozmetika, d.d., Koprivnica, Republic of Croatia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	4 capsules in a blister (PVC/PE/PVDC/Al), supplied in a box	YES			YES				
Izosorbid MN retard 40 mg tablets	prolonged release tablets (film coated)	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	Box with 50 tablets (blister, 5x10 tablets)	YES			YES				
Izosorbid MN retard 60 mg tablets	prolonged release tablets (film coated)	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	Box with 50 tablets (blister, 5x10 tablets)	YES			YES				
Isotonic solution of sodium chloride 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Sodium chloride isotonic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES				
Sodium chloride isotonic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	250-mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				

Sodium chloride isotinic solution 0.9% Braun	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of infusion solution in a plastic bottle (20 bottles in a box)		YES		YES				
Jeanine film tablets	film coated tablets	Jenapharm GmbH & Co KG, Jena, Germany	3x21 tablets in a blister, supplied in a box		YES	YES					
Jeanine film tablets	film coated tablets	Jenapharm GmbH & Co KG, Jena, Germany	1x21 tablets in a blister, supplied in a box		YES	YES					
Jumex 5 mg	tablets	CHINOIN Pharmaceutical and Chemical Works Co. Ltd., Budimpešta, Madarska i CHINOIN Pharmaceutical and Chemical Works Co. Ltd.,Veresegyhaz, Madarska	50 (5x10) tablets in an Al/OPA/PVC/Al blister, supplied in a box		YES	YES					
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1540 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES		YES			YES	
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1026 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES		YES			YES	
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 2053 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES			YES	
Kabiven	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 2566 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES			YES	
Kabiven Peripheral	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1440 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES		YES			YES	
Kabiven Peripheral	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag for 1920 mL of blend (in three separate compartments) in a plastic protective casing, 2 bags in a box		YES		YES			YES	
Calsium folinate Pliva injection 200 mg/20 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	20-mL bottle containing solution, with bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium folinate Pliva injection 500 mg/50 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	50-mL bottle with solution, closed bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium Folinate Pliva injection100 mg/10 mL	solution for injection	Pliva Lachema, Karasek 1, 62133 Brno, Czech Republic	10-mL bottle containing solution, with bromobutyl stopper and aluminum cap, supplied in a box		YES		YES				
Calcium carbonate Krka 1 g tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	50 tablets in a bottle, supplied in a box		YES		YES				
KALETRA 133.3 mg/33.3 mg soft capsules	capsules, soft	Abbott Laboratories Ltd., Kent, Great Britain, Abbott S.p.A., Campoverde di Aprilia,	2 plastic (HDPE) bottles each containing 90 capsules, supplied in a box		YES	YES		YES	YES		

		Italy									
KALETRA 200 mg/50 mg film-tablets	film coated tablets	Abbott Laboratories Ltd, Kent, Great Britain, Abbott GmbH&Co. KG, Ludwigshafen, Germany	120 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES		YES	YES		
Kaletra 80 mg + 20 mg/mL oral solution	oral solution	Abbott Laboratories Ltd., Kent, Great Britain, Abbott S.p.A., Campoverde di Aprilia, Italy	5 plastic (PET) brown bottles for multiple use with 60 mL of solution, supplied in a box		YES	YES		YES	YES		
Kaletra capsules	capsules	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 2 plastic bottles each containing 90 capsules		YES	YES		YES	YES		
Kaletra oral solution	oral solution	Abbott Laboratories Ltd, Queenborough, Great Britain	Box with 5 plastic bottles each with 60 mL of solution and 5 filling syringes of 5 mL		YES	YES		YES	YES		
POTASSIUM CHLORIDE JADRAN 500 mg tablets for oral solution	tablets for oral solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets for oral solution in a blister (PVC/Al), supplied in a box	YES			YES				
Kalinor effervescent tablets	effervescent tablets	Nordmark Arzneimittel GmbH & Co. KG, Pinnauallee 4, Uetersen, Germany	Plastic tube with 15 effervescent tablets, supplied in a box		YES		YES				
KAMIREN tablets 1 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	21 (2x10 tablets in PVC/PVDC/Al blister, supplied in a box		YES		YES				
KAMIREN tablets 2 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	22 (2x10 tablets in PVC/PVDC/Al blister, supplied in a box		YES		YES				
KAMIREN tablets 4 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	23 (2x10 tablets in PVC/PVDC/Al blister, supplied in a box		YES		YES				
Kamiren XL	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in an OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Kamiren XL	modified release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Katena 100 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) capsules in a blister, supplied in a box	YES			YES				
Katena 300 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES			YES				
Katena 400 mg tablets	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister, supplied in a box	YES			YES				
Kenalog 40 mg/1 mL suspension for injection	suspension for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 ampoules (each with 1 mL of suspension) in a blister, supplied in a box		YES		YES				
Keppra 100 mg/mL oral solution	oral solution	NextPharma SAS, Limay, France	300 mL of solution in an amber glass bottle with a plastic temper-evident stopper, supplied in a box		YES	YES		YES	YES		
Keppra 1000 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
Keppra 250 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		

Keppra 500 mg film coated tablets	film coated tablets	UCB S.A., Braine l'Alleud, Belgium	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES		
KERASAL ointment	ointment	Spirig Pharma AG, Egerkingen, Switzerland	50 g of ointment in an aluminium tube with a plastic stopper, supplied in a box		YES		YES				YES
Ketek 400 mg	film coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	10 (1x10) tablets in a blister, supplied in a box		YES	YES					
Ketocef injection 1.5 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES				
Ketocef injection 250 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES				
Ketocef injection 750 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES				
KetoGel 2.5% gel	gel	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 g of gel in an aluminium tube, supplied in a box		YES		YES				YES
Ketonal 100 mg suppositories	suppositories	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	12 suppositories in a strip (Al/PE), supplied in a box		YES		YES				
Ketonal 100 mg/2 mL injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	2 mL of solution for injection in a glass ampoule, 10 ampoules in a box		YES		YES				
Ketonal 150 mg prolonged-release tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 prolonged-release tablets in an amber glass bottle with plastic cap, supplied in a box		YES		YES				
Ketonal 5% cream	cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of cream in an aluminium tube, supplied in a box		YES		YES				YES
Ketonal 50 mg capsules	capsules, hard	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	25 capsules in an amber glass bottle with plastic cap , supplied in a box		YES		YES				
Ketonal DUO 150 mg capsules	modified release capsules, hard	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) capsules in a blister (PVC/TE/PVDC//PVC/Al), supplied in a box		YES		YES				
Ketonal forte 100 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 film coated tablets in an amber glass bottle with plastic cap, supplied in a box		YES		YES				
KLAVAX BID 1000 mg tablets	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Bilim Pharmaceuticals Inc., Turkey	14 tablets in a A/Al blister, supplied in a box	YES			YES				

KLAVAX BID syrup 400/57 mg	powder for preparation of oral suspension	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Bilim Pharmaceuticals Inc., Turkey	Glass bottle of 100 mL with a polyethylene cap, supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 70 mL of suspension (by the addition of 59 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene/polyethylene low density), supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 140 mL of suspension (by the addition of 118 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene), supplied in a box	YES			YES				
Klavocin bid syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for preparation of 35 mL of suspension (by the addition of 29.5 mL of water) in an amber glass bottle with a plastic stopper (high density polyethylene) and a 5 mL measuring syringe (polystyrene/polyethylene low density), supplied in a box	YES			YES				
Klavocin bid tablets 1 g	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (2x5) film coated tablets in a Al/Al blister, supplied in a box	YES			YES				
Klavocin 1.2 g injection	powder for injection solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 bottles (glass of hydrolytic group I) with a rubber stopper and a protective flip-off Al cap, supplied in a box	YES			YES				
Klavocin injection 600 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 bottles (glass of hydrolytic group I) with a rubber stopper and a protective flip-off Al cap, supplied in a box	YES			YES				
Klimicin 150 mg capsules	capsules	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	16 capsules in an amber glass bottle, supplied in a box		YES		YES				
Klimicin 300 mg capsules	capsules	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	16 capsules in an amber glass bottle, supplied in a box		YES		YES				
Klimicin 300 mg/2 mL injection	solution for intramuscular and intravenous injection	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	10 glass ampoules each containing 2 mL of solution, supplied in a box		YES		YES				
Klimicin 600 mg/4 mL injection	solution for intramuscular and intravenous injection	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	10 glass bottles with à 4 mL of solution, supplied in a box		YES		YES				
Klimicin T 1% gel	gel	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 g of gel in a tube, supplied in a box		YES		YES				
Klimicin T 1% dermal solution	dermal solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of	30 mL of solution in a plastic bottle, supplied in a box		YES		YES				

		Slovenia									
Klimicin V 2% vaginal cream	vaginal cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	40 g of cream in a tube with 7 plastic applicators, supplied in a box		YES		YES				
Kliogest	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 film-coated tablets in a plastic container (dispenser with marked days of the week), supplied in a box		YES	YES					
Klomifen 50 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Klosterfrau Sedinal sugar-coated tablets	sugar-coated tablets	M.C.M. Klosterfrau Vertriebs GmbH, Germany	60 (2x30) sugar coated tablets in a blister, supplied in a box		YES						YES
Knavon 100 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 (2x6) suppositories in a strip, supplied in a box	YES			YES				
Knavon 100 mg/2 mg injection	intramuscular injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 glass ampoules with á 2 mL of solution in a plastic container, supplied in a box	YES			YES				
Knavon 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	25 (1x25) capsules in a blister, supplied in a box	YES			YES				
Knavon forte 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle with Al cap, supplied in a carton box	YES			YES				
Knavon retard 150 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box	YES			YES				
Kofan tablets	tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				YES
Kogenate Bayer 1000 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES		
Kogenate Bayer 250 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES		
Kogenate Bayer 500 IU powder and diluent for injection solution	powder and diluent for solution for injection	Bayer Biologicals S.r.l., Torri-Sovicille, Italy	Vial with Bio-set device containing powder, pre-filled syringe with diluent, separate plunger, venipuncture set, two disposable sterile cotton pads drenched in a Acohol, two dry cotton pads and two plasters, supplied in a box		YES	YES		YES	YES		

Kompensan	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				YES
Konakion MM injection 10mg/1mL	solution for intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules (amber glass) with 1 mL of solution, supplied in a box		YES	YES					
Konakion MM 2 mg/0.2 mL, paediatric	solution for peroral, intramuscular and intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules (amber glass) with 0.2 mL of solution and 5 plastic measuring devices, supplied in a box		YES	YES					
Kreon 10 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	20 tablets in a plastic bottle		YES		YES				
Kreon 10 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	100 capsules in a plastic bottle		YES		YES				
Kreon 25 000	capsules filled with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Hannover, Germany	100 capsules in a plastic bottle		YES		YES				
KREON 40 000	hard capsules with gastric-resistant granules	Solvay Pharmaceuticals GmbH, Neustadt, Germany	50 capsules in a plastic (HDPE) container, supplied in a box		YES	YES					
Kromoglicin STADA eye drops	eye drops, solution	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 mL of solution in a polyethylene bottle with dropper attachment and cap, supplied in a box		YES		YES				YES
Kromoglicin STADA nasal spray	nasal spray, solution	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	15 mL of solution in a polyethylene bottle with nebulizer, supplied in a box		YES		YES				YES
Kuterid 0.05 % cream	cream	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 grams of cream in an aluminum tube, supplied in a box		YES		YES				
Kuterid 0.05% ointment	ointment	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 grams of ointment in an aluminum tube, supplied in a box		YES		YES				
Kybernin P 500	powder for solution for injection or infusion	CSL Behring GmbH, Marburg, Germany	One glass vial with powder, one glass vial with 10 mL of diluent and one transfer spike, supplied in a box		YES						
Kytril 1mg/1 mL concentrate for solution for infusion	concentrate for infusion solution (for intravenous use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 1 mL of solution, supplied in a box		YES	YES					
Kytril 3 mg/3 mL concentrate for solution for infusion	concentrate for solution for intravenous infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	5 ampoules with 3 mL of solution, supplied in a box		YES	YES					
Kytril film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 tablets in a PVC/Al blister, supplied in a box		YES	YES					

Laaven HD tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	60 (6x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Laaven HD tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	33 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Laaven HL 20 tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	34 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Laaven HL tablets	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	30 (3x10) in a blister (PVC/PVDC/Al), supplied in a box	YES			YES				
Laaven tablets 10 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	31 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Laaven tablets 10 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	90 (9x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Laaven tablets 2.5 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	90 (9x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Laaven tablets 20 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	32 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Laaven tablets 5 mg	tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	33 (3x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
LACIDIPIN PLIVA tablets 4 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) film coated tablets in a blister (PA/Al/PVC//PE/Al), supplied in a box	YES			YES				
Lacipil tablets 4 mg	film coated tablets	Glaxo Wellcome S.A., Burgos, Aranda de Duero, Spain and GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	28 (4x7) tablets in a blister, supplied in a box		YES	YES					
Lacipil tablets 6 mg	film coated tablets	Glaxo Wellcome S.A., Aranda de Duero, Burgos, Spain	28 (4x7) tablets in a blister (OPA/AL/PVC//Al) , supplied in a box		YES	YES					
Lakea 50 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Lamal 100 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	33 (2x15) capsules in a PVC/Al blister, supplied in a box		YES		YES				
Lamal 200 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar	34 (2x15) capsules in a PVC/Al blister, supplied in a		YES		YES				

		Makedonski 12, Skopje, FYROM	box								
Lamal 25 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 (3x10) tablets in a blister (PVC/Al) , supplied in a box		YES		YES				
Lamal 50 mg tablets	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 (3x10) tablets in a blister (PVC/Al) , supplied in a box		YES		YES				
Lameptil 100 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	30 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES		YES			YES	
Lameptil 200 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	31 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES		YES			YES	
Lameptil 25 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	32 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES		YES			YES	
Lameptil 50 mg dispersible tablets	dispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	33 (3x10) dispersible tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES		YES			YES	
Lamictal 100 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lamictal 25 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lamictal 50 mg tablets	tablets	Glaxo Wellcome Operations, Greenford, Great Britain	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lamictal 5 mg chewing tablets / tablets for oral suspension 5 mg	chewing tablets/ tablets for oral suspension	Glaxo Operations UK Limited, Ware, Hertfordshire, Great Britain (Glaxo Wellcome Operations, Greenford, Great Britain), GlaxoSmithKline Pharmaceuticals, Poznan, Poland	30 (3x10) tablets in a blister (PVC/PVDC//Al), inserted in a carton box		YES	YES					
LAMISIL 1 % aerosol for external use	aerosol for external use, solution	Novartis Pharma S.A.S., Huningue Cedex, France	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box		YES	YES					
LAMISIL 1% cream	cream	Novartis Pharma Produktions GmbH, Wehr, Germany and Novartis Consumer Health SA, Nyon, Switzerland	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Lamisil 250 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	14 (1x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Lamisil DermGel 1% gel	gel	Novartis Pharma Produktions GmbH, Wehr, Germany and Novartis Consumer	5 g of gel in an aluminium tube with a propylene stopper, supplied in a box		YES	YES					

		Health SA, Nyon, Switzerland									
Lamisil once 1% dermal solution	dermal solution	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	4 g of solution in an aluminium (PE/Al/PE) tube with a plastic stopper, supplied in a protective plastic box		YES	YES				YES	
Lanicor tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	22 (2x10) tablets in a blister (PVC/Al) , supplied in a box	YES			YES				
Lanitop injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 2-mL ampoules supplied in a box	YES			YES				
Lanitop tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 (5x10) tablets in a blister, supplied in a box	YES			YES				
Lantus 100 IU/mL (3-mL cartridge for OptiClik)	solution for subcutaneous injection	Sanofi - Aventis Deutschland GmbH, Frankfurt am Main, Germany	5 glass cartridges with 3 mL of solution (with an integrated plastic injector holder), supplied in a box		YES	YES			YES		
Lantus 100 IU/mL (3 mL glass cartridge)	solution for subcutaneous injection	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	Box with 5 glass cartridges each with 3 mL of solution (in a blister)		YES	YES					
Lantus 100 IU/mL OptiSet (injector with glass cartridge of 3 mL)	solution for injection in a cartridge	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	5 injectors with cartridges each with 3 mL of solution, supplied in a box		YES	YES					
Lanzul capsules 30 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 (2X7) capsules in a PVC/PE/PVDC – Al blister, supplied in a box		YES		YES				
LARONA 15 mg	gastric-resistant capsules, hard	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 capsules in a plastic (HDPE) bottle with PP closure (with desiccant), supplied in a box	YES			YES				
LARONA 30 mg	gastric-resistant capsules, hard	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	29 capsules in a plastic (HDPE) bottle with PP closure (with desiccant), supplied in a box	YES			YES				
Lazid tablets 80 mg	tablets	CP Pharmaceuticals Ltd, Wrexham, Great Britain	60 (3x20) tablets in a blister (PVC/Al), supplied in a box		YES		YES				
LAZOL 15 mg capsules	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) capsules in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
LAZOL 30 mg capsules	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	14 (2x7) capsules in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Legofer	oral solution	Alkaloid AD, Skopje, Bulevar A. Makedonski 12, FYROM in cooperation-under the licence (concession) Italfarmaco S.p.a.A., Milano, Italy	150 mL of solution in an amber glass bottle with plastic cap and **measuring vessel** , supplied in a box		YES		YES				
Lekadol 500 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of	18 (3x6) tablets in a blister, supplied in a box		YES		YES				YES

		Slovenia									
Lekadol direkt 500 mg tablets	orodispersible tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	12 (2x6) dispersible tablets in PA/Al/PVC-Al blister, supplied in a box		YES		YES				YES
Lekadol plus C granules	granules for preparation of suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 bags each containing 5 g of granules, supplied in a box		YES		YES				YES
Lekadol tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Lekoklar 250 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) tablets in a A/PVC blister, supplied in a box		YES		YES				
Lekoklar 500 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) tablets in a A/PVC blister, supplied in a box		YES		YES				
Lekoklar XL 500 mg film-coated tablets with modified release	modified-release film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 (1x5) tablets in an Al/Al blister, supplied in a box		YES		YES				
Lekotam 1.5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	45 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Lekotam 3 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	46 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Lekotam 6 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				
Lendacin 1g power for injection solution	powder for preparation of injection for i.v. and i.m. solution	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 glass bottles with powder, supplied in a box		YES		YES				
Lendacin 2 g powder for solution for infusion	powder for solution for infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	5 glass bottles with powder for solution for infusion, supplied in a box		YES		YES				
Leponex 100 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	50 (5x10) tablets in a blister, supplied in a box		YES	YES					
Leponex 25 mg tablets	tablets	Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, Great Britain	50 (5x10) tablets in a blister, supplied in a box		YES	YES					

Lercanil	film coated tablets	Berlin-Chemie AG (Menarini Group), Berlin, Germany; Recordati Industria Chimica e Farmaceutica S.p.A., Milano, Italy	7 (1x7) tablets in a blister (non-transparent PVC/Al), supplied in a box		YES	YES					
Lescol 40 mg capsules	capsules	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	28 (4x7) capsules in a blister, supplied in a box		YES	YES					
Lescol XL 80 mg prolonged-release tablets	prolonged-release tablets	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Letizen film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) film coated tablets in a (PVC/Al) blister, supplied in a box		YES		YES				
Letizen oral solution 1 mg/1 mL	oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	120 mL of solution in an amber glass botlle with plastic cap, supplied in a box		YES		YES				
Letizen S 10 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coted tablets in a PVC/Al) blister, supplied in a box		YES		YES				YES
Letrox 100	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//Al) blister, supplied in a box		YES		YES				
Letrox 150	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//Al) blister, supplied in a box		YES		YES				
Letrox 50	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	50 (2x25) tablets in a white non-transparent (PVDC/PVC//Al) blister, supplied in a box		YES		YES				
Levemir FlexPen	solution for injection in cartridge for subcutaneous use	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens with a FlexPen glass cartridge containing 3 mL of solution, supplied in a carton box		YES	YES			YES		
Levemir Penfill	solution for injection in cartridge for subcutaneous use	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 Penfill glass cartridges with 3 mL of solution, supplied in a carton box		YES	YES			YES		
Levitra 10 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/Al blister, supplied in a box		YES	YES					
Levitra 20 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/Al blister, supplied in a box		YES	YES					
Levitra 5 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	2 tablets in a PP/Al blister, supplied in a box		YES	YES					
Lexaurin tablets 1.5 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (2x15) tablets in a blister, supplied in a box		YES		YES				
Lexaurin tablets 3 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (2x15) tablets in a blister, supplied in a box		YES		YES				
Lexaurin tablets 6 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (2x15) tablets in a blister, supplied in a box		YES		YES				
Lexilium 1.5 mg tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES		YES				

Lexilium 3 mg tablets	tablets	Alkaloid AD, Skopje, FYORM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Lexilium 6 mg tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with F. Hoffmann-La Roche Ltd, Basel, Switzerland	30 (3x10) tablets in a blister, supplied in a box		YES		YES				
Lidacef injection 1g	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	Glass bottle (10 mL) with powder, supplied in a box		YES		YES				
Lidacef injection 2 g	powder for preparation of solution for i.v. infusion	Pliva Krakow, Krakow, Poland	Glass bottle (20 mL) with powder, supplied in a box		YES		YES				
LINOLA FETT ÖLBAD	bath additive, solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	200 mL of solution, dropper, cap, and measuring 20 mL cup, supplied in a box		YES		YES				YES
LINOLA UREA	cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	75 g of cream in an aluminium tube, supplied in a box		YES		YES				YES
Linoladiol	vaginal cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of cream in an aluminum tube and a plastic vaginal applicator in a protective bag, supplied in a box		YES		YES				
Linoladiol	vaginal cream	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	50 g of cream in an aluminium tube and a plastic vaginal applicator in a protective bag, supplied in a box		YES		YES				
Linola-fett	oily cream (water/oil emulsion)	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	Box with 75 g of cream in an Al tube		YES		YES				YES
Lioresal 10 mg tablets	tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Lioresal 25 mg tablets	tablets	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	50 (5x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES					
Lipex 10 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Lipex 20 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Lipex 40 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Lipex 80 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 (2x14) film coated tablets in a blister, supplied in a box		YES	YES					
Lipidil 145 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	31 (3x10) film coated tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES		YES		YES	
Lipidil 160 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les	32 (3x10) film coated tablets in a blister		YES	YES		YES		YES	

		Dijon, France	(PVC/PE/PVDC/Al), supplied in a box								
LIPIDIL 200 M	capsules, hard	Laboratories Fournier S.A., Fontaine Les Dijon, France	30 (3x10) capsules in a blister (PVC/Al), supplied in a box		YES	YES				YES	
Lipofundin MCT/LCT 10%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of emulsion for infusion in a glass bottle, 10 bottles per box		YES		YES				
Lipofundin MCT/LCT 10%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of emulsion in a glass bottle, 10 bottles in a box		YES		YES				
Lipofundin MCT/LCT 20%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of emulsion for infusion in a glass bottle, 10 bottles per box		YES		YES				
Lipofundin MCT/LCT 20%	emulsion for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	100 mL of emulsion for infusion in a glass bottle, 10 bottles in a box		YES		YES				
LISINOLEX 10 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	36 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES		YES				
LISINOLEX 20 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	37 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES		YES				
LISINOLEX 5 mg	tablets	Galex d.d., Murska Sobota, Republic of Slovenia	38 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES		YES				
Litak 2 mg/mL solution for injection	solution for injection	Lipomed AG, Arlesheim, Switzerland	Clear type I glass vial, containing 5 mL of solution, with a rubber bromobutyl stopper and protective aluminum ring, supplied in a box		YES	YES		YES	YES		
Litak 2 mg/mL solution for injection	solution for injection	Lipomed AG, Arlesheim, Switzerland	5 colourless glass bottles (glass type I) with a rubber bromobutyl stopper and a protective aluminium ring containing 5 mL of solution, supplied in a box		YES	YES		YES	YES		
Litalir capsules	capsules	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	100 capsules in a brown plastic bottle, supplied in a box		YES	YES					
LITIJ KARBONAT JADRAN 300 mg tablets	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	100 tablets in an amber glass bottle, supplied in a box	YES			YES				
Livial 2.5 mg tablets	tablets	N.V. Organon, Oss, the Netherlands; Organon Republic of Ireland Ltd., Co. Dublin, Republic of Ireland	28 tablets in a blister, supplied in a box		YES	YES					
Lizinopril 10 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
Lizinopril 20 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
Lizinopril 5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				

LIZINOPRIL H 10 mg/12.5 mg tablets	tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Actavis hf., Hafnarfjordur, Island	30 (3x10) tablets, supplied in a box	YES			YES				
LIZINOPRIL H 20 mg/12.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 (3x10) tablets, supplied in a box	YES			YES				
Lizinopril Lek 10 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES			YES	
Lizinopril Lek 2.5 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES			YES	
Lizinopril Lek 20 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES			YES	
Lizinopril Lek 5 mg tablets	tablets	Salutas Pharma GmbH, Dieselstrasse 5, Gerlingen, Germany	30 (3x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES			YES	
Lodoz 10 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lodoz 2.5 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Lodoz 5 mg/6.25 mg film coated tablets	film coated tablets	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany; Merck SANTE s.a.s., 2, Rue du Pressoir Vert, Semoy, France	30 (3x10) tablets in a blister, supplied in a box		YES	YES					
Logest coated tablets	coated tablets	Schering S.A., Lys Lez Lannoy, France	Box with 21 coated tablets in a blister		YES	YES					
Lopin tablets 10 mg	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	30 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Lopin tablets 5 mg	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	31 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Lorista 50 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a PVC/PVDC/Alu blister, supplied in a box		YES		YES				
Lorista H	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) film coated tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES		YES	
Lorsilan 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister (PVC/Al), supplied in a carton box	YES			YES				
Lorsilan 2.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/Al) , supplied in a carton box	YES			YES				
Losartic Plus tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of	28 (2x14) tablets in a blister, supplied in a box	YES			YES				

		Croatia									
Losartic tablets 25 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Losartic tablets 50 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Loseprazol 20 mg	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	14 (2x7) capsules in a OPA/Al/PVC//Al blister, supplied in a box		YES		YES				
Loseprazol 20 mg	capsules	Pro. Med.CS Praha a.s., Prag, Czech Republic	14 (2x7) capsules in a blister, supplied in a box		YES		YES				
Lotriderm cream	cream	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Lubor 10 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/Al) , supplied in a box	YES			YES				
Lubor 20 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip, supplied in a box	YES			YES				
Lubor 20 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a blister (PVC/Al) , supplied in a box	YES			YES				
Luboreta cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 g of cream in an aluminium tube with a polyethylene stopper, supplied in a box	YES			YES				YES
Lucentis 10 mg/mL solution for injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass bottle with 0.3 mL of solution, supplied in a box		YES	YES		YES	YES		
Lumidol 100 mg/2 mL injections	solution for injection (i.v., i.m. and s.c.)	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 glass ampoules with 2 mL of solution, supplied in a box	YES			YES				
LUMIDOL 100 mg/mL oral drops	oral drops, solution	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 mL of solution in an amber glass bottle with fitted plastic dropper and plastic cap, supplied in a box	YES			YES				
LUMIDOL 50 mg capsules	capsules, hard	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 capsules in a 50 mL plastic brown bottle with temper-proof closure, supplied in a box	YES			YES				
Lumidol 50 mg/mL injection	solution for injection (i.v., i.m. and s.c.)	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 glass ampoules with 1 mL of solution, supplied in a box	YES			YES				
Lumigan 0.3 mg/mL eyel drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	3 mL solution in a plastic bottle, supplied in a box		YES	YES			YES		
LUPOCET 250 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip foil, supplied in a box	YES			YES				YES

Lupocet 500 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				YES
Lupocet BABY 120 mg suppositories	suppositories	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (2x5) suppositories in a PE/Al strip, supplied in a box	YES			YES				YES
Lupocet flu	effervescent tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 effervescent tablets in a plastic tube, supplied in a box	YES			YES				YES
Lupocet JUNIOR syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle, supplied in a box	YES			YES				YES
Lupocet TEEN 300 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) capsules in a (PVC/Al) blister, supplied in a box	YES			YES				YES
Luveris 75 IU	powder and diluent for preparation of solution for injection (for subcutaneous use)	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and vial with diluent, in a protective container, supplied in a box		YES	YES			YES		
Luxeta tablets 100 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 tablets in a blister, supplied in a box	YES			YES				
Luxeta tablets 50 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 tablets in a blister, supplied in a box	YES			YES				
Lyrica 100 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	84 (4x21) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 150 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 200 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	84 (4x21) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 25 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 300 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 50 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Lyrica 75 mg capsules	capsules, hard	Pfizer GmbH Arzneimittelwerk Gödecke, Mooswaldallee 1, Freiburg, Germany	56 (4x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES			YES		

LYSOBACT oriblets	tablets for oral cavity oral (**orbilettes**)	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	30 (3x10) tablets in a blister, supplied in a box		YES		YES				YES
MabCampath 30 mg/mL concentrate for infusion solution	concentrate for infusion solution	Schering AG, Muellerstrasse 170-178, Berlin, Germany	3x1 glass bottles with 1 mL of concentrate for solution for infusion, supplied in a box		YES	YES			YES		
MabThera 100 mg solution concentrate for infusion	solution concentrate for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 mL of infusion solution concentrate in a glass bottle, 2 bottles in a box		YES	YES		YES	YES		
MabThera 500 mg concentrate of solution for infusion	concentrate of solution for infusion	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 mL of solution for infusion concentrate in a glass bottle, supplied in a box		YES	YES		YES	YES		
Macugen 0.3 mg	solution for injection	Pfizer Health AB, Stockholm, Sweden	One glass pre-filled syringe with needle, in a protective bag, supplied in a box		YES	YES		YES	YES		
Madopar 125 tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 tablets in an amber glass bottle (with desiccant), supplied in a box		YES	YES					
Madopar HBS 125 capsules	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 capsules in an amber glass bottle (with a desiccant), supplied in a box		YES	YES					
Madopar LIQ 125 tablets for oral suspension	tablets for oral suspension	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 tablets in an amber glass bottle (with dessicant), supplied in a box		YES	YES					
Magnevist solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	20 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES					
Magnevist solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 mL of solution in a glass bottle with rubber stopper, supplied in a box		YES	YES					
Makcin 500 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				
MANIT 10%	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution in a glass infusion bottle with a rubber stopper and a protective cap, 10 bottles in a box	YES			YES				
MANIT 20%	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution in a glass bottle for infusion with rubber stopper and protective cap, 10 bottles in a box	YES			YES				
Marivarin 3 mg tablets	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Orion Corporation, Espoo, Finland	50 tablets in an amber glass bottle with an aluminium stopper		YES		YES				
Materna with selenium	film coated tablets	Wyeth Lederle S.p.A., Catania, Italy	30 tablets in a HDPE bottle, supplied in a box		YES		YES				YES
MAXALT RPD 10 mg oral lyophilisates	oral lyophilisate	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	2 (2x1) oral lyophilisate in a blister (PVC/PVDC//Al) and protective bag (paper/PE/Al), in a plastic box, supplied in a carton box		YES	YES				YES	

MAXALT RPD 5 mg oral lyophilisates	oral lyophilisate	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	2 (2x1) oral lyophilisate in a blister (PVC/PVDC//Al) and protective bag (paper/PE/Al), in a plastic box, supplied in a carton box		YES	YES				YES		
MAXFLU lemon flavour	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets with or without an Al foil, in a polypropylene tube with a cap (PE) with silicagel and tamper-proof ring, supplied in a box	YES			YES					YES
Maxidex 1 mg/g eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES						
Maxidex 1 mg/mL eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of suspension in a polyethylene bottle with a dropper, supplied in a box		YES	YES						
Maxipime 1 g	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxipime 2 g	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxipime 500 mg	powder for preparation of i.m. and i.v. injections	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Glass bottle with powder, supplied in a box	YES			YES					
Maxitrol eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	Polyethylene bottle with 5 mL of drops, supplied in a box		YES	YES						
Maxitrol eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES						
Medazol 0.5 % solution for infusion	solution for infusion	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of solution in a glass bottle for infusion, supplied in a box	YES			YES					
Medazol 250 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in a plastic (polypropylene) bottles, supplied in a box	YES			YES					
Medazol 400 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Medazol 500 mg vaginal tablets	vaginal tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 (1x10) vaginal tablets in a PVC/Al blister, supplied in a box	YES			YES					
Medical gas, O2 medical	medical gas	Messer Croatia Plin d.o.o., Zaprešić, Industrijska 1, Republic of Croatia	Pressurized steel bottles (150 or 200 bar) with 2, 3, 5, 10, 20, 27, 30, 40 or 50 liters of gaseous medical oxygen	YES			YES					
MEDROL tablets 16 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	50 (5x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES						
MEDROL tablets 32 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	20 (2x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES						
MEDROL 4 mg tablets	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	30 tablets in an amber glass bottle with a plastic stopper, supplied in a box		YES	YES						
Megace tablets 160 mg	tablets	Haupt Pharma Regensburg GmbH,	100 tablets in a plastic (HDPE) bottle, supplied in a		YES	YES						

		Regensburg, Germany for Bristol-Myers Squibb	box								
Meglimid 1 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in transparent PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Meglimid 2 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in transparent PVC//Al blister, supplied in a box		YES		YES	YES		YES	
Meglimid 3 mg tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in transparent PVC//Al blister, supplied in a box		YES		YES	YES		YES	
MEGOSTAT oral suspension	oral suspension	Bristol-Myers Squibb, Epernon, France	240 mL suspension in a plastic (HDPE) bottle with child resistant closure, 20 mL plastic measuring glass, supplied in a box		YES	YES					
Mendilex	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 (5x10) tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Menopur	lyophilisate and diluent for preparation of solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany	10 bottles with lyophilisate and 10 ampoules with diluent, supplied in a carton box		YES	YES				YES	
Menopur	lyophilisate and diluent for preparation of solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany	5 bottles with lyophilisate and 5 ampoules with solvent, supplied in a box		YES	YES				YES	
MERIEUX INACTIVATED RABIES VACCINE	lyophilisate for preparation of intramuscular injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 bottle with 1 dose of lyophilised vaccine, 1 pre-filled syringe containing 1 mL of water for injection and a needle		YES						
Meronem i.v. 1 g	powder for preparation of i.v. injection	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	10 bottles with powder, supplied in a box		YES	YES					
Meronem i.v. 500 mg	powder for preparation of i.v. injection	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	10 bottles with powder, supplied in a box		YES	YES					
METHOTREXATE PLIVA injection 1000	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 20 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES				
METHOTREXATE PLIVA injection 20	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 2 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES				
METHOTREXATE PLIVA injection 5	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 2 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES				
METHOTREXATE PLIVA injection 50	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 5 mL of solution for injection (with rubber stopper, aluminum cap and plastic cover), supplied in a box	YES			YES				
Metopran	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	40 (4x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES				

Metronidazol Genericon 0.5 % solution for infusion	solution for infusion	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	10 (10x1) glass bottles with 100 mL of infusion solution, supplied in a box		YES		YES				
Mexitil 200 mg capsules	capsules	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer Strasse 65, Biberach an der Riss, Germany	50 (5x10) capsules in a blister, supplied in a box		YES	YES					
Miacalcic 100 IU injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules with 1 mL of solution, supplied in a box		YES	YES					
Miacalcic 200 IU aerosol	nasal spray, solution	Novartis Pharma S.A.S., Huningue Cedex, France	Solution in a glass bottle with spray (for nasal use), supplied in a box		YES	YES					
Micardis 40 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/Al/PVC/Al), supplied in a box		YES	YES			YES		
Micardis 80 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/Al/PVC/Al), supplied in a box		YES	YES			YES		
MicardisPlus 40/12.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/Al/PVC/Al), supplied in a box		YES	YES			YES		
MicardisPlus 80/12.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	28 (4x7) tablets in a blister (PA/Al/PVC/Al), supplied in a box		YES	YES			YES		
MIDAZOLAM TORREX 15 mg/3 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 3 mL of solution, on a plastic tray, supplied in a box		YES		YES				
MIDAZOLAM TORREX 2 mg/2 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 2 mL of solution, on a plastic tray, supplied in a box		YES		YES				
MIDAZOLAM TORREX 5 mg/5 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 5 mL of solution, on a plastic tray, supplied in a box		YES		YES				
MIDAZOLAM TORREX 5 mg/mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 1 mL of solution, on a plastic tray, supplied in a box		YES		YES				
MIDAZOLAM TORREX 50 mg/10 mL	solution for injection	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, Vienna, Austria	10 (2x5) ampoules with 10 mL of solution, on a plastic tray, supplied in a box		YES		YES				
Minerva sugar-coated tablets	sugar-coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	63 (3x21) tablets in a PVC/Al blister, supplied in a box		YES	YES					
Minirin Melt 120 µg	oral lyophilisate	Ferring AB, Limhamn, Sweden	30 (3x10) oral lyophilisate in a blister (Al/Al), supplied in a box		YES	YES					
Minirin Melt 60 µg	oral lyophilisate	Ferring AB, Limhamn, Sweden	31 (3x10) oral lyophilisate in a blister (Al/Al), supplied in a box		YES	YES					
Minirin nasal spray	nasal spray (solution)	Ferring AB, Limhamn, Sweden; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	5 mL of solution (50 doses à 10 µg) in an amber glass bottle with a spray attachment and a plastic attachment for nasal use, supplied in a box		YES	YES					

Minirin 0.2 mg tablets	tablets	Ferring AB, Limhamn, Sweden; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	30 tablets in a plastic bottle, supplied in a box		YES	YES					
Mirapexin tablets 0.25 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	30 (3x10) tablets in a PA/Al/PVC-Al blister, supplied in a box		YES	YES			YES		
Mirapexin tablets 1 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	31 (3x10) tablets in a PA/Al/PVC-Al blister, supplied in a box		YES	YES			YES		
Mirena intrauterine system	intrauterine system (20 mcg/24 h release of active substance) with integrated applicator	Schering OY, Turku, Finland	Intrauterine system with integrated applicator in a blister (APET/Tyvek), supplied in a box		YES	YES					
Mirocef injection 1 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES				
Mirocef injection 500 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES			YES				
Mirzaten 30 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets (3x10) in a PVC//PVDC/Al blister, supplied in a box		YES		YES				
Mirzaten 45 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets (3x10) in a PVC/PVDC/Al blister, supplied in a box		YES		YES				
Misar 0.25 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES				
Misar 0.5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES				
Misar 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) tablets in a blister, supplied in a box	YES			YES				
Misar SR 0.5 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES				
Misar SR 1 mg tablets	prolonged-release tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) tablets in a blister, supplied in a box	YES			YES				
Mitoxantrone Pliva	concentrate of solution for infusion solutio	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Colourless glass bottle with 15 mL of concentrate of solution for infusion, closed with a rubber stopper and an aluminium cap with a plastic lid, supplied in a box	YES			YES				
Mixtard 30 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Alle, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES					

Mixtard 40 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES					
Mixtard 50 Penfill 3 mL	suspension for isubcutaneous injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES					
Moditen depo injections 25 mg/1 mL	oily solution for intramuscular injection	Krka d.d., Novo mesto, R. Republic of Slovenia in cooperation with Bristol-Myers Squibb, New York, USA	5 amber glass ampoules each with 1 mL of solution, supplied in a carton box		YES		YES				
Moditen coated tablets 1 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	25 tablets in an amber glass bottle, supplied in a box		YES		YES				
Moditen coated tablets 2.5 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	100 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Moditen coated tablets 5 mg	coated tablets	KRKA d.d., Novo Mesto, Republic of Slovenia in cooperation with Bristol-Myers Squibb, NY, USA	100 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Moduretic tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	40 tablets in an amber glass bottle, supplied in a box		YES		YES				
Monopril 10 mg	tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	28 (2x14) tablets in a blister (white PVC/PVDC//Al), supplied in a box	YES			YES				
Monopril 20 mg	tablets	Jadran -Galenski laboratorij d.d., Rijeka, Republic of Croatia, in cooperation with Bristol-Myers Squibb S.p.A., Contrada Fontana del Cerasp. Anagni, Italy	28 (2x14) tablets in a blister (white PVC/PVDC//Al), supplied in a box	YES			YES				
Monopril plus 20/12.5	tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (2x14) tablets in a nontransparent PVC/PVDC/Alu blister, supplied in a box	YES			YES				
Monsalic ointment	ointment	Schering-Plough Farma, Lda, Casal do Colaride, Agualva Cacem, Portugal	25 grams of ointment in a white enamel tube with white polypropylene screw cap, supplied in a carton box		YES	YES		YES		YES	
ALKALOID Morphine hydrochloride 20 mg/1 mL	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 1 mL of solution, supplied in a box		YES		YES				
ALKALOID Morphine hydrochloride 4 mg/1 mL	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 amber glass ampoules each containing 1 mL of solution, supplied in a box		YES		YES				
Mostrafin tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES			YES				

Mostrafin tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Movalis 15 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	20 (1x20) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Movalis 15 mg/1.5 mL injection	solution for injection	Boehringer Ingelheim Espana, S.A., Sant Cugat del Valles (Barcelona), Spain	5 ampoules with 1.5 mL of solution, supplied in a box		YES	YES					
Movalis 7.5 mg tablets	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	20 (1x20) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
MST CONTINUS 10 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge,Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/Al), supplied in a box		YES	YES					
MST Continus 10 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njemačka, Mundipharma Ges.m.b.H, Beč, Austria	60 (2x30) tablets in a blister (PVC/PVDC-Al), supplied in a box		YES	YES					
MST Continus 100 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njemačka, Mundipharma Ges.m.b.H, Beč, Austria	60 (2x30) tablets in a blister (PVC/PVDC-Al), supplied in a box		YES	YES					
MST CONTINUS 100 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge,Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/Al), supplied in a box		YES	YES					
MST Continus 30 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njemačka, Mundipharma Ges.m.b.H, Beč, Austria	60 (2x30) tablets in a blister (PVC/PVDC-Al), supplied in a box		YES	YES					
MST CONTINUS 30 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge,Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma	30 (3x10) tablets in ablister (PVdC/PVC/Al), supplied in a box		YES	YES					

		Ges.m.b.H, Vienna, Austria									
MST CONTINUS 60 mg	prolonged-release film coated tablets	Bard Pharmaceuticals Ltd., Cambridge,Great Britain, Mundipharma Gm.b.H., Limburg, Germany, Mundipharma Ges.m.b.H, Vienna, Austria	30 (3x10) tablets in a blister (PVdC/PVC/Al), supplied in a box		YES	YES					
MST Continus 60 mg	film coated tablets with prolonged-release	Bard Pharmaceuticals Limited, Cambridge, Great Britain, Mundipharma Gm.b.H., Limburg, Njemačka, Mundipharma Ges.m.b.H, Beč, Austria	60 (2x30) tablets in a blister (PVC/PVDC-Al), supplied in a box		YES	YES					
Mukolen coated tablets 50 mg	coated tablets	Krka tovarna zdravil, d.d., Novo mesto,Republic of Slovenia in cooperation with E Pharma, France	20 (2x10) coated tablets in PVC/Al blister, supplied in a box		YES		YES				
MULTIBIONTA FORTE N capsules	capsules, soft	Merck Selbstmedikation GmbH, Darmstadt, Germany	20 (2x10) capsules in PVC/PVDC-Al blister, supplied in a box		YES		YES				YES
Myfortic 180 mg tablets	gastric-resistant tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (12x10) tablets in a PA/Al/PVC- Al blister, supplied in a box		YES	YES				YES	
Myfortic 360 mg tablets	gastric-resistant tablets	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	120 (12x10) tablets in a PA/Al/PVC- Al blister, supplied in a box		YES	YES				YES	
Myoflex	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Naclof	eye drops, solution	EXCELVISION, Annonay, France	5 mL of solution in a white plastic (LDPE) bottle with a dropper and a plastic (HDPE) stopper with a safety ring, supplied in a box		YES	YES					
NAGLAZYME 5 mL concentrate for solution for infusion	concentrate for solution for infusion	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	One glass vial with 5 mL of concentrate, supplied in a box		YES	YES		YES	YES		
Naklofen suppositories 50 mg	suppositories	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (2x5) suppositories in a Al/PE//PE/AL strip, supplied in a carton box		YES		YES				
Naklofen duo capsules 75 mg	hard capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) hard capsules in a blister (PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES				
Naklofen gel	gel	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 g of gel in an aluminium tube, supplied in a carton box		YES		YES				YES
Naklofen solution for injection 75 mg/3mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	3 mL solution for injectionin a glass ampoule, 5 ampoules in a box		YES		YES				
Naklofen SR	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) prolonged-release tablets in PVC/Al blister, supplied in a box		YES		YES				

Naklofen gastric-resistant tablets 50 mg	gastric-resistant tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) gastric-resistant tablets in PVC/Al blister, supplied in a box		YES		YES				
Nakom 250 mg / 25 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	100 (10x10) tablets in PVC/Al blister, supplied in a box		YES		YES				
Nalgesin forte 550 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coated tablets in a PVC/Al blister, supplied in a box		YES		YES				
Nalgesin S 275 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) film coated tablets in a PVC/Al blister, supplied in a box		YES		YES				
Nanotiv 1000 IU	powder and diluent for solution for injection	Octapharma AB, Stockholm, Sweden	Box with powder and a box with a bottle containing 10 mL of water for injection, application kit, supplied in a box		YES						
Nanotiv 500 IU	powder and diluent for solution for injection	Octapharma AB, Stockholm, Sweden	Box with powder and a box with a bottle containing 5 mL of water for injection, application kit, supplied in a box		YES						
Nasivin 0.05% nasal spray	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in a whilte plastic bottle with a plastic attachment (with internal atomizing tube) and plastic cap, supplied in a box		YES		YES				YES
Nasivin 0.05% nasal spray without preservative	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES		YES				YES
Nasivin D 0.05% nasal spray	nasal spray, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with a plastic atomizer pump and protective cap, supplied in a box		YES		YES				YES
Nasivin K 0.01% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	5 mL of solution in an amber glass bottle with a plastic stopper and a glass dropper with a rubber pump, supplied in a box		YES		YES				YES
Nasivin K 0.025% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with a yellow plastic cap and glass dropper with rubber bulb, supplied in a box		YES		YES				YES
Nasivin K 0.05% nasal drops	nasal drops, solution	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	10 mL of solution in an amber glass bottle with while plastic cap and glass dropper with rubber bulb, supplied in a box		YES		YES				YES
Nasonex nasal spray	nasal spray, suspension	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	Plastic bottle with an attachment for nasal administration containing 120 doses, supplied in a box		YES	YES					
Natrii chloridi infundibile compositum Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass bottle with a rubber stopper and an aluminium cap with a plastic lid, 10 bottles in a box	YES			YES				
Natrii chloridi infundibile solution for intravenous infusion, 100 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	100 mL in a glass infusion bottle, (10 bottles with plastic holders in a box)	YES			YES				

Natrii chloridi infundibile solution for intravenous infusion, 1000 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	1000 mL in a glass infusion bottle (10 bottles with plastic holders in a box)	YES			YES				
Natrii chloridi infundibile solution for intravenous infusion, 250 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	250 mL in a glass infusion bottle, (10 bottles with plastic hoders, supplied in a box)	YES			YES				
Natrii chloridi infundibile solution for intravenous infusion, 500 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL in a glass infusion bottle (10 bottles with plastic holders, supplied in a box)	YES			YES				
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 bags with 2000 mL of solution, supplied in a box	YES			YES				
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 bags with 1000 mL of solution, supplied in a box	YES			YES				
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	12 bags with 500 mL of solution, supplied in a box	YES			YES				
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 250 mL of solution, supplied in a box	YES			YES				
Natrii chloridi infundibile Pliva	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass vials with 500 mL of solution, supplied in a box	YES			YES				
SODIUM HYDROGENCARBONATE 1-molar solution PLIVA	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 mL of infusion solution in a glass ampoule (clear glass, colourbreak), 10 ampoules in a box	YES			YES				
Sodium chloride 0.9% Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	10 plastic Viaflo bags with sa 1000 mL of infusion solution, in a protective bag, supplied in a box		YES		YES				
Sodium chloride 0.9%, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	50 plastic Viaflo bags with 100 mL of solution for infusion in a protective bag, supplied in a box		YES		YES				
Sodium chloride 0.9% Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES		YES				
Sodium chloride 0.9%, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Viaflo bags with 250 mL of solution for infusion in a protective bag, supplied in a box		YES		YES				
Sodium chloride 0.9%, Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe	50 plastic Viaflo bags with 50 mL of solution for infusion in a protective bag, supplied in		YES		YES				

		Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	a box									
Sodium chloride 10% electrolytes concentrate , 50 mL	concentrate for intravenous use after reconstitution	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	50 mL in a glass injection bottle (40 bottles per bag)	YES			YES					
Natural Wealth Ginkgo Forte	film coated tablets	NBTY Inc., New York, USA	48 (2x24) film coated tablets in a blister (PVC/Al), supplied in a box		YES						YES	
Natural Wealth Vitamin E-200 IU, capsules	capsules	NBTY Inc. New York, USA	100 capsules in a brown plastic bottle, supplied in a box		YES		YES					
Navoban injection 5 mg/5 mL	solution for injection and infusion, oral solution	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 mL of solution in a glass ampoule, 10 ampoules in a box		YES	YES						
Navoban capsules 5 mg	capsules, hard	Novartis Farmacéutica S.A., Ronda Santa María 158, Barcelona, Spain	5 (1x5) capsules in a blister (PVC/PVDC//Al), supplied in a box		YES	YES						
Nazol 0.05% nasal drops, solution	nasal drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES			YES				YES	
Nazol 0.1% nasal drops, solution	nasal drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES			YES				YES	
Nebido 1000 mg/4 mL solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	4 mL of solution in an amber glass ampoule, 1 ampoule in a box		YES	YES		YES		YES		
Nebilet	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	14 (2x7) tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES		YES		
Nebilet	tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	14 (1x14) tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES		YES		
Neloren 300 mg/mL injection	solution for injection for intramuscular use and intravenus infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 ampoules each containing 1 mL of solution, supplied in a box		YES		YES					
Neloren 600 mg/2 mL injection	solution for injection for intramuscular use and intravenus infusion	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 ampoules each containing 2 mL of solution, supplied in a box		YES		YES					
Neo-angin sugar-free lozenges	lozenges	DIVAPHARMA GmbH, Motzener Straße 41, Berlin, Germany	24 (2x12) lozenges in a PVC/PE/PVDC-Al blister, supplied in a box		YES		YES				YES	
Neo-angin lozenges	lozenges	DIVAPHARMA GmbH, Motzener Straße 41, Berlin, Germany	24 (2x12) lozenges in a PVC/PVDC-Al blister, supplied in a box		YES		YES				YES	
Neodolpasse	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Box with 10 glass bottles with 250 mL of solution		YES		YES					
Neofen 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (2x10) tablets in a blister (PVC/Al) , supplied in a box	YES			YES				YES	
Neofen forte	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica,	10 (1x10) tablets in a PVC/Al blister, supplied in a carton box	YES			YES				YES	

		Republic of Croatia									
NeoRecormon 10.000 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.6 mL of solution, in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 1000 IU solution for injection in a pre-filled syringe	solution for in injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 2000 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 30.000 IU solution for injection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	One glass syringe (with needle) containing 0.6 mL of solution, in a protective container, supplied in a carton box		YES	YES			YES		
NeoRecormon 3000 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 4000 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 500 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution, in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon 6000 IU solution for in ajection in a pre-filled syringe	solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	6 (2x3) glass syringes (with a needle) each with 0.3 mL of solution in protective packaging, supplied in a carton box		YES	YES			YES		
NeoRecormon Multidose 100 000 IU powder and diluent for solution for injection	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	Vial with powder for solution for injection and ampoule with diluent, supplied in a box		YES	YES			YES		
NeoRecormon Multidose 50 000 IU powder and diluent for solution for injection	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	Vial with powder for solution for injection and ampoule with diluent, supplied in a carton box		YES	YES			YES		
Neostigmin injection	solution for injection (for i.m., i.v. and s.c.use)	Rotexmedica GmbH, Trittau, Germany	1-mL of solution in an amber glass ampoule, 10 ampoules in a box		YES		YES				
Neotigason capsules 10 mg	capsules, hard	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) capsules in a blister (PVC/PE/PVDC//Al) , supplied in a box		YES	YES					
Neotigason capsules 25 mg	capsules, hard	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) capsules in a blister (PVC/PE/PVDC//Al) , supplied in a box		YES	YES					
Nephrotect	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 250 mL (10x250mL) of solution, supplied in a carton box		YES		YES				

Nephrotect	solution for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass infusion bottles with 500 mL (10x500mL) of solution, supplied in a carton box		YES		YES				
Netromycine injection 150 mg/1.5 mL	solution for injection for intramuscular and intravenous use	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	1.5-mL of solution in a glass vial, supplied in a box		YES	YES					
Neupogen 30	solution for injection (for s.c. and i.v. use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with needle containing 0.5 mL of solution, in a plastic container, supplied in a box		YES	YES					
Nexavar 200 mg film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	112 (4x28) tablets in transparent (PP/Al) blister, supplied in a box		YES	YES		YES	YES		
Nexium 20 mg	gastric-resistant tablets	AstraZeneca AB, Södertälje, Sweden	14 (2x7) tablets in a A/Al blister, supplied in a box		YES	YES					
Nexium 40 mg	gastric-resistant tablets	AstraZeneca AB, Södertälje, Sweden	14 (2x7) tablets in a A/Al blister, supplied in a box		YES	YES					
Nexium i.v. 40 mg	powder for preparation of injection/infusion solution	AstraZeneca AB, Södertälje, Sweden	10 bottles, supplied in a box		YES	YES					
Niaspan 1000 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 1000 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 375 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 375 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 500 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 500 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 750 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany Merck SANTE s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
Niaspan 750 mg tablets	prolonged-release tablets	Merck KGaA, Darmstadt, Germany, Merck Santé s.a.s., Semoy, France	14 (1x14) tablets in a blister (PVC/PE/Aclar-Al), supplied in a box		YES		YES				
NIBEL 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box	YES			YES				
Nicorette Freshmint Gum 2 mg	chewing gum	Pfizer Health AB, Norrbroplatsen 2, Helsingborg, Sweden	15 (1x15) chewing gums in a blister (PVC/PVDC//Al), supplied in a box		YES		YES			YES	
Nicorette Freshmint Gum 4 mg	chewing gum	Pfizer Health AB, Norrbroplatsen 2, Helsingborg, Sweden	15 (1x15) chewing gums in a blister (PVC/PVDC//Al), supplied in a box		YES		YES			YES	
Nicorette patch 10 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2,	7 (7x1) transdermal patches in a protective (PE/A1/Barex)		YES		YES			YES	

		Helsingborg, Sweden	bag, supplied in a box								
Nicorette patch 15 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2, Helsingborg, Sweden	7 (7x1) transdermal patches in a protective (PE/A1/Barex) bag, supplied in a box		YES		YES				YES
Nicorette patch 5 mg/16 h	transdermal patch	Pfizer Health AB, Norrbroplasten 2, Helsingborg, Sweden	7 (7x1) transdermal patches in a protective (PE/A1/Barex) bag, supplied in a box		YES		YES				YES
Nifedipin retard 20 mg tablets	prolonged release tablets	Farmal d.d., Ludbreg, Republic of Croatia, in cooperation with Valpharma Int. s.a., San Marino	Box with 30 tablets (blister, 3x10 tbl.)	YES			YES				
Nimotop S film coated tablets	film coated tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	100 (10x10) film coated tablets in PP/Al blisters, supplied in a box		YES	YES					
Nimotop S solution for infusion	solution for infusion	Bayer HealthCare AG, 51368 Leverkusen, Germany	50 mL of solution for infusion in an amber glass bottle and a plastic (PE) infusion pipe, supplied in a box		YES	YES					
Ninur 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Box with 30 capsules (blister, 3x10 capsules)	YES			YES				
NINUR 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/Al blister, supplied in a box	YES			YES				
Niquitin CQ 14 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/Al/acrylonitrile) bag, supplied in a box		YES		YES			YES	YES
Niquitin CQ 21 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/Al/acrylonitrile) bag, supplied in a box		YES		YES			YES	YES
Niquitin CQ 7 mg	transdermal patch	Cardinal Health, Northamptonshire, Great Britain; Cardinal Health, Westhoughton, Bolton, Great Britain	7 (7x1) transdermal patches in a protective (PET/LDPE/Al/acrylonitrile) bag, supplied in a box		YES		YES			YES	YES
Nistatin Pliva drops	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Amber glass bottle with a dropper containing powder, supplied in a box	YES			YES				
Nistatin Pliva ointment	ointment	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Aluminum tube containing 20 g of ointment, supplied in a box	YES			YES				
Nitrolingual aerosol	sublingual spray	G.Pohl- Boskamp GmbH&Co., Germany	12.2 mL of solution in a clear glass bottle (coated with red plastic layer on the outside) with metering pump and plastic spray activator with plastic protective cap, supplied in a box		YES		YES				
Nolicin film coated tablets 400 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Noliprel 2 mg/0.625 mg	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd.,	30 (1x30) tablets in a blister (PVC/Al) inserted into a protective bag (PE/Al/PE) with desiccant, supplied in a box		YES	YES					

		Arcklow, Co. Wicklow, Republic of Ireland									
Nolpaza 20 mg	gastric-resistant film-coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Nolpaza 40 mg	gastric-resistant film-coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Nolvadex tablets	film tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	30 (3x10) tablets in an aluminium blister, supplied in a box		YES	YES					
Norcuron 4 mg	powder for solution for i.v. Injection	N.V. Organon, Oss, the Netherlands; Organon S.A., Eragny Sur Epte, France	50 ampoules with powder and 50 ampoules with 1 mL of water for injection, supplied in a box		YES	YES					
Norditropin SimpleXx 10 mg/1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES				YES	
Norditropin SimpleXx 15 mg/ 1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES				YES	
Norditropin SimpleXx 5 mg/1.5 mL	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass cartridge with 1.5 mL of solution (with a rubber plunger and rubber stopper with aluminium ring and plastic closure) in a plastic container, supplied in a box		YES	YES				YES	
Normabel 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
Normabel 10 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	10 amber glass ampoules each containing 2 mL of solution, supplied in a box	YES			YES				
Normabel 2 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (1x30) film coated tablets in a PVC/Al blister, supplied in a box	YES			YES				
Normabel 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	31 (1x30) film coated tablets in a PVC/Al blister, supplied in a box	YES			YES				
Norprolac tablets 150 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	30 (3x10) tablets in a blister (A1/A1), supplied in a box		YES	YES				YES	
Norprolac tablets 25 µg/ 50 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	3 tablets of 25 µg + 3 tablets of 50 µg in a blister(PVC/PVDC//A1), inserted a protective aluminium sachet, supplied in a box		YES	YES				YES	
Norprolac tablets 75 µg	tablets	Ferring GmbH, Wittland 1, Kiel, Germany	31 (3x10) tablets in a blister (A1/A1), supplied in a box		YES	YES				YES	

Novantrone 20 concentrate for preparation of infusion solution	concentrated solution for infusion	Wyeth Medica Republic of Ireland, Co. Kildare, Republic of Ireland and Wyeth Lederle S.p.A., Catania, Italy	Vial with 10 mL of concentrated solution and stopper with aluminium cap, supplied in a box		YES	YES					
Novocef tablets 125 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES				
Novocef tablets 250 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES				
Novocef tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film tablets in a blister, supplied in a box	YES			YES				
Novofem	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 tablets (16 red and 12 white tablets) in a plastic, circular calendar pack, supplied in a box		YES	YES					
NovoMix 30 FlexPen	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Alle, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	Box with 5 injection devices each with 3 mL of suspension in a glass cartridge		YES	YES		YES	YES		
NovoMix 30 Penfill	suspension for subcutaneous injection	Novo Nordisk A/S, Novo Alle, Bagsvaerd, Denmark Novo Nordisk Production SAS, 45, Avenue d' Orleans, Chartres, France	5 glass cartridges with 3 mL of suspension in a blister, supplied in a box		YES	YES		YES	YES		
NovoMix 50 FlexPen	suspension for injections, cartridge in a pre-filled pen	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens (injectors) with a glass cartridge containing 3 mL of suspension, supplied in a box		YES	YES			YES		
NovoMix 50 Penfill	suspension for injection in a cartridge	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges each with 3 mL of suspension in protective packaging, supplied in a box		YES	YES			YES		
NovoMix 70 FlexPen	suspension for injection, cartridge in a pre-filled pen	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 pens (injectors) with a glass cartridge containing 3 mL of suspension, supplied in a box		YES	YES			YES		
NovoMix 70 Penfill	suspension for injection in a cartridge	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 glass cartridges each with 3 mL of suspension in protective packaging, supplied in a box		YES	YES			YES		
NovoNorm 0.5 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
NovoNorm 1 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
NovoNorm 2 mg	tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	30 (2x15) tablets in a blister, supplied in a box		YES	YES					
NovoRapid	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with 10 mL of solution, supplied in a box		YES	YES					
NovoRapid FlexPen	solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	5 injectors, with 3 mL of solution per glass cartridge, supplied in a box		YES	YES					

NovoRapid Penfill	solution for injection	Novo Nordisk A/S, Bagsvaerd, Denmark i Novo Nordisk Productions SAS, Chartes, France	5 glass cartridges each with 3 mL of solution in protective packaging, supplied in a box		YES	YES		YES	YES		
NovoSeven 1.2 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 2.2 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set		YES	YES		YES	YES		
NovoSeven 2.4 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 4.3 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set		YES	YES		YES	YES		
NovoSeven 4.8 mg	powder and diluent for solution for injection	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	One glass vial with powder and one glass vial with 8.5 mL of Water for Injection in a box, one sterile attachment for reconstitution vial, one disposable sterile syringe for reconstitution and administration of medicinal product, one sterile infusion set		YES	YES		YES	YES		
Novuroxim injection 1500 mg	powder for preparation of solution for i.v. injection	Pliva Krakow, Krakow, Poland	5 (20 mL) glass bottles with powder, supplied in a box		YES		YES				
Novuroxim injection 250 mg	powder for preparation of solution/suspension for i.m. and i.v. injection	Pliva Krakow, Krakow, Poland	5 (7.5 mL) glass bottles with powder, supplied in a box		YES		YES				
Novuroxim 750 mg injection	powder for preparation of solution/suspension for i.m. and i.v. injection	Pliva Krakow, Krakow, Poland	5 (10 mL) glass bottles with powder, supplied in a box		YES		YES				
Novuroxim tablets 125 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Novuroxim tablets 250 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Novuroxim tablets 500 mg	film tablets	Pliva Krakow, Krakow, Poland	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Nozid 5 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 tablets in an amber glass bottle, supplied in a box	YES			YES				
Nozinan 100 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gualle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Nozinan 100 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES					

Nozinan 25 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Nozinan 25 mg tablets	film coated tablets	Famar Lyon, 29 Avenue du General de Gaulle 69230 Saint Genis Laval, France	20 (2x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
NUROFEN Cold and Flu film coated tablets	film coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) film coated tablets in PVC/PVdC/Al blister, supplied in a box		YES		YES				YES
NUROFEN Cold and Flu film coated tablets	film coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) film coated tablets in PVC/PVdC/Al blister, supplied in a box		YES		YES				YES
Nurofen Liquid capsules	capsules, soft	Reckitt Benckiser Healthcare International Ltd., Nottingham, Great Britain, in cooperation with Banner Pharmacaps Europe B.V., Tilburg, the Netherlands	10 (1x10) capsules in a PVC/PVdC/Al blister, supplied in a box		YES		YES				YES
Nurofen Liquid capsules	capsules, soft	Reckitt Benckiser Healthcare International Ltd., Nottingham, Great Britain in cooperation with Banner Pharmacaps Europe B.V., Tilburg, the Netherlands	10 (1x10) capsules in a PVC/PVdC/Al blister, supplied in a box		YES		YES				YES
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a carton box		YES		YES				YES
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a plastic box		YES		YES				YES
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a plastic box		YES		YES				YES
NUROFEN coated tablets	coated tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) coated tablets in a PVC/PVdC/Al blister, supplied in a carton box		YES		YES				YES
NUROFEN oral suspension for children	oral suspension	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great	101 mL of suspension in a brown plastic (PET) bottle with temper-proof closure with protective plastic ring, and 5-mL graduated plastic		YES		YES				

		Britain	syringe, supplied in a box								
NUROFEN oral suspension for children	oral suspension	Boots Contract Manufacture Ltd., Nottingham, Great Britain or Hermal Kurt Herrmann GmbH&Co., Reinbeck, Germany	100 mL of suspension in a brown plastic (PET) bottle with temper-proof closure with protective plastic ring, and 5-mL graduated plastic syringe, supplied in a box		YES		YES				
Nutrineal PD4 with 1.1% amino acids	solution for peritoneal dialysis	BAXTER Healthcare S.A., Monreen Road, Castlebar, County Mayo, Republic of Ireland	Plastic (PVC) Viaflex bag containing 2000 mL of solution for peritoneal dialysis, feeding tube (PVC), connector with protective cap, drain tube, drug administration attachment and a Vialex plastic collection bag (individual packages)		YES		YES				
NuvaRing	intravaginal ring	N.V. Organon, Oss, The Nederlands; Organon Republic of Ireland Ltd., Co. Dublin, Republic of Ireland	Intravaginal ring in protective Al sachet, supplied in a box		YES	YES				YES	
OCTAGAM 1 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 20 mL of solution for infusion, supplied in a box		YES						
OCTAGAM 10 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 200 mL of solution for infusion, supplied in a box		YES						
OCTAGAM 2.5 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial containing 50 mL of solution for infusion, supplied in a box		YES						
OCTAGAM 5 g	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria, Octapharma S.A.S., Lingolsheim, France and Octapharma AB, Stockholm, Sweden	One glass vial with 100 mL of solution for infusion, supplied in a box		YES						
Octaplas SD blood type 0	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film		YES						
Octaplas SD blood type A	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film		YES						
Octaplas SD blood type AB	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film		YES						

Octaplas SD blood type B	solution for infusion	Octapharma Pharmazeutika Produktionsges.m.b.H., Vienna, Austria	200 mL of solution in sterile PVC transfusion bags coated with polyamide/polyethylene film		YES						
Octenisept	solution	Schulke & Mayr GmbH, Norderstedt, Germany	50 mL of solution in a plastic bottle with a spray pump		YES		YES				YES
Oikamid	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 60 capsules in a blister (5x12)	YES			YES				
Oikamid injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 ampoules each containing 5 mL of solution, supplied in a box	YES			YES				
Oikamid injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 ampoules each containing 5 mL of solution, supplied in a box	YES			YES				
Oikamid capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 60 capsules in a blister (5x12)	YES			YES				
Oksazepam 10 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3X10) tablets in a PVC/Al foil blister, supplied in a carton box	YES			YES				
Oksazepam 30 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Olanzapin CIPLA 10 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	30 (3x10) film coated tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Olanzapin CIPLA 2.5 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	31 (3x10) film coated tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Olanzapin CIPLA 5 mg	film coated tablets	Cipla Ltd., Kurkumbh Industrial Area, Maharashtra State, India	32 (3x10) film coated tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Olicard 40 mg retard	prolonged release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister (PVC/Al), supplied in a box	YES			YES				
Olicard 60 mg retard	prolonged release capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 (5x10) capsules in a blister (PVC/Al), supplied in a box	YES			YES				
OliClinomel N4 - 550E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES					
OliClinomel N4 - 550E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag with 1000 mL of blend (in three separate compartments) in a plastic protective casing, 6 bags in a carton box		YES	YES					
OliClinomel N6 - 900 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES					

OliClinomel N7 - 1000 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag for 2000 mL of blend (in three separate compartments) in a plastic protective casing, 4 bags in a box		YES	YES					
OliClinomel N7 - 1000 E	emulsion for infusion	Clintec Parenteral S.A., France; Baxter S.A., Lessines, Belgium	Plastic bag with 1000 mL of blend (in three separate compartments) in a plastic protective casing, 6 bags in a carton box		YES	YES					
Olivin 10 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Olivin 20 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Olivin 5 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Olynth 0.05% nasal spray	nasal spray, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with a plastic atomizer extension and protective cap, supplied in a box		YES		YES				YES
Olynth 0.1% nasal drops	nasal drops, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with dropper, supplied in a box		YES		YES				YES
Olynth 0.1% nasal spray	nasal spray, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with a plastic atomizer extension and protective cap, supplied in a box		YES		YES				YES
Olynth 0.5% nasal drops	nasal drops, solution	Pfizer PGM, Orleans Cedex, France	10 mL of solution in an amber glass bottle with dropper, supplied in a box		YES		YES				YES
Olynth HA 0.05% nasal spray	nasal spray, solution	URSAPHARM Arzneimittel GmbH&Co., Saarbrucken, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES		YES				YES
Olynth HA 0.1% nasal spray	nasal spray, solution	URSAPHARM Arzneimittel GmbH&Co., Saarbrucken, Germany	10 mL of solution in a white plastic bottle with a 3K system and protective cap, supplied in a box		YES		YES				YES
Omacor	capsules (soft, transparent, gelatinous)	Solvay Pharmaceuticals GmbH, Neustadt, Germany	28 capsules in a plastic bottle		YES	YES				YES	
Omegaven	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass bottles with 100 mL of emulsion (10x100 mL), supplied in a box		YES		YES				
Omegaven	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	10 glass bottles with 50 mL of emulsion (10x50 mL), supplied in a box		YES		YES				
Omezol capsules 20 mg	gastric-resistant capsules, hard	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	14 (2x7) capsules in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Omnic 0.4 mg	prolonged-release capsules	Astellas Pharma Europe B.V., Elisabethhof 19, Leiderdorp, the	Box with 3x10 prolonged release capsules in an Al/polypropylene blister		YES	YES					

		Netherlands										
Omnipaque 240 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 10 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 100 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 50 mL of solution, supplied in a box		YES	YES						
Omnipaque 300 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 10 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	6 bottles with 200 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	25 bottles each with 20 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 50 mL of solution, supplied in a box		YES	YES						
Omnipaque 350 solution	solution for injection/infusion	Amersham Health IDA Business Park, Carrigtwohill, Co. Cork, Republic of Ireland	10 bottles containing 100 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 glass bottles with 20 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 glass bottles with 10 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 20 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 10 mL of solution, supplied in a box		YES	YES						
Omniscan 0.5 mmol/mL solution for injection (pre-filled syringe)	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	10 plastic syringes with 5 mL of solution, supplied in a box		YES	YES						
Opatanol 1 mg/mL eye drops	eye drops	Alcon Couvreur N.V., Rijksweg 14, Puurs, Belgium; Alcon Cusi S.A., Camil Fabra 58, El Masnou, Barcelona, Spain	Plastic bottle (low density polyethylene) with a dropper and a stopper (polypropylene) containing 5 mL of solution, supplied in a box		YES	YES						
Operil 0.05% nasal drops	nasal drops	Lek farmacevtska družba d.d.,	10 mL of solution in a plastic bottle with a dropper,		YES		YES				YES	

		Verovškova 57, Ljubljana, Republic of Slovenia	supplied in a box								
Operil 0.05% nasal spray	nasal spray (solution)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic box with atomizer extension, supplied in a box		YES		YES				YES
Operil P 0.025% nasal drops	nasal drops	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic bottle with a dropper, supplied in a box		YES		YES				YES
Operil P 0.025% nasal spray	nasal spray (solution)	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of solution in a plastic box with atomizer extension, supplied in a box		YES		YES				YES
Optimon 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Optimon 20 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in ablister (PVC/Al), supplied in a box	YES			YES				
Optimon 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Optimon Plus 10/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/PVDC/Al), supplied in a box	YES			YES				
Optimon Plus 20/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (PVC/PVDC/Al), supplied in a box	YES			YES				
Ormidol 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				
Ormidol 25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets (3x10) in a PVC/Al blister, supplied in a box	YES			YES				
Ormidol 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets (3x10) in a PVC/Al blister, supplied in a box	YES			YES				
Oronazol cream	cream	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 g of cream in a tube, supplied in a box		YES		YES				
Oronazol shampoo	shampoo	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	100 mL of shampoo in a plastic bottle, supplied in a box		YES	YES					YES
Oronazol tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				

Ortalox 10 mg	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	14 capsules in a plastic bottle (HDPE), supplied in a box	YES			YES				
Ortalox 20 mg	capsules	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	14 capsules in a plastic bottle (HDPE), supplied in a box	YES			YES				
Ortanol 20 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 capsules in an amber glass bottle, supplied in a box		YES		YES				
Ortanol 40 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 (1x7) capsules in a blister, supplied in a box		YES		YES				
Ortanol S 10 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	7 (1x7) capsules in a blister, supplied in a box		YES		YES				
Ortanol S 10 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	28 (4x7) capsules in a blister, supplied in a box		YES		YES				
Osseor 2 g	granules for oral suspension	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	7 bags (paper/PE/Al/PE) with granules, supplied in a box		YES	YES			YES		
OVITRELLE 250 mg	powder and diluent for preparation of solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy	Vial with powder and vial with diluent with 1 mL of Water for Injection, supplied in a box		YES	YES			YES		
OVITRELLE 250 micrograms/0.5 mL	solution for injection in a syringe	Industria Farmaceutica Serono S.p.A., Bari, Italy	One glass syringe with needle in a plastic container, supplied in a box		YES	YES			YES		
Oxaliplatin Pliva 100 mg	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for solution for infusion in a glass bottle (50 mL) with a rubber stopper, aluminium ring and plastic cap, supplied in a box	YES			YES				
Oxaliplatin Pliva 50 mg	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Powder for solution for infusion in a glass bottle (26 mL) with a rubber stopper, aluminium ring and plastic cap, supplied in a box	YES			YES				
Oxetin film coated tablets 20 mg	film coated tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina in cooperation with JMP, Jordan	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES				
OxyContin 10 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin 20 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin 40 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES					

		GES.m.b.H., Vienna, Austria									
OxyContin 80 mg	prolonged-release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 tablets (3x10) in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin tablets 10 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin tablets 20 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin tablets 40 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES					
OxyContin tablets 80 mg	prolonged release tablets	Bard Pharmaceuticals Ltd., Cambridge, Great Britain	56 (4x14) tablets in a PVC/Al blister, supplied in a box		YES	YES					
Paclitaxel Ebewe 150 mg/25 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	25 mL of solution in a glass bottle, supplied in a box		YES		YES				
Paclitaxel Ebewe 30 mg/5 mL	concentrate of solution for infusion	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	5 mL of solution in a glass bottle, supplied in a box		YES		YES				
Paclitaxel Pliva 100 mg/16.7 mL	concentrate for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial in a box	YES			YES				
Paclitaxel Pliva 30 mg/5 mL	concentrate for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One glass vial in a box	YES			YES				
PACLITAXEL PLIVA 300 mg/50 mL	concentrate of solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 mL of solution concentrate in a glass bottle (multy dose vial) with a rubber stopper, an aluminium cap and a protective lid, supplied in a box	YES			YES				
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	16.7 mL of concentrate for infusion solution in a clear glass bottle with teflon-coated rubber (bromobutyl) stopper and aluminium ring with plastic (PP) lid, supplied in a box		YES		YES	YES		YES	
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	5 mL of solution for infusion concentrate in a colourless glass bottle with a rubber (bromobutyl) stopper coated with Teflon and an Al ring with a plastic (PP) lid, supplied in a box		YES		YES	YES		YES	
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	25 mL of concentrate for infusion solution in a clear glass bottle with rubber (bromobutyl) stopper coated with teflon and Al ring with plastic (PP) lid, supplied in a box		YES		YES	YES		YES	
Paclitaxin 6 mg/mL	concentrate of solution for infusion	Pharmachemie B.V., Haarlem, the Netherlands	50 mL of solution for infusion concentrate in a colourless glass bottle with a rubber (bromobutyl) stopper coated with Teflon and an aluminium		YES		YES	YES		YES	

			ring with a plastic (PP) lid, supplied in a box								
Palladone SR capsules 16 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Palladone SR capsules 4 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Palladone SR capsules 8 mg	prolonged-release capsules	Mundipharma Ges.m.b.H., Vienna, Austria	56 (4x14) capsules in a blister (PVDC/PVC//Al), supplied in a box		YES	YES					
Pamitor 15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	One clear glass ampoule containing 4 mL of solution, supplied in a box		YES		YES				
Pamitor 15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 2 mL of solution, supplied in a box		YES		YES				
Pamitor 15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	A clear glass ampoule containing 6 mL of solution, supplied in a box		YES		YES				
Pamitor 15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 4 mL of solution, supplied in a box		YES		YES				
Pamitor15 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Torrex-Pharma GmbH, Vienna, Austria	Polyethylene ampoule containing 6 mL of solution, supplied in a box		YES		YES				
Pamitor15 mg/mL concentrate for infusion solution	concentrate for infusion solution	Torrex-Pharma GmbH, Vienna, Austria	One clear glass ampoule containing 2 mL of solution, supplied in a box		YES		YES				
Panadol	film coated tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in a PVC/Al blister, supplied in a box		YES		YES				YES
Panadol Baby	oral suspension	Glaxo Wellcome Production, Avenue du General de Gaulle, Herouville Saint Clair, France	300 mL of suspension in an amber glass bottle with a plastic temper-evident stopper and a plastic measuring device (0.5 mL to 8 mL), supplied in a box		YES		YES				YES
Panadol Baby	oral suspension	Glaxo Wellcome Production, Avenue du General de Gaulle, Herouville Saint Clair, France	100 mL of suspension in an amber glass bottle with plastic temper-proof closure and plastic dispenser (0.5 mL to 8 mL), supplied in a box		YES		YES				YES
Panadol Extra	film coated tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in PVC/Al blister, supplied in a carton box		YES		YES				YES
Panadol Rapid	film coated tablets	GlaxoSmith Kline Dungarvan Limited, Republic of Ireland	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				YES
Panaze 10000 capsules	capsules (with gastric-resistant microfilm tablets)	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 capsules in an amber glass bottle, supplied in a box		YES		YES				
Pancuronium injection BP 4 mg	solution for intravenous injection	Rotexmedica GmbH, Trittau, Germany	2 mL of solution in a glass ampoule, 10 ampoules in a box		YES		YES				
Pankreoflat	coated tablets	Solvay Pharmaceuticals GmbH, Hannover, Germany	50 (2x25) tablets in a blister, supplied in a box		YES		YES				YES

Pantexol cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an aluminium tube with plastic cap, supplied in a box	YES			YES				YES
Pantexol ointment	ointment	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of ointment in an aluminium tube with plastic cap, supplied in a box	YES			YES				YES
Paracetamol JADRAN syrup 150 mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in an amber glass bottle and a plastic measuring glass, supplied in a box	YES			YES				YES
Paraplatin 150 mg/15 mL concentrate for solution for infusion	concentrate of solution for infusion	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	15 mL of concentrate for infusion solution in a glass bottle, supplied in a box		YES	YES					
Paraplatin 50 mg/5 mL concentrate for solution for infusion	concentrate of solution for infusion	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	5 mL of solution for infusion concentrate in a glass bottle, supplied in a box		YES	YES					
Partobulin SDF 1250 IU	solution for injection	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	Box with one pre-filled syringe and a needle with one dose of 250 ug (1250 IU) of preparation		YES						
Patentex Oval N	pessary	Merz Pharma GmbH & Co KGaA, Frankfurt am Main, Germany	6 (1x6) pessaries in a PVC/PVDC/PE strip, supplied in a box		YES		YES				YES
Pavulon 4 mg=2 mL	solution for injection	N.V. Organon, Oss, the Netherlands; Organon S.A., Eragny Sur Epte, France	50 ampoules with 2 mL of solution, supplied in a box		YES	YES					
PEDIACEL vaccine against diphtheria, tetanus, pertussis (acellular, five component), poliomyelitis (inactivated) and Haemofilus influenzae type B (conjugated), absorbed	suspension for injection	Sanofi Pasteur Limited, Toronto, Canada	0.5-mL of suspension in a glass bottle (glass type I, Ph.Eur), with a bromobutyl stopper that does not contain latex, supplied in a box		YES						
PEGASYS 135 micrograms of solution for injection in pre-filled syringe	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Box with 1 syringe containing 0.5 mL of solution and a needle		YES	YES		YES	YES		
PEGASYS 180 micrograms of solution for injection in pre-filled syringe	solution for injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Box with 1 syringe containing 0.5 mL of solution and a needle		YES	YES		YES	YES		
PegIntron 100 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES		
PegIntron 100 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES		
PegIntron 120 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent		YES	YES			YES		

			cotton-wool roll, supplied in a box								
PegIntron 120 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES		
PegIntron 150 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES		
PegIntron 150 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES		
PegIntron 50 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES		
PegIntron 50 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES		
PegIntron 80 ug powder and diluent for injection solution	powder and diluent for preparation of solution for injection	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Vial containing powder and ampoule with diluent for solution for injection (Water for Injection), one syringe for injection, two needles for injection and one absorbent cotton-wool roll, supplied in a box		YES	YES			YES		
PegIntron 80 ug powder and diluent for solution for injection in syringe with cartridge	powder and diluent for solution for injection in a cartridge	Schering-Plough (Brinny) Company, Innishannon, County Cork, Republic of Ireland	Syringe with cartridge containing powder and diluent for solution for injection (Water for injection), one injection needle and two absorbent cotton wool rolls, supplied in a box		YES	YES			YES		
Penbritin injection 1 g	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 colourless glass bottles with powder, supplied in a box	YES			YES				
Penbritin injection 500 mg	powder for solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 colourless glass bottles with powder, supplied in a box	YES			YES				
Pentamon	film coated tablets with prolonged-release	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/Al) blister, supplied in a box	YES			YES				

Pentasa 1 g suppositories	suppositories	Ferring A/S, Vanlose, Denmark	28 (4x7) suppositories in an aluminium blister, supplied in a box		YES	YES					
Pentasa 1 g suspension for rectal administration	suspension for rectal administration	Ferring-Lečiva a.s., Jesenice u Prahy, Czech Republic	7 individually packed containers (in bags) with 100 mL of suspension and an application attachment, in a protective bag and 7 plastic hygiene bags, supplied in a box		YES	YES					
Pentasa 500 mg tablets	prolonged release tablets	Ferring A/S, Vanlose, Denmark; Ferring Intercontinental Center SA, St-Prex, Switzerland	100 (10x10) tablets in auminum blisters, supplied in a box		YES	YES					
PENTAXIM, diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated), and Haemophilus influenzae type B conjugated vaccine	powder and suspension for suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with a glass bottle with powder and a glass syringe with 0.5 mL of suspension with a needle and a needle protection		YES						
PENTILIN solution for injection 100 mg/5 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 mL of solution for injection in a glass ampoule, 5 ampoules in a box		YES		YES				
PENTILIN tablets 400 mg	prolonged-release tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) prolonged-release tablets in PVC/Al blister, supplied in a box		YES		YES				
Peptoran 75 tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film coated tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES			YES	
Perfalgan 10 mg/mL	solution for infusion	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	One glass vial with 100 mL of solution for infusion, 12 vials in a transparent protective container (polyethylene with thermo film)		YES		YES	YES		YES	
Perfalgan 10 mg/mL	solution for infusion	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	One glass vial with 50 mL of solution for infusion, 12 vials in a transparent protective container (polyethylene with thermo film)		YES		YES	YES		YES	
Persantin 75 mg coated tablets	coated tablets	Boehringer Ingelheim France, 12, Rue Andre Huet, Reims, Cedex, France	50 coated tablets in a white plastic container (PP) with a white stopper (PE), supplied in a box		YES		YES				
Persen sugar-coated tablets	sugar-coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 40 sugar coated tablets (blister, 4x10 sugar coated tablets)		YES					YES	
Persen forte capsules	capsules, hard	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	20 (2x10) capsules in a (PVC/PCTFE//Al) blister, supplied in a box		YES					YES	
Persen forte capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	Box with 20 capsules (blister, 2x10 capsules)		YES					YES	
Persen tablets	coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 (4x10) coated tablets in a blister (PVC/TE/PVDC//Al), supplied in a box		YES					YES	
Phenobarbiton sodium injection	powder (lyophilisate) and diluent for preparation of injections	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules with powder and 5 ampoules each with 2 mL of solvent (water for injection), supplied in a box	YES			YES				

PHENOBARBITON PLIVA 100 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/Al), supplied in a box	YES			YES				
PHENOBARBITON PLIVA15 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in an orange blister (PVC/Al), supplied in a box	YES			YES				
PHOLCODIN 10 mg capsules	capsules	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 capsules in an amber glass bottle, supplied in a box		YES		YES				
PHOLCODIN 15 mg/15 mL oral solution	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	150 mL of solution in an amber glass bottle with plastic closure and 15-mL plastic dispenser, supplied in a box		YES		YES				
PHOLCODIN 4 mg/5 mL oral solution for children	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	60 mL of solution in an amber glass bottle with a plastic stopper and a plastic measuring unit of 2.5 mL, supplied in a box		YES		YES				
Physiotens 0.2	film coated tablets	Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	28 (1x28) film coated tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Physiotens 0.4	film coated tablets	Solvay Pharmaceuticals S.A.S., Châtillon sur Chalaronne, France	28 (1x28) film coated tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Pigrel	film coated tablets	Jadran -Galenski laboratorij d.d., Rijeka in cooperation with Krka Farma d.o.o., Zagreb	28 (4x7) tablets in a blister, supplied in a box	YES			YES				
Pilfud 2% lotion	lotion	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	60 mL of lotion in an amber glass bottle, supplied in a box		YES		YES				YES
Pilfud 5% lotion	skin spray, solution	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	60 mL of solution in a plastic bag with a spray pump and a temper-evident stopper, supplied in a box		YES		YES				YES
Piramil 1.25 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a strip , supplied in a box		YES		YES				
Piramil 10 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES				
Piramil 2.5 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES				
Piramil 5 mg tablets	tablets	LEK S.A., Stryków, Poland; LEK S.A., Warszawa, Poland	28 (7x4) tablets in a blister, supplied in a box		YES		YES				
"Planinski čaj" - herbal laxative tea	herbal laxative tea	Trešnjevka laboratorij d.o.o., Jukićeva 32, Zagreb, Republic of Croatia	75 g of tea in a plastic (PP) bag, supplied in a box	YES							YES
Platinex 10 mg/20 mL concentrate for infusion solution	concentrate for infusion solution	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	20 mL of infusion solution concentrate in an amber glass bottle, supplied in a box		YES	YES					
Platinex 50 mg/100 mL concentrate for infusion solution	concentrate for infusion solution	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	100 mL of concentrate for infusion solution in an amber glass bottle, supplied in a box		YES	YES					

Plavix	film coated tablets	Sanofi Winthrop Industrie, Ambares et Lagrave, Carbon Blanc Cedex, France	28 (2x14) film coated tablets in a blister (Al/Al), supplied in a box		YES	YES			YES		
PLICET EFFECT tablets	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) film coated tablets in an orange PVC/PVDC//Al blister, supplied in a box	YES			YES				YES
Plicet syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL spoon, supplied in a box	YES			YES				YES
Plicet tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in PVC/Al blister, supplied in a box	YES			YES				YES
Plicet tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				YES
Plimycol cream	cream	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 grams of cream in an aluminium tube, supplied in a box	YES			YES				
PLIVADON	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in an orange blister (PVC/PVDC//Al), supplied in a box	YES			YES				YES
PLIVIT B1 injection 100 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	1-mL of solution for injection in a glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B1 injection 250 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution for injection in a glass ampoule , 50 ampoules in a box	YES			YES				
PLIVIT B1 tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES				YES
PLIVIT B6 injection 250 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 mL of solution for injection in an amber glass ampoule, 50 ampoules in a box	YES			YES				
PLIVIT B6 injection 50 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	2 mL of solution for injection in an amber glass ampoule , 50 ampoules in a box	YES			YES				
PLIVIT B6 tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES				YES
PLIVIT C 1000 mg sugar-free effervescent tablets, lemon flavoured	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets in a polypropylene tube (cap with silicagel and tamper-proof ring), supplied in a box	YES			YES				YES
PLIVIT C 1000 mg sugar-free effervescent tablets, lemon flavoured	effervescent tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 effervescent tablets in a polypropylene tube (cap with silicagel and tamper-proof ring), supplied in a box	YES			YES				YES
PLIVIT C tablets 50 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				YES
PLIVIT C tablets 500 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES				YES

		Croatia									
PLIVIT C 500 mg prolonged-release tablets	film coated prolonged-release tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) prolonged-release film coated tablets in a PVC/PVDC//Al blister, supplied in a box	YES			YES				YES
Plivit D3	oral drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic dropper attachment, supplied in a box	YES			YES				
Plymicol vaginal tablets	vaginal tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	3 vaginal tablets in a blister, supplied in a box	YES			YES				
PNEUMO 23 Pneumococcal polysaccharide vaccine	solution for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 glass syringe containing 0.5 mL of vaccine and a needle with protection		YES						
Poliosabin (Oral) trovalent live, attenuated vaccine against poliomyelitis, Sabin strain, stabilized in MgCl	oral suspension	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Box with 25 plastic tubes with one vaccine dose		YES						
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	One 1.5 mL of suspension in a glass vial, 3 glass syringes and 4 needles for injection, supplied in a box	YES							
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 red glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	3 glass bottles each containing 1 mL of suspension, 5 syringes and 6 needles for injection, supplied in a box	YES							
Pollinex tree, extract of birch, hazel and alder tree pollen for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	One 1.5 mL of suspension in a glass vial, 3 glass syringes and 4 needles for injection, supplied in a box	YES							
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	4 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	4 glass bottles each containing 1 mL of suspension, 5 syringes and 6 needles for injection, supplied in a box	YES							
Pollinex grass and rye, extract of grass and rye for specific immunotherapy	suspension for subcutaneous injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia and Allergy Therapeutics Ltd., Worthing, Great Britain	5 glass syringes each containing 0.5 mL of suspension and 4 needles for injection, supplied in a box	YES							
Portal 20 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	28 (4x7) capsules in a blister, supplied in a box		YES		YES				

Portal 20 mg capsules	capsules	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	14 (2x7) capsules in a blister, supplied in a box		YES		YES					
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 bags (PET/Al/PE) with à 15 mL of syrup, supplied in a box	YES			YES				YES	
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	5 (PET/Al/PE) bags each with 15 mL of syrup, supplied in a box	YES			YES				YES	
Portalak syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	250-mL of syrup in a plastic bottle with screw cap, supplied in a box	YES			YES				YES	
Prazine sugar-coated tablets 100 mg	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 sugar coated tablets (5x10) in a blister, supplied in a box	YES			YES					
Prazine sugar-coated tablets 25 mg	sugar-coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	50 sugar coated tablets (5x10) in a blister, supplied in a box	YES			YES					
Prazine injection 100 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 ampoules with 2 mL of solution	YES			YES					
Prazine injection 50 mg	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 ampoules with 1 mL of solution	YES			YES					
Preductal	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	60 (2x30) tablets in a PVX/Al blister, supplied in a box		YES	YES						
PRENESSA tablets 4 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia; KRKA Polska Sp.z.o.o., Warszawa, Poland	30 (3x10) tablets in PVC/PE/PVDC//Al blister, supplied in a box		YES		YES	YES		YES		
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	One glass vial with 0.5 mL of vaccine suspension, one syringe and two needles, supplied in a box		YES							
Prevenar, saccharide, conjugated and absorbed vaccine against S. pneumoniae	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	10 syringes with 0.5 mL of vaccine suspension, supplied in a box		YES							
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injections	John Wyeth & Brother Ltd., Hants, Great Britain	One syringe with 0.5 mL of vaccine suspension, supplied in a box		YES							
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injections	John Wyeth & Brother Ltd., Hants, Great Britain	One syringe with 0.5 mL of vaccine suspension, with separate needle, supplied in a box		YES							
Prevenar S. Pneumoniae saccharide conjugated vaccine, absorbed	suspension for injection	John Wyeth & Brother Ltd., Hants, Great Britain	One glass vial with 0.5 mL of vaccine suspension, supplied in a box		YES							
Prexanil 4 mg	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES						

PREXANIL 8 mg tablets	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Prexanil Combi	tablets	Les Laboratoires Servier Industrie, Gidy, France; Servier Republic of Ireland Industries Ltd., Arcklow, Co. Wicklow, Republic of Ireland	30 (1x30) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Primolut-Nor tablets	tablets	Schering GmbH und Co. Produktions KG, Doebereinerstrasse 20, Weimar, Germany	20 tablets in an amber glass bottle, supplied in a carton box		YES	YES					
Primus tea	tea	Fitofarmacija d.o.o., Zagreb, Republic of Croatia	14 bags each containing 5 g of tea, supplied in a box	YES							YES
Prinivil 10 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Prinivil 20 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Prinivil 5 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Prinzide 20/12.5 mg tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PVC/Al blister, supplied in a box		YES	YES					
PRIORIX, combined, live lyophilized vaccine against morbilli, parotitis and rubella	powder and diluent for solution for injection	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Vial containing single dose of lyophilised vaccine (powder), syringe with pre-filled 0.5 mL of diluent, Water for injection, and two needles with protective caps, supplied in a box		YES	YES		YES		YES	
PRITOR 40 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES		YES	YES		
PRITOR 80 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (PA/Al/PVC//Al), supplied in a box		YES	YES		YES	YES		
PritorPlus 40/12.5 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (OPA/Al/PVC/Al blister), supplied in a box		YES	YES			YES		
PritorPlus 80/12.5 mg tablets	tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	28 (4x7) tablets in a blister (OPA/Al/PVC/Al blister), supplied in a box		YES	YES			YES		
Procoralan 5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co.	29 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		

		Wicklow, Republic of Ireland; Przedsiebiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszava, Poland									
Procoralan 7.5 mg film coated tablets	film coated tablets	Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France; Servier (Republic of Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Republic of Ireland; Przedsiebiorstwo Farmaceutyczne Anpharm S.A., Ul. Annopol 603-236, Warszava, Poland	30 (2x14) film coated tablets in a PVC/Al blister, supplied in a carton box		YES	YES		YES	YES		
Proctosan	ointment	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	20 grams of ointment in an aluminum tube with a plastic cap, supplied in a box		YES		YES				YES
Proctosan forte	suppositories	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	10 (2x5) suppositories in a strip (PVC/LDPE foil), supplied in a box		YES		YES				YES
Proculin	eye drops, solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 mL of solution in an amber glass bottle and plastic sterile dropper attachment in a protective plastic bag, supplied in a box		YES		YES				
Pro-famosal 20 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 20 tablets (blister)		YES		YES				
Pro-famosal 20 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 20 tablets (blister)		YES		YES				
Pro-famosal 40 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 10 tablets (blister)		YES		YES				
Pro-famosalL 40 mg	coated tablets	Pro. Med.CS Praha a.s., Prag, Czech Republic	Box with 10 tablets (blister)		YES		YES				
Prograf capsules 0.5 mg	capsules, hard	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	30 (3x10) capsules in a blister (PVC/PVDC//Al), in protective aluminum envelope with desiccant, supplied in a box		YES	YES				YES	
Prograf capsules 1 mg	capsules	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	60 (6x10) capsules in a blister, in protective aluminium foil, supplied in a box		YES	YES				YES	
Prograf capsules 5 mg	capsules	Astellas Republic of Ireland Co. Ltd., Killorglin, Republic of Ireland	30 (3x10) capsules in a blister, in protective aluminum envelope, supplied in a box		YES	YES				YES	
Prolax suppositories for children	suppositories	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip, supplied in a box	YES			YES				YES
Prolax suppositories for children	suppositories	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (2x5) suppositories in a Al/PE strip, supplied in a box	YES			YES				YES
Propafenon Alkaloid 150 mg film coated tablets	film coated tablets	Alkaloid AD - Skopje, Bulevar Aleksandar	50 tablets in an amber glass bottle with an aluminium		YES		YES				

		Makedonski 12, Skopje, FYROM	stopper, supplied in a box								
Propafenon Alkaloid 35 mg/10 mL solution for injection	solution for injection	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	10 (2x5) ampoules each containing 10 mL of solution, supplied in a box		YES		YES				
Propafenon Genericon 150 mg film coated tablets	film coated tablets	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Propafenon Genericon 300 mg film coated tablets	film coated tablets	Genericon Pharma Ges.m.b.H., Hafnerstrasse 211, Graz, Austria	50 (5x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES		YES				
Propecia 1 mg	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Propiltiouracil Alkaloid 50 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	20 tablets in an amber glass bottle, supplied in a carton box		YES		YES				
Propranolol Lek 40 mg tablets	tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 tablets in a glass bottle, supplied in a box		YES		YES				
Proscar 5 mg	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a blister, supplied in a box		YES	YES					
Prospan acute effervescent tablets	effervescent tablets	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	10 effervescent tablets in a plastic tube (desiccant in polyethylene cap), supplied in a box		YES						YES
Prospan Liquid	oral solution	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	30 bags each with 5 mL of solution, supplied in a box		YES						YES
Prospan oral solution	oral solution	Engelhard Arzneimittel GmbH & Co.KG, Niederdorfelden, Germany	100 mL of solution in an amber glass bottle with plastic extensionattachment, screw cap and 10 mL measuring glass, supplied in a box		YES						YES
Prospera 1 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/Al blister, supplied in a box	YES			YES				
Prospera 2 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/Al blister, supplied in a box	YES			YES				
Prospera 3 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/Al blister, supplied in a box	YES			YES				
Prospera 4 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/PE/PVDC/Al blister, supplied in a box	YES			YES				
Protecta 10 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a transparent blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				

Protecta 20 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (2x14) tablets in a transparent blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES					
Protecta 40 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	29 (2x14) tablets in a transparent blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES					
PROVERA tablets 10 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	30 (3x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES						
PROVERA tablets 5 mg	tablets	Pfizer Italia S.r.l., Marina De Tronto, Ascoli Piceno, Italy	24 tablets in an amber glass bottle with plastic cap, supplied in a box		YES	YES						
Prozac 20 mg capsules	capsules	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	14 (1x14) capsules in a blister (PVC/Al), supplied in a box		YES	YES						
Prozac dispersible tablets 20 mg	freely dispersible tablets	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain	14 (1x14) tablets in a blister (PVC/PE/Aclar//Al), supplied in a box		YES	YES						
Prozac Liquid 20 mg/5 mL oral solution	oral solution	Lilly, S.A., Avendia de la Industria 30, Alcobendas, Madrid, Spain; Patheon France, 40, boulevard de Champaret, Bourgoin-Jallieu, France	70 mL of oral solution in an amber glass bottle and a plastic measuring cup (with a 5 mL graduate line), supplied in a box		YES	YES						
Psorimed	dermal solution	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	100 grams of solution in a plastic (HDPE) bottle with applicator-shaped PP cap, supplied in a box		YES		YES					
Pulmozyme	solution for inhalation	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	2.5 mL of solution in a plastic (polyethylene) ampoule, 6 ampoules in a protective foil, supplied in a box		YES	YES						
Purisan granules	granules	Cedevita d.o.o., Zagreb, Republic of Croatia	14 bags in a box	YES							YES	
PYRAZINAMID Krka tablets 500 mg	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 tablets in an amber glass bottle with aluminum cap, supplied in a box		YES		YES					
Ramipril 10 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES			YES					
Ramipril 2.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES			YES					
Ramipril 5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES			YES					
Ramipril H 2.5mg/12.5 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES			YES					
Ramipril H 5 mg/25 mg tablets	tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (4x7) tablets in a Al/OPA/PVC/Al blister, supplied in a box	YES			YES					

RAMIPRIL PLIVA 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA//PVC/Al), supplied in a box	YES			YES					
RAMIPRIL PLIVA 2.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA//PVC/Al), supplied in a box	YES			YES					
RAMIPRIL PLIVA 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA//PVC/Al), supplied in a box	YES			YES					
RAMIPRIL PLUS PLIVA 2.5/12.5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA//PVC/Al), supplied in a box	YES			YES					
RAMIPRIL PLUS PLIVA 5/25 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (Al/OPA//PVC/Al), supplied in a box	YES			YES					
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	20 (2x10) tablets in a blister, supplied in a box		YES		YES					
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	60 (6x10) tablets in a blister (Al/Al), supplied in a box		YES		YES					
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	20 (2x10) tablets in a blister (Al/Al), supplied in a box		YES		YES					
Ranisan 150 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	30 (3x10) tablets in a blister (Al/Al), supplied in a box		YES		YES					
Ranisan 75 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	10 (1x10) tablets in a blister, supplied in a box		YES		YES				YES	
Ranisan 75 mg	film coated tablets	Pro. Med.CS Praha a.s., Prague, Czech Republic	10 (1x10) tablets in a Al/Al blister, supplied in a box		YES		YES				YES	
Ranital injection 50 mg/2 mL	solution for injection	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	5 ampoules each with 2 mL of water for injection in a blister, supplied in a box	YES			YES					
Ranital tablets 150 mg	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	20 (2x10 tablets in Al/Al blister, supplied in a box	YES			YES					
Ranital tablets 300 mg	film coated tablets	Farmal d.d., Ludbreg, Republic of Croatia in cooperation with Lek d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a Al/Al blister, supplied in a box	YES			YES					
Ranitidin Europharma injection 50 mg/2 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules each with 2 mL of solution, supplied in a box	YES			YES					
Ranitidin Europharma tablets 150 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES					
Ranitidin Europharma tablets 300 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES					

Ranix 150	film tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Ranix 300	film tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 (1x10) tablets in a blister, supplied in a box	YES			YES				
Ranix injection	solution forintramuscular and intravenous injection	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	5 amber glass ampoules with 2 mL of solution, supplied in a box	YES			YES				
Rapamune 1 mg coated tablets	coated tablets	Wyeth Pharmaceuticals, New Lane, Havant, Hampshire P09 2NG, Great Britain	30 (3x10) tablets in a PVC/PE/Aclar/Al blister, supplied in a box		YES	YES			YES		
Rapilysin 10 U powder and diluent for injection solution	powder and diluent for solution for injection	Roche Diagnostics GmbH, Sandhofeer Strasse 116, D-68305 Mannheim, Germany	2 glass bottles with 10 units of powder, 2 pre-filled syringes with 10 mL of diluent, 2 reconstitution kits and 2 injection needles		YES	YES		YES	YES		
Raptiva 100 mg/mL	powder and diluent for solution for injection	Laboratories Serono S.A., Aubonne, Switzerland i Industria Farmaceutica Serono S.p.A., Rome, Italy	One glass vial with powder, a syringe with 1.3 mL of diluent, a reconstitution needle and an injection needle, supplied in a box		YES	YES			YES		
RAWEL SR	prolonged-release film-coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES		YES	
RAWEL SR	film coated tablets with prolonged-release	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES	YES		YES	
REBETOL 200 mg hard capsules	hard capsules	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	84 (7x12) capsules in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
REBETOL 40 mg/mL oral solution	oral solution	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	100 mL of oral solution in an amber glass bottle with temper-proof plastic closure, 1 glass bottle in a box		YES	YES		YES	YES		
Rebif 22 micrograms - solution for injection	solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy i Laboratories Serono S.A., Aubonne, Switzerland	Pre-filled 1-mL glass syringe with fixed stainless steel needle containing a single 0.5 mL dose of solution for injection, supplied in a box		YES	YES					
Rebif 44 micrograms - solution for injection	solution for injection	Industria Farmaceutica Serono S.p.A., Bari, Italy; Laboratories Serono S.A., Aubonne, Switzerland	Pre-filled 1-mL glass syringe with fixed stainless steel needle containing a single 0.5 mL dose of solution for injection, supplied in a box		YES	YES					
Recombinate 1000 IU	lyophilisate and solvent for preparation of intravenous solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile syringe, supplied in a box		YES						
Recombinate 250 IU	lyophilisate and solvent for intravenous solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile syringe, supplied in a box		YES						

Recombinate 500 IU	lyophilisate and solvent for preparation of i.v. solution (injections/infusion)	Baxter S.A, Hyland Immuno, Lessines, Belgium	30 mL bottle with lyophilized drug, bottle with 10 mL of solvent (water for injection), sterile double needle for dissolution, sterile filter needle, sterile mini infusion kit, disposable sterile syringe, supplied in a box		YES						
Rectodelt 100 mg suppositories	suppositories	Trommsdorff GmbH & Co.KG Arzneimittel, Alsdorf, Germany	4 suppositories in a white non-transparent strip (PVC/PE), supplied in a box		YES		YES				
Reductil 10 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box		YES	YES					
Reductil 15 mg capsules	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 (2x14) capsules in a blister, supplied in a box		YES	YES					
Reglan injection	solution for intramuscular injection and intravenous infusion	Alkaloid AD, Skopje, FYROM in cooperation with Sanofi-Synthelabo, France	30 ampoules (6 x 5 on a plastic pad) with 2 mL of solution, supplied in a box		YES		YES				
REGLAN solution	oral solution	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	120 mL of solution in an amber glass bottle with dispenser, supplied in a box		YES		YES				
Reglan tablets	tablets	Alkaloid AD, Skopje, FYROM in cooperation with Sanofi-Synthelabo, France	40 tablets in an amber glass bottle, supplied in a box		YES		YES				
Relenza	inhalation powder, dosed	GlaxoWellcome Production, Evreux, France and GlaxoSmithKline Australia Pty Ltd., Australia	5 rotadisk blisters (PVC/Al) each with 4 doses of powder, in a plastic box with 1 diskhaler (applicator), supplied in a box		YES	YES				YES	
Remicade powder for concentrate of infusion solution	powder for preparation of concentrate for infusion solution	Centocor B.V., Einsteinweg 101, 2333 CB Leiden, the Netherlands	One glass vial with powder supplied in a box		YES	YES					
Renagel 800 mg film coated tablets	film coated tablets	Genzyme Limited Great Britain; Genzyme Republic of Ireland Limited, Republic of Ireland	180 tablets in a plastic bottle		YES	YES		YES	YES		
Rennie	chewing tablets	Bayer Sante Familiale, 33 rue de L'industrie, 74240 Gaillard, France	24 (4x6) tablets in a blister, supplied in a box		YES		YES				YES
Replagal 1 mg/1 mL concentrate for infusion solution	concentrate for infusion solution	TKT Europe AB, Danderyd, Sweden	5-mL glass bottle with 3.5-mL of concentrate supplied in a box		YES	YES		YES	YES		
Replagal 1 mg/1 mL concentrate for solution for infusion	concentrate for infusion solution	TKT Europe AB, Danderyd, Sweden	3-mL glass bottle with 1-mL of concentrate supplied in a box		YES	YES		YES	YES		
Requip 0.25 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	210 tablets in a PVC/PVDC blister, supplied in a box		YES	YES					
Requip 1 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box		YES	YES					
Requip 2 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box		YES	YES					

Requip 5 mg tablets	film coated tablets	SmithKline Beecham Pharmaceuticals, Crawley, West Sussex, Great Britain	21 tablets in a PVC/PVDC blister, supplied in a box		YES	YES						
Retafer 100 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 tablets in an amber glass bottle with an aluminium stopper, supplied in a box		YES		YES					
Revatio 20 mg tablets	film coated tablets	Pfizer PGM, Poce sur Cisse, France	90 (6x15) tablets in a blister (PVC/Al), supplied in a box		YES	YES		YES	YES			
Revia	film coated tablets	Bristol-Myers Squibb, Epernon, France	28 (4x7) tablets in a white nontransparent PVC/PE/Aclar/Al blister, supplied in a box		YES	YES						
Rhesogamma P	solution for intramuscular injection	Aventis Boehring GmbH, Emil-von-Behring Strasse 76, Marburg, Germany	Box with 1 ampoule with 1.5 mL of solution (not less than 300 µg = 1500 IU)		YES							
Rhesonativ 1250 IU	lyophilisate and diluent for preparation of solution for i.m. injection	Octapharma AB, Stockholm, Sweden	Lyophilisate in a glass bottle (8 mL) and 2 mL of solvent (water for injection) in an ampoule, supplied in a box		YES							
RHINOSTOP syrup	syrup	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	100 mL of syrup in an amber glass bottle with plastic cap and a 5-mL plastic measuring spoon, supplied in a box		YES		YES				YES	
RHINOSTOP tablets	tablets	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	10 (1x10) tablets in a Al/PVC blister, supplied in a box		YES		YES				YES	
Ringer's solution for intravenous infusion, 500 mL	solution for intravenous infusion	Hrvatski zavod za transfuzijsku medicinu, Petrova 3, Zagreb, Republic of Croatia	500 mL in a glass infusion bottle with a chlorobutyl stopper protected with an aluminium cap with a plastic lid (10 bottles with plastic holders, supplied in a box)	YES			YES					
Ringer's solution	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	10 polyethylene bottles with 1000 mL of solution, supplied in a box		YES		YES					
Ringer's solution	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	10 polyethylene bottles with 500 mL of solution, supplied in a box		YES		YES					
Ringer's solution Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain	10 plastic Viaflo bags with 1000 mL of infusion solution, in a protective bag, supplied in a box		YES		YES					
Ringer's solution Viaflo	solution for infusion	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES		YES					
Rinolan syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in a 125 mL amber glass bottle with aluminum cap and a 5-mL plastic (poylethyrene) spoon, supplied in a box	YES			YES					
Rinolan tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES					
Rispolept 1 mg/mL solution for oral use	oral solution	Janssen Pharmaceutica NV, Turnhouseweg 30,	100 mL of oral solution in an amber glass bottle with temper-prooft plastic closure		YES	YES						

		Beerse, Belgium	and pipette, supplied in a box								
Rispolept Consta 25 mg	prolonged-release suspension for i.m. injections	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	65.6 mg of powder (microspheres) in a glass bottle, 2 mL of solvent in a syringe, 2 needles for preparation of suspension and 1 needle for i.v. administration, in a plastic container, supplied in a box		YES	YES					
Rispolept Consta 37.5 mg	prolonged-release suspension for i.m. injections	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	98.4 mg of powder (microspheres) in a glass bottle, 2 mL of solvent in a syringe, 2 needles for preparation of suspension and a needle for i.v. administration, inserted into a plastic container, supplied in a box		YES	YES					
Rispolept Consta 50 mg	prolonged-release suspension for i.m. injection	Cilag AG, Schaffhausen, Switzerland for Janssen Pharmaceutica N.V., Beerse, Belgium	131.2 mg powder (microsphere) in a glass bottle, 2 mL of diluent in a syringe, 2 needles for suspension preparation and one needle for intramuscular administration, inserted in a plastic container, supplied in a box		YES	YES					
Rispolept tablets 1 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al) , supplied in a box		YES	YES					
Rispolept tablets 2 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES					
Rispolept tablets 3 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES					
Rispolept tablets 4 mg	film coated tablets	Janssen-Cilag S.p.A., Borgo San Michele, Latina, Italy	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES					
Rispolux 1 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box		YES		YES			YES	
Rispolux 2 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box		YES		YES			YES	
Rispolux 3 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box		YES		YES			YES	
Rispolux 4 mg	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/PE/PVDC/Al blister, supplied in a box		YES		YES			YES	
Risset tablets 1 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES			YES				
Risset tablets 2 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES			YES				

		Croatia									
Risset tablets 3 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES			YES				
Risset tablets 4 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) film coated tablets in an orange PVC/PVDC/A1 blister, supplied in a box	YES			YES				
Rivotril 0.5 mg tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	50 tablets in an amber glass bottle with a plastic (PE) stopper, supplied in a box		YES	YES					
Rivotril 2 mg tablets	tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 tablets in an amber glass bottle with a plastic (PE) stopper, supplied in a box		YES	YES					
Roaccutane soft capsules 10 mg	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) soft capsules in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES					
Rocaltrol 0.25 µg capsules	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (5x20) capsules in PVC/Al blister, supplied in a box		YES	YES					
Rocaltrol 0.5 µg capsules	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 (5x20) capsules in a PVC/Al blister, supplied in a box		YES	YES					
Rocephin 1 g i.m.	powder for preparation of solution for intramuscular injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	2 g of powder in a vial and 3.5 mL of diluent (Water for Injection) in an ampoule, supplied in a box		YES	YES					
Rocephin 1 g i.v.	powder for preparation of solution for intravenous injection	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	1 g of powder in a vial and 10mL of diluent (Water for Injection) in an ampoule, supplied in a box		YES	YES					
Rocephin 2g powder for infusion solution	powder for solution for infusion (for i.v. use)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One 50 mL glass vial for infusion containing powder,with rubber cap, supplied in a vial		YES	YES					
Roferon-A 3 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe containing 0.5 mL of solution, closed with protective cap and a needle (in a plastic container), supplied in a box		YES	YES					
Roferon-A 4.5 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES					
Roferon-A 6 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES					

Roferon-A 9 MIU/0.5 mL	solution for injection (for single s.c. administration)	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	One glass syringe with 0.5 mL of solution closed with a protective cap and one needle (in a plastic container), supplied in a box		YES	YES						
ROJAZOL 200 mg pessary	pessary	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 (1 x7) pessaries in an Al/PE strip, supplied in a box	YES			YES					
ROJAZOL cream	cream	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 g of cream in an aluminium tube with a plastic stopper, supplied in a box	YES			YES					
ROJAZOL oral gel	oral gel	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	40 g of oral gel in an aluminium tube with a 5 mL plastic measuring spoon, supplied in a box	YES			YES					
Rosalgin granules	granules for vaginal solution	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	4 bags (2x2), each with 9.44 g of granulate, supplied in a box		YES		YES					
Rosalgin solution	vaginal solution	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	140 mL of solution in a plastic bottle with plastic applicator attachment, 5 bottles in a carton box		YES		YES					
ROWAchol capsules	capsules	ROWA PHARMACEUTICALS LTD., Newtown, Bantry, Co. Cork, Republic of Ireland	30 (3x10) capsules in a blister, supplied in a box		YES						YES	
ROWAtinex capsules	capsules	ROWA PHARMACEUTICALS LTD., Newtown, Bantry, Co. Cork, Republic of Ireland	30 (3x10) capsules in a blister, supplied in a box		YES						YES	
Rozamet 1% cream	cream	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	25 grams of cream in an Al tube, supplied in a carton box	YES			YES					
RUDAKOL 135 mg coated tablets	coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	50 coated tablets in an amber glass bottle with an aluminium stopper, supplied in a box	YES			YES					
Rupurut chewing tablets	chewing tablets	Bayer HealthCare AG, 51368 Leverkusen, Germany	20 (2x10) chewing tablets in a blister, supplied in a box		YES	YES					YES	
Rutacid chewing tablets 500 mg	chewing tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES	
Rytmonorm 150 mg film tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) film coated tablets in a blister (PVC/Al or PP/Al) , supplied in a box		YES	YES						
Rytmonorm 300 mg film tablets	film coated tablets	Abbott GmbH & Co. KG, Ludwigshafen, Germany	50 (5x10) film coated tablets in a blister (PVC/Al or PP/Al), supplied in a box		YES	YES						
Rytmonorm solution for injection	solution for injection	Ebewe Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, Unterach, Austria	20 mL of injection solution in a glass ampoule, 5 ampoules supplied in a box		YES		YES					
Salazopyrin EN tablets 500 mg	gastric-resistant tablets	Pfizer Health AB, Uppsala, Sweden	100 tablets in a polyethylene bottle, supplied in a box		YES	YES						
Salofalk suppositories 250 mg	suppositories	dr. Falk Pharma GmbH, Freiburg, Germany	30 (6x5) suppositories in a strip (PVC/LDPE), supplied in a box		YES		YES					
Salofalk suppositories 500 mg	suppositories	dr. Falk Pharma GmbH, Freiburg,	30 (6x5) suppositories in a strip (PVC/LDPE), supplied		YES		YES					

		Germany	in a box								
Salofalk suspension for rectal administration 4 g/60 mL	suspension for rectal administration	dr. Falk Pharma GmbH, Freiburg, Germany	7 plastic containers each with 60 mL of suspension (with attachment for rectal administration) in a protective blister, supplied in a box		YES		YES				
Salofalk 250 mg tablets	gastric-resistant tablets	dr. Falk Pharma GmbH, Freiburg, Germany	100 (10x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES				
Salofalk 500 mg tablets	gastric-resistant tablets	dr. Falk Pharma GmbH, Freiburg, Germany	100 (10x10) tablets in a PVC/PVDC//Al blister, supplied in a box		YES		YES				
Salviamin L8b.UH	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	250-mL of solution for infusion in a plastic bottle for infusion, 10 bottles and plastic bottle holders in a box	YES			YES				
Salviamin L8b.UH	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass infusion bottle, 10 bottles and plastic bottle holders in a box	YES			YES				
Salviamin LX6	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	500 mL of solution for infusion in a glass infusion bottle, 10 bottles in a box	YES			YES				
Sandimmun 50 mg/mL concentrate for infusion	concentrate for intravenous infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	10 ampoules containing 5 mL of concentrate for infusion, supplied in a box		YES	YES					
Sandimmun Neoral 100 mg capsules	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an Al blister, supplied in a box		YES	YES					
Sandimmun Neoral capsules 25 mg	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an Al blister, supplied in a box		YES	YES					
Sandimmun Neoral capsules 50 mg	soft gelatinous capsules	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	50 (10x5) capsules in an Al blister, supplied in a box		YES	YES					
Sandimmun Neoral 100 mg/mL oral solution	oral solution	Novartis Pharma S.A.S., Huningue Cedex, France	50 mL of solution in an amber glass bottle with a measuring kit (in a protective container), supplied in a box		YES	YES					
Sandostatin 0.05 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES					
Sandostatin 0.1 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES					
Sandostatin 0.5 mg injection	solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 ampoules each with 1 mL of solution for injection, supplied in a box		YES	YES					
Sandostatin LAR 10 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, and two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into protective plastic container, supplied in a carton box		YES	YES					

Sandostatin LAR 20 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into a protective plastic container, supplied in a carton box		YES	YES						
Sandostatin LAR 30 mg	powder and diluent for suspension for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial with powder, pre-filled syringe with 2.5 mL of diluent for suspension, two needles (1.1x40 mm, 19 G x 1 1/2") in individual packages, inserted into a protective plastic container, supplied in a carton box		YES	YES						
Sanval 10 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
Sanval 10 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
Sanval 5 mg tablets	film coated tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	20 (2x10) tablets in PVC/Al blister, supplied in a box		YES		YES					
Saridon	tablets	Bayer Sante Familiale, 33 rue de L'industrie, 74240 Gaillard, France	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				YES	
Seldiar capsules	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 capsules in an amber glass bottle, supplied in a box		YES		YES					
Septolete	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) lozenges in a blister, supplied in a box		YES		YES				YES	
Septolete D	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) lozenges in a blister, supplied in a box		YES		YES				YES	
Septolete wild cherry	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES	
Septolete lemon	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES	
Septolete Plus lozenges	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES	
Septolete green apple	lozenges	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	18 (2x9) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES	
Serdolect 12 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES				YES		
Serdolect 16 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES				YES		
Serdolect 20 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	28 (4x7) tablets in a blister (PVC/PVdC/Al), supplied in a box		YES	YES				YES		

Serdolect 4 mg film coated tablets	film coated tablets	H. Lundbeck A/S, Ottilavej 9, Copenhagen-Valby, Denmark	31 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES	YES				YES	
Seretide 100 discus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES				YES	
Seretide 125 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES				YES	
Seretide 250 diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES				YES	
Seretide 250 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES				YES	
Seretide 50 Inhaler	inhalation aerosol	Glaxo Wellcome Production, Evreux, France	One metal container (120 doses) with metering valve in plastic atomizer for oral administration, supplied in a box		YES	YES				YES	
Seretide 500 diskus	inhalation powder	Glaxo Wellcome Operations, Greenford, Great Britain	60 doses of powder in an aluminium blister (with protective foil) in a plastic housing, supplied in a box		YES	YES				YES	
Serevent Discus	inhalation powder	Glaxo Wellcome Production, Evreux, France	60 doses of powder in an aluminium blister, in a plastic housing, supplied in a box		YES	YES					
Serevent Inhaler	inhalation aerosol (suspension)	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Polish Glaxo Wellcome Production, 23 Rue Lavoisier, Evreux, France	120 doses in a metal (aluminum) bottle with metering valve in plastic nebulizer, supplied in a box		YES	YES					
SEROQUEL tablets 100 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES				YES	
SEROQUEL tablets 200 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES				YES	
SEROQUEL tablets 25 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 tablets (6x10) in a blister, supplied in a box		YES	YES				YES	
Seroquel tablets 300 mg	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES				YES	
Seroxat 20 mg tablets	film coated tablets	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	30 (3x10) tablets in a blister, supplied in a box	YES			YES				

Seroxat 30 mg tablets	film coated tablets	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Seroxat oral suspension	oral suspension	Belupo lijekovi i kozmetika d.d., Koprivnica, Republic of Croatia in cooperation with GlaxoSmithKline, Great Britain	150 mL of suspension in an amber glass bottle, supplied in a box	YES			YES				
Setronon injection 4 mg/2 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 5 ampoules containing 2 mL of solution	YES			YES				
Setronon injection 8 mg/4 mL	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 5 ampoules containing 4 mL of solution	YES			YES				
Setronon tablets 4 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Setronon tablets 8 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 10 tablets (blister)	YES			YES				
Sevorane	inhalate, solution	Abbott Laboratories Ltd., Queenborough, Great Britain	Brown polyethylene bottle with 250 mL of solution and a temper-evident stopper, supplied in a box		YES	YES					
Sevredol 10 mg film coated tablets	film coated tablets	Bard Pharmaceuticals Ltd., Milton Road, Cambridge, Great Britain	56 (4x14) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Sevredol 10 mg film coated tablets	film coated tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	30 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES	YES					
Sevredol 20 mg film coated tablets	film coated tablets	Bard Pharmaceuticals Ltd., Milton Road, Cambridge, Great Britain	56 (4x14) tablets in a PVC/PVDC/Al blister, supplied in a box		YES	YES					
Sevredol 20 mg film coated tablets	film coated tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	31 (3x10) tablets in a PVC/PVdC/Al blister, supplied in a box		YES	YES					
Silapen 1000 oral suspension	oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	150 mL of suspension in an amber glass bottle, supplied in a box	YES			YES				
Silapen 1000 tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	15 tablets in a plastic bottle, supplied in a box	YES			YES				
Silapen 1500 tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 tablets in a blister, supplied in a box	YES			YES				
Silymarin capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) capsules in a PVC/Al blister, supplied in a box	YES						YES	

Simcard 10	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	20 (2x10) tablets in a blister (white PVC/PVDC/Al), supplied in a box		YES		YES				
Simcard 20	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	20 (2x10) tablets in a blister (white PVC/PVDC/Al), supplied in a box		YES		YES				
Simcard 40	film coated tablets	Cipla Ltd., MIDC Industrial Area, Kurkumbh, Pune, Maharashtra State, India	28 (2x14) tablets in a blister (white PVC/PVDC/Al), supplied in a box		YES		YES				
Simdax 2.5 mg/mL concentrate for solution for infusion	concentrate for solution for infusion	Orion Corporation ORION PHARMA, Espoo, Finland	One glass vial with 5 mL of solution concentrate, supplied in a box		YES	YES				YES	
Simulect 10 mg	powder and solvent for preparation of solution for injection or infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial containing medicinal product (powder) and ampoule with 5mL of diluent (Water for Injection), supplied in a box		YES	YES					
Simulect 20 mg	powder and solvent for preparation of solution for injection or infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Vial containing medicinal product (powder) and ampoule with 5mL of diluent (Water for Injection), supplied in a box		YES	YES					
Simvastatin Lek 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/Al blister, supplied in a box		YES		YES			YES	
Simvastatin Lek 20 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/Al blister, supplied in a box		YES		YES			YES	
Simvastatin Lek 40 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia, LEK S.A., Warszawa, Poland and Salutas Pharma GmbH, Barleben, Germany	28 (2x14) tablets in a PVC/Al blister, supplied in a box		YES		YES			YES	
Simvax 10 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Simvax 10 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (1x28) film coated tablets in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
Simvax 20 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Simvax 40 mg film coated tablets	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	20 (2x10) film coated tablets in a (PVC/PVDC/Al) blister, supplied in a box	YES			YES				
Sinecod 50 film coated tablets	film coated tablets	Novartis Saglik, Turkey za Novartis Consumer	10 (1x10) tablets in a blister, supplied in a box		YES	YES					

		Health S.A., Switzerland									
Sinecod oral drops	oral drops, solution	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	20 mL of solution in a plastic bottle with dropper attachment, supplied in a box		YES	YES					
Sinecod syrup	syrup	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland	200 mL of syrup in an amber glass bottle and a plastic measuring vessel, supplied in a box		YES	YES					
Sinemet CR tablets	controlled-release tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	100 tablets in an amber glass bottle, supplied in a box		YES	YES					
Sinemet tablets	tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	100 (10x10) tablets in a blister, supplied in a box		YES	YES					
SINERSUL forte tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 (1x10) tablets in a PVC/Al blister, supplied in a box	YES			YES				
SINERSUL syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	100 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL plastic spoon, supplied in a box	YES			YES				
SINERSUL tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Singulair 10 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/Al blister, supplied in a box		YES	YES					
Singulair junior 5 mg chewing tablets	chewing tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/Al blister, supplied in a box		YES	YES					
Singulair mini 4 mg oral granules	granules for oral solution	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 aluminum bags each containing 500 mg of granules, supplied in a box		YES	YES					
Singulair mini 4 mg chewing tablets	chewing tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	28 (2x14) tablets in a PA/PVC/Al blister, supplied in a box		YES	YES					
Siofor 500	film coated tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	39 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Siofor 850	film coated tablets	Berlin-Chemie AG (Menarini Group), Glienicker Weg 125, Berlin, Germany	30 (2x15) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Iceland lichen syrup	syrup	Trešnjevka laboratorij d.o.o., Jukićeva 32, Zagreb, Republic of Croatia	220 mL of syrup in an amber glass bottle with aluminum cap, supplied in a box	YES						YES	
Skinoren cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	30 g of cream in an aluminium tube, supplied in a box		YES	YES					
Skinoren cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	30 g of cream in an aluminium tube, supplied in a box		YES	YES					
Skopryl 10 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar	36 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				

		Makedonski 12, Skopje, FYROM									
Skopryl 20 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	37 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Compound sodium lactate solution (Hartmann's solution)	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	1000 mL of infusion solution in a plastic bottle (10 bottles in a box)		YES		YES				
Compound sodium lactate solution (Hartmann's solution)	solution for infusion	B. Braun Melsungen AG, Carl-Braun-Straße 1, Melsungen, Germany	500 mL of solution for infusion in a plastic bottle (10 bottles in a box)		YES		YES				
Smecta	powder for preparation of oral suspension	Beaufor Ipsen Industrie, Dreux, France	30 bags (LDPE/Al/paper) each with 3.76 g of powder for oral suspension, supplied in a box		YES		YES			YES	
Smecta	powder for oral suspension	Beaufor Ipsen Industrie, Dreux, France	10 bags (LDPE/Al/paper) each containing 3.76 g of powder for oral suspension, supplied in a box		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 100 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 250 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 500 mL of emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 250 mL emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box		YES		YES			YES	
SMOFlipid 20% emulsion for infusion	emulsion for infusion	Fresenius Kabi Austria GmbH, Graz, Austria	Glass infusion bottle with 100 mL of emulsion (with rubber stopper, aluminum ring and plastic protective cap), 10 bottles in a carton box		YES		YES			YES	

SOLPADEINE capsules	capsules	Glaxo Wellcome Production, Mayenne, France	12 (1x12) capsules in a PVC/Al blister, supplied in a box		YES		YES				YES
SOLPADEINE effervescent tablets	effervescent tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (3x4) effervescent tablets in multilayer strip packing (paper/PE/Al/PE), supplied in a box		YES		YES				YES
SOLPADEINE tablets	tablets	GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Republic of Ireland	12 (1x12) tablets in PVC/Al blister, supplied in a box		YES		YES				YES
Solu-Cortef injection 100 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (2 mL) in the upper part, supplied in a box		YES	YES					
Soludeks 1	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass bottles with à 20 mL of solution for injection (with rubber stopper and aluminum cap), supplied in a box	YES			YES				
Soludeks 40	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 glass nfusion bottles each contiaining 500 mL of infusion solution and plastic holders for infusion bottles, supplied in a box	YES			YES				
Soludeks 70	solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	11 glass nfusion bottles each contiaining 500 mL of infusion solution and plastic holders for infusion bottles, supplied in a box	YES			YES				
SOLU-MEDROL injection 1000 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (15.60 mL for reconstitution of lyophilisate), supplied in a box		YES	YES					
SOLU-MEDROL injection 125 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (2 mL) in the upper part, supplied in a box		YES	YES					
SOLU-MEDROL injection 250 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (4 mL) in the upper part, supplied in a box		YES	YES					
SOLU-MEDROL injection 40 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (1mL) in the upper part, supplied in a box		YES	YES					
SOLU-MEDROL injection 500 mg	lyophilisate and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle with lyophilisate in a lower part and solvent (7.8 mL for reconstitution of lyophilisate), supplied in a box		YES	YES					
SOMAVERT injection 10 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES		
SOMAVERT injection 15 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES		

SOMAVERT injection 20 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 30 bottles with powder and 30 bottles with solvent, supplied in a box		YES	YES		YES	YES		
SOMAVERT injection 20 mg	powder and diluent for solution for injection	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	Glass bottle of 6 mL with powder and a glass bottle with 8 mL of water for injection 1 bottle with powder and 1 bottle with solvent, supplied in a box		YES	YES		YES	YES		
Sonalia 50 mg	film coated tablets	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	28 (2x14) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Sortis 10 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Nacf. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertisen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	14 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES					
Sortis 20 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Nacf. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertisen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	15 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES					
Sortis 40 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Nacf. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertisen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	16 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES					
Sortis 80 mg tablets	film coated tablets	Gödecke GmbH, Mooswaldalle 1, Freiburg, Germany; Heinrich Mack Nacf. GmbH&Co.KG, Heinrich Mack Strasse 35, Illertisen, Germany; Pfizer Italia S.r.l., Strada statale 156, km 50, Borgo san Michele, Latina, Italy	17 (2x7) tablets in a (PA/Al/PVC//Al) blister, supplied in a box		YES	YES					
Spasmex 0.2 mg/5 mL injection	solution for injection	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	50 (5x10) amber glass ampoules with 5 mL of solution for injection in a plastic container, supplied in a box		YES		YES				
Spasmex forte 5 mg tablets	tablets	Lek farmacevtska družba d.d.,	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in		YES		YES				

		Verovškova 57, Ljubljana, Republic of Slovenia	a box								
Spiriva 18 micrograms, inhalation powder, hard capsule	inhalation powder, hard capsules	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, Ingelheim am Rhein, Germany	30 capsules (3 blisters with 10 (2x5) capsules) in a blister (Al/PVC/Al) and an inhaler (HandiHaler), supplied in a box		YES	YES				YES	
Stalevo 100 mg/25 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES		
Stalevo 150 mg/37.5 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES		
Stalevo 50 mg/12.5 mg/200 mg	film coated tablets	Orion Corporation ORION PHARMA, Espoo, Finland	100 tablets in a plastic (HDPE) bottle, supplied in a box		YES	YES			YES		
STAMARIL, attenuated vaccine against yellow fever , 1 dose	powder and diluent for suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	One glass vial with a single dose of lyophilized vaccine and a pre-filled glass syringe with fixed needle containing 0.5mL of diluent, supplied in a box		YES						
Starcitin tablets 10 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Starcitin tablets 20 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Starcitin tablets 40 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister, supplied in a box	YES			YES				
Statex 20	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 tablets (blister, 2x10 tbl.)	YES			YES				
Stediril-d sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES					
Stediril-m sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland or Haupt Pharma Munster GmbH, Munster, SR Germany	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES					
Stediril-m sugar coated tablets	sugar coated tablets	Wyeth Medica Republic of Ireland, Newbridge, Republic of Ireland or Haupt Pharma Munster GmbH, Munster, SR Germany	21 (1x21) tablets in PVC/Al blister, supplied in a carton box		YES	YES					
Stocrin 100 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES		
STOCRIN 200 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	90 tablets in a plastic (HDPE) bottle with a temper-evident stopper, supplied in a box		YES	YES		YES	YES		

Stocrin 200 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	90 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES		
STOCRIN 50 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES		
Stocrin 50 mg capsules	capsules	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 capsules in a HDPE bottle with a PP stopper, supplied in a box		YES	YES		YES	YES		
STOCRIN 600 mg film coated tablets	film coated tablets	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	30 tablets in a plastic (HDPE) bottle with a temper-evident stopper and desiccant, supplied in a box		YES	YES		YES	YES		
STOMATIDIN solution	solution	Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosnia and Herzegovina	200 mL of solution in an amber glass bottle with aluminum cap, supplied in a carton box		YES		YES				YES
STRATTERA 10 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	7 (1x7) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
STRATTERA 18 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	7 (1x7) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
STRATTERA 25 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
STRATTERA 40 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
STRATTERA 60 mg hard capsules	capsules, hard	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (2x14) capsules in a PVC/PE/PCTFE/Al blister, supplied in a box		YES	YES		YES		YES	
STREPSILS sugar-free lozenges, lemon flavour	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	16 lozenges (2x8) in a blister, supplied in a box		YES		YES				YES
Strepsils sugar-free lozenges, lemon flavour	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	16 (2x8) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils lozenges - honey and lemon	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES
Strepsils honey and lemon lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	12 (1x12) lozenges in PVC/PVDC-Al blister, supplied in a tin box		YES		YES				YES
Strepsils honey and lemon lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd.,	12 (1x12) lozenges in a blister, supplied in a tin box		YES		YES				YES

		Thane Road, Nottingham, Great Britain									
Strepsils lozenges - menthol and eucalyptus	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils lozenges - menthol and eucalyptus	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES
Strepsils lozenges - orange with vitamin C	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES
Strepsils lozenges - orange with vitamin C	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils original lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils original lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils Plus lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister, supplied in a box		YES		YES				YES
Strepsils Plus lozenges	lozenges	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	24 (2X12) lozenges in a blister (PVC/PVDC-Al), supplied in a box		YES		YES				YES
Structolipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 500 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag containing oxygen absorber, and one bag with solution for packaging airtightness control		YES		YES			YES	
Structolipid 20%	emulsion for infusion	Fresenius Kabi AB, Uppsala, Sweden	Plastic bag ("Excel") containing 250 mL of emulsion for infusion with two attachments for drug administration and for infusion, one small bag		YES		YES			YES	

			containing oxygen absorber, and one bag with solution for packaging airtightness control								
Stugeron forte tablets	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	50 (5x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Subutex 0.4 mg sublingual tablets	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-Al blister, supplied in a box		YES	YES				YES	
Subutex sublingvalne tablets 2 mg	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-Al blister, supplied in a box		YES	YES				YES	
Subutex sublingvalne tablets 8 mg	sublingual tablets	Reckitt Benckiser Healthcare International Ltd., Thane Road, Nottingham, Great Britain	7 tablets, supplied in a box		YES	YES				YES	
Subutex sublingvalne tablets 8 mg	sublingual tablets	Reckitt Benckiser Healthcare (UK) Limited, East Yorkshire, Great Britain for Schering-Plough Corporation, USA	7 (1x7) tablets in a PVC/PVDC-Al blister, supplied in a box		YES	YES				YES	
Sulfasol 4%	eye drops, solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in a PE bottle with dropper attachment and PP cap, supplied in a box	YES			YES				
Sulotrim 100/20 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 (1x20) tablets in a PVC/Al blister, supplied in a box	YES			YES				
Sulotrim 400/80 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box	YES			YES				
Sulotrim Forte 800/160 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	20 tablets in an amber glass bottle, supplied in a carton box	YES			YES				
Sulotrim oral suspension	oral suspension	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of suspension in an amber glass bottle and a plastic measuring spoon, supplied in a box	YES			YES				
Sulpirid 100 mg/2 mL injection	solution for injection	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	2 mL of solution for injection in a glass ampoule, 6 ampoules in a box	YES			YES				
Sulpirid 200 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	12 capsules in a plastic bottle with closure, supplied in a box	YES			YES				
Sulpirid 50 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/Al blister, supplied in a box	YES			YES				

Sumamed forte syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES					
Sumamed injection	powder for solution for infusion	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 glass bottles with powder, supplied in a box	YES		YES					
Sumamed capsules	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) capsules in a PVC/PVDC//Al blister, supplied in a box	YES		YES					
Sumamed S capsules 250 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 4 capsules (blister)	YES		YES					
Sumamed S tablets 500 mg	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 2 film tablets (blister)	YES		YES					
Sumamed syrup	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES					
Sumamed syrup 1200	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES					
Sumamed syrup 1200 XL	powder for preparation of oral suspension	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One HDPE bottle with powder, one plastic spoon and one plastic syringe for dose delivery, supplied in a box	YES		YES					
Sumamed tablets 125 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	6 (1x6) tablets in a PVC/Al blister, supplied in a box	YES		YES					
Sumamed tablets 500 mg	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	4 (1x3) tablets in a PVC/Al blister, supplied in a box	YES		YES					
Supremin	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and a 5-mL polystyrene spoon, supplied in a box	YES			YES				
Sutent 12.5 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES		
Sutent 25 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES		
Sutent 50 mg capsules	capsules, hard	Pfizer Italia S.r.l., Marina del Tronto, Ascoli Piceno, Italy	30 capsules in a plastic (HDPE) bottle with a plastic stopper, supplied in a box		YES	YES		YES	YES		
Symbicort Turbuhaler 160/4.5 µg	inhalation powder	AstraZeneca Södertälje, Sweden or AstraZeneca GmbH, Plankstadt, Germany	120 doses in a plastic inhaler with mouthpiece, supplied in a box		YES	YES					
Symbicort Turbuhaler 160/4.5 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES					

Symbicort Turbuhaler 320/9 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES					
Symbicort Turbuhaler 80/4.5 µg	inhalation powder	AstraZeneca AB, S-151-85 Södertälje, Sweden; AstraZeneca GmbH, D-68721 Plankstadt, Germany	60 doses in a plastic inhaler with a mouthpiece, supplied in a box		YES	YES					
Symbicort Turbuhaler 80/4.5 µg	inhalation powder	AstraZeneca Södertälje, Sweden or AstraZeneca GmbH, Plankstadt, Germany	120 doses in a plastic inhaler with mouthpiece, supplied in a box		YES	YES					
Synagis 100 mg powder and diluent for injections	lyophilisate and diluent for preparation of solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Box with one bottle with 100 mg of preparation, 1 mL of solvent in an ampoule and a leaflet		YES	YES			YES		
Synagis 50 mg powder and diluent for injections	lyophilisate and diluent for preparation of solution	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	Box with one bottle with 50 mg of preparation and 1 mL of solvent in an ampoule		YES	YES			YES		
Synopen injection	solution for injection	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis, Basel, Switzerland	2 mL of solution for injecion in an ampoule, 10 ampoules in a box	YES			YES				
Synopen ointment	ointment	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis, Basel, Switzerland	20 grams of ointment in an Al tube, supplied in a box	YES			YES				
Syntocinon 5 IU injection	solution for intramuscular/intravenous injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	Box with 10 ampoules with 1 mL of solution		YES	YES					
Syntocinon aerosol	nasal aerosol	Novartis Pharma S.A.S., Huningue Cedex, France for Novartis Pharma AG, Basel, Switzerland	Bottle with 5 mL of solution with a spray attachment, supplied in a box		YES	YES					
Tabex forte syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL plastic measuring spoon, supplied in a box	YES			YES			YES	
Tabex syrup	syrup	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	100 mL of syrup in an amber glass bottle and a 5-mL plastic measuring spoon, supplied in a box	YES			YES			YES	
TachoComb 2.5x3.0x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter-Strasse 25, Linz, Austria	One collagen sponge for wound dressing (2.5x3.0x0.5 cm) in a double package (plastic foil/alufoil) and a silicagel bag, supplied in a box		YES						
TachoComb 9.5x4.8x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter-Strasse 25, Linz, Austria	One collagen sponge for wound dressing (9.5x4.8x0.5 cm) in a double package (plastic foil/alufoil) and a silicagel bag, supplied in a box		YES						
TachoSil 2.5x3.0x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter Strasse 25, Linz, Austria	One collagen sponge for wound dressing (2.5x3.0x0.5 cm) in a double package (blister) and a silicagel bag, supplied in a box		YES						

TachoSil 9.5x4.8x0.5 cm	spongy absorbent wound dressing	Nycomed Austria GmbH, St. Peter Strasse 25, Linz, Austria	One collagen sponge for wound dressing (9.5x4.8x0.5 cm) in a double package (blister) and a silicagel bag, supplied in a box		YES						
Tadenan	capsules, soft	Laboratoires Fournier S.A., Fontaine Les Dijon, France	60 (6x10) soft capsules in a blister (PVC/Al), supplied in a box		YES	YES					
Tafen 50 µg nasal spray	nasal spray, suspension	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	10 mL of suspension (200 inhalation doses) in a brown glass bottle with a plastic atomizer pump and plastic protective cap, supplied in a box		YES		YES				
Tafen Novolizer 200 µg inhalation powder	inhalation powder	Lek d.d., Ljubljana, Republic of Slovenia in cooperation with Sofotec GmbH & Co.KG, Germany	One cartridge with 2.18 g of powder on average (teh cartridge contains 200 doses of powder), supplied in a box		YES		YES				
Tafen Novolizer 200 µg powder for inhalation	inhalation powder	Lek d.d., Ljubljana, Republic of Slovenia in cooperation with Sofotec GmbH & Co.KG, Germany	One inhaler and one cartridge with approx. 2.18 g of powder (the cartridge contains 200 doses of powder), supplied in a box		YES		YES				
Tagren 250 mg film coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	40 (3x10) tablets in a PVC/Al blister, supplied in a box		YES		YES				
Tamiflu 12 mg/mL powder for oral suspension	powder for preparation of oral suspension	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 g of powder for oral suspension in a glass bottle with a plastic temper-evident stopper, a plastic measuring cup for solvent, a plastic attachment affixed to the bottle and a plastic syringe for application of oral suspension, supplied in a box		YES	YES		YES	YES		
Tamiflu 75 mg hard capsules	hard capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	10 (1x10) capsules in a blister, supplied in a box		YES	YES		YES	YES		
Tamosin 0.4 mg extended-release capsules	prolonged-release capsules, hard	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (2x15) capsules in a PVC/PVDC//Al blister, supplied in a box	YES			YES				
Tanakan 40 mg/mL oral solution	oral solution	Beaufor Ipsen Industrie, Dreux, France	30 mL of solution in an amber glass bottle with a plastic stopper and 1 mL measuring plastic syringe with a protective casing, supplied in a box		YES						YES
Tanakan film coated tablets	film coated tablets	Beaufor Ipsen Industrie, Dreux, France	90 (6x15) film coated tablets in a PVC/Al blister, supplied in a box		YES						YES
Tantum Lemon lozenges	lozenges	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	10 individually paper-wrapped lozenges in a protective PE/paper/Al wrapping, 20 (2x10) lozenges in a box		YES		YES				YES
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	1000 mL of solution in a plastic bottle with temper-proof closure and metering pump, supplied in a box		YES		YES				YES
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	1000 mL of solution in a plastic bottle with temper-proof closure, supplied in a		YES		YES				YES

			box								
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	150 mL of solution in a plastic bottle with temper-proof closure and atomizer pump, supplied in a box		YES		YES				YES
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	150 mL of solution in a plastic bottle with temper-proof closure cap, supplied in a box		YES		YES				YES
Tantum Verde gargling solution	oromucosal solution	Sanochemia Pharmazeutika AG, Neufeld/Leitha, Austria	60 mL of solution in a glass bottle with a temper--evident stopper, supplied in a box		YES		YES				YES
Tantum Verde lozenges	lozenges	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	11 individually paper-wrapped lozenges in a protective PE/paper/Al wrapping, 20 (2x10) lozenges in a box		YES		YES				YES
Tantum Verde spray 0.15%	oromucosal spray	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	30 mL of solution in a plastic bottle with a spray attachment, supplied in a box		YES		YES				YES
Tantum Verde spray 0.30%	oromucosal spray	A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy	15 mL of solution in a plastic bottle with nebullizer attachment, supplied in a box		YES		YES				YES
TANYZ 0.4 mg	prolonged release capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	60 (6x10) capsules in a PVC/PE/PVDC/Al blister, supplied in a box		YES		YES	YES		YES	
TANYZ 0.4 mg	prolonged-release capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) capsules in a PVC/PE/PVDC/Al blister, supplied in a box		YES		YES	YES		YES	
Tarceva 100 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al) , supplied in a box		YES	YES			YES		
Tarceva 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Tarceva 25 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	30 (3x10) film coated tablets in a blister (PVC/Al) , supplied in a box		YES	YES			YES		
Target 10	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in an amber glass bottle, supplied in a box	YES			YES				YES
Target Plus capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 capsules in an amber glass bottle, supplied in a box	YES			YES				
Targocid 200 mg	powder for preparation of solution for injection	Gruppo Lepetit S.p.A, Anagni, Italy	Vial with powder and ampoule with diluent supplied in a box		YES	YES					
Targocid 400 mg	powder for preparation of solution for injection	Gruppo Lepetit S.p.A, Anagni, Italy	Vial with powder and ampoule with diluent supplied in a box		YES	YES					
Tarka	capsules	Abbott GmbH & Co. KG, Ludwigshafen, Germany	28 capsules (2x14) in a PVC/Al blister , supplied in a box		YES	YES					
Tarka 180 mg/2 mg tablets	modified-release tablets	Abbott GmbH & Co. KG, Ludwigshafen,	28 (2x14) modified-release tablets in a blister		YES	YES					

		Germany	(PVC/PVDC//Al) , supplied in a box								
TARKA 240 mg/2 mg tablets	modified-release tablets	Abbott GmbH & Co.KG., Ludwigshafen, Germany	28 (2x14) modified-release tablets in a blister (PVC/PVDC//Al) , supplied in a box		YES	YES					
TARKA 240 mg/4 mg tablets	modified-release tablets	Abbott GmbH & Co.KG., Ludwigshafen, Germany	28 (2x14) modified-release tablets in a blister (PVC/PVDC//Al) , supplied in a box		YES	YES					
Tavanic 250 mg tablets	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES				YES	
Tavanic 500 mg tablets	film tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES				YES	
Tavanic i.v. 500 mg	solution for intravenous infusion	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	100 mL of solution in a glass bottle, supplied in a box		YES	YES				YES	
Taxol injection 100 mg / 16.7 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 16.7 mL of solution concentrate, supplied in a carton box		YES	YES				YES	
Taxol injection 30 mg / 5 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 5 mL of solution concentrate, supplied in a carton box		YES	YES				YES	
Taxol injection 300 mg / 50 mL	concentrate for solution for infusion	Bristol Myers-Squibb S.r.l., Sermoneta, Latina, Italy	One glass vial with 50 mL of solution concentrate, supplied in a carton box		YES	YES				YES	
Taxotere 20 mg	concentrate for solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	One glass vial with 0.5 mL of concentrate and one glass vial containing 1.5 mL of diluent in a blister, supplied in a box		YES	YES					
Taxotere 80 mg	concentrate for solution for infusion	Aventis Pharma Dagenham, Dagenham, Essex, Great Britain	One glass vial with 2 mL of concentrate and one glass vial with 6mL of diluent in a blister, supplied in a box		YES	YES					
Tazocin 4.5 g injection for intravenous use	powder for preparation of solution for injection or infusion	Wyeth Lederle S.p.A., Catania, Italy; Wyeth Laboratories, New Lane, Havant, Great Britain	Clear glass 72-mL bottle with 4.5 g of lyophilisate equipped with a grey bromobutyl stopper and flip-off cap of aluminum and plastic coloured pink, supplied in a box		YES	YES					
Telebrix 35	solution for injection	Guerbet, Cedex, France	Vial with 50 mL of solution, supplied in a box		YES	YES					
Telfast 120 mg	film coated tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES					
Telfast 180 mg	film coated tablets	Aventis Pharma Deutschland GmbH, Brunningstrasse 50, Frankfurt am Main, Germany	10 tablets in a blister, supplied in a box		YES	YES					
Telfast 30 mg	film coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	60 (4x15) tablets in a blister, supplied in a box		YES	YES					

Temodal capsules 100 mg	capsules, hard	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES					
Temodal capsules 20 mg	capsules, hard	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES					
Temodal capsules 250 mg	capsules, hard	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES					
Temodal capsules 5 mg	capsules, hard	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	5 capsules in a glass bottle with a plastic stopper, supplied in a box		YES	YES					
Tenicef 0.5 g injection	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	5 (10 mL) glass bottles with powder, supplied in a box		YES		YES				
Tenicef 1g injection	powder for preparation of solution for i.v. and i.m. injection	Pliva Krakow, Krakow, Poland	5 (15 mL) glass bottles with powder, supplied in a box		YES		YES				
Tenicef 2g injection	powder for preparation of injection/infusion solution for i.v. use	Pliva Krakow, Krakow, Poland	5 (15 mL) glass bottles with powder, supplied in a box		YES		YES				
Tenormin 100 mg tablets	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	28 (2x14) film coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES					
Tenormin 50 mg tablets	film coated tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	29 (2x14) film coated tablets in a blister (PVC/PVDC//Al), supplied in a box		YES	YES					
Tenox 10 mg tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Tenox 5 mg tablets	tablets	Krka d.d., Novo Mesto, Republic of Slovenia; Krka Farma d.o.o., DPC Jastrebarsko, Republic of Croatia	30 (3x10) tablets in a blister, supplied in a box	YES			YES				
Teolin retard 125 mg tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 tablets in a glass bottle, supplied in a carton box		YES		YES				
Teolin retard 300 mg tablets	prolonged-release tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	40 (4x10) tablets in a PVC/Al blister, supplied in a carton box		YES		YES				
Teotard 200 mg prolonged-release capsules	prolonged-release capsules, hard	Krka d.d., Novo mesto, Šmarješka cesta 6, Republic of Slovenia in cooperation with Astellas Pharma GmbH, Germany	40 (4x10) capsules in a blister (PVC/Al), supplied in a box		YES		YES				
Teotard capsules prolonged-release 350 mg	prolonged-release capsules, hard	Krka d.d., Novo mesto, Šmarješka cesta 6, Republic of Slovenia in cooperation with Astellas Pharma GmbH, Germany	40 (4x10) capsules in a blister (PVC/Al), supplied in a box		YES		YES				
Tertensif	film coated tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	30 (1x30) tablets in a PVC/Alu blister , supplied in a box		YES	YES					

Tertensif SR	sustained-release film tablets	Les Laboratories Servier Industrie, 905 route de Saran, 45520 Gidy, France	Box with 30 tablets (2x15) in a blister		YES	YES					
Tetanus antitoxin (equine) 1500 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 ampoule with 1500 IU of preparation	YES							
Tetanus antitoxin (equine) 1500 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 ampoules each with 1500 IU of preparation	YES							
Tetanus antitoxin (equine) 3000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 50 ampoules each with 3000 IU of preparation	YES							
Tetanus antitoxin (equine) 3000 IU	solution for parenteral use	Imunološki zavod d.d., Rockefellerova 2, Zagreb, Republic of Croatia	Box with 1 ampoule with 3000 IU of preparation	YES							
TETRAct - HIB, combined diphtheria, tetanus, pertussis and Haemophilus influenzae type B vaccine	lyophilisate and suspension for preparation of suspension for i.m. and deep subcutaneoud use	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 bottle containing lyophilisate and 1 glass syringe with 0.5 mL of suspension		YES						
TETRAXIM diphtheria, tetanusa, pertussis (acellular) and poliomyelitis (inactivated) vaccine , absorbed	suspension for injections	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Glass syringe with a needle containing 0.5 mL of suspension for injections		YES						
TEVETEN 600 mg	film coated tablets	Solvay Pharmaceuticals B.V., Weesp, the Netherlands	30 (2x14) film coated tablets in a blister (PVC/Aclar//Al), supplied in a box		YES	YES					
TEVETEN 600 mg	film coated tablets	Solvay Pharmaceuticals B.V., C.J. van Houtenlaan 36, 1381 CP Weesp, the Netherlands	28 (2x14) tablets in a blister (PVC/Aclar/Al), supplied in a box		YES	YES				YES	
Teveten plus	film coated tablets	Solvay Pharmaceuticals GmbH, Hannover, Germany Solvay Pharmaceuticals B.V., Weesp, the Netherlands	28 (2x14) tablets in a nontransparent PVC/Aclar/Alu blister, supplied in a box		YES	YES				YES	
Thyrogen 0.9 mg powder for solution for injection	powder for solution for injection	Genzyme Ltd., 37 Hollands Road, Haverhill, Suffolk CB9 8PU, Great Britain	Clear type I glass 5-mL vials with siliconized butyl stopper with tamper proof flip-off cap, supplied in a box		YES	YES		YES	YES		
TIAREN	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	40 (4x10) capsules in blister (PVC/Al), supplied in a box	YES			YES				
Tienam i.v. Infusion	powder for preparation of solution for infusion	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, The Nederlands	5 (115 mL) glass bottles with powder for solution for infusion, supplied in a box		YES	YES					
Timalen 0.25% eyel drops	eye drops	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 5 mL of solution in a plastic bottle with a dropper	YES			YES				
Timalen 0.5% eyel drops	eye drops	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	Box with 5 mL of solution in a plastic bottle with a dropper	YES			YES				

TINIDIL	sublingual tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	40 (4x10) lozenges in an orange blister (PVC/PVDC//Al), supplied in a box	YES			YES				
TIRAMAT 100 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (3x20) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
TIRAMAT 200 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (5x12) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
TIRAMAT 25 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PE/PVDC-Al), supplied in a box	YES			YES				
TIRAMAT 50 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (2x30) tablets in a blister (PVC/PE/PVDC-Al), supplied in a box	YES			YES				
Tissucol kit 1.0 mL	lyophilisates for preparation of two-component fibrin adhesives	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 1 mL of aprotinin solution, Trombin 4 lyophilisate, trombin 500 lyophilisate, 1 mL of calcium chloride solution; application kit (Duploject)		YES						
Tissucol kit 2.0 mL	lyophilisates for preparation of two-component fibrin adhesive	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 2 mL of aprotinin solution, Trombin 4 lyophilisate, trombin 500 lyophilisate, 2 mL of calcium chloride solution; application kit (Duploject)		YES						
Tissucol kit 5.0 mL	lyophilisates for preparation of two-component fibrin adhesive	Baxter AG, Industriestrasse 67, A-1220 Vienna, Austria	5 glass bottles: Tissucol lyophilisate, 5 mL of aprotinin solution, Trombin 4 lyophilisate, trombin 500 lyophilisate, 5 mL of calcium chloride solution; application kit (Duploject)		YES						
TOBRADEX eye drops, suspension	eye drops, suspension	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of suspension in a polyethylene bottle with a drop tainer and an LDPE dropper with a PP temper-evident screw cap, supplied in a box		YES	YES					
TOBRADEX eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES					
Tobrex eye drops	eye drops, solution	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	5 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES					
Tobrex eye ointment	eye ointment	Alcon-Couvreur s.a., Rijksweg 14, Puurs, Belgium	3.5 g of ointment in an aluminum tube, supplied in a box		YES	YES					
TONOCARDIN 2 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PVDC//Al), supplied in a box	YES			YES				
TONOCARDIN 4 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	23 (2x10 tablets in PVC/PVDC/Al blister, supplied in a box	YES			YES				
Topamax 100 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES					

Topamax 200 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES					
Topamax 25 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES					
Topamax 50 mg tablets	film coated tablets	Cilag AG, Schaffhausen, Switzerland	60 (6x10) tablets in a blister, supplied in a box		YES	YES					
Torecan suppositories 6.5 mg	suppositories	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	6 (1x6) suppositories in a strip (Al/LDPE), supplied in a box		YES		YES				
Torecan solution for injection 6.5 mg/1 mL	solution for injection (for i.m., i.v. and s.c.use)	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Novartis Pharma Ltd., Switzerland	1-mL of solution for injection in a glas ampoule ; 50 (5x10) ampoules in a blister, supplied in a box		YES		YES				
Torendo 1-mg film coated tablets	film coated tablets	Krka, d.d., Novo mesto, Republic of Slovenia or Krka-Farma d.o.o., Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Torendo 2-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Torendo 3-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Torendo 4-mg film coated tablets	film coated tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box	YES			YES				
Torendo oral solution 1 mg/1 mL	oral solution	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 mL of solution in an amber glass bottle with plastic (PP) cap and 3 mL metered-dose syringe, supplied in a box		YES		YES				
Torendo Q-Tab 0.5-mg orodispersible tablets	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Torendo Q-Tab 1-mg orodispersible tablets	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Torendo Q-Tab 2-mg orodispersible tablets 2 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box	YES			YES				
Tractocile 7.5 mg/mL concentrate of solution for infusion	concentrate of solution for infusion	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	5 mL of concentrate in a glass bottle, supplied in a box		YES	YES					
Tractocile 7.5 mg/mL, solution for injection	solution for injection	Ferring GmbH, Wittland 1, Kiel, Germany; Ferring International Center SA, Chemin de la Vergognausaz, Switzerland	0.9-mL of solution in a glass bottle, supplied in a box		YES	YES					

TRALIN tablets 100 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
TRALIN tablets 50 mg	film coated tablets	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	28 (2x14) tablets in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
Tramadol injection 100 mg/2 mL	solution for injection	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 ampoules each with 2 mL of solution, supplied in a box	YES			YES				
Tramadol injection 50 mg/mL	solution for injection	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 ampoules each with 1 mL of solution, supplied in a box	YES			YES				
Tramadol kapi 100 mg/mL	oral drops, solution	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	10 mL of solution in an amber glass bottle with dropper attachment and plastic cap, suplied in a box	YES			YES				
Tramadol capsules 50 mg	capsules	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	20 (2x10) capsules in a blister (PVC/Al), supplied in a box	YES			YES				
Tramadol suppositories 100 mg	suppositories	Farmal d.d., Branitelja domovinskog rata 8, Ludbreg, Republic of Croatia	5 suppositories in an Al/PE pack, supplied in a box	YES			YES				
Tramal 100 mg solution for injection	solution for injection	Grünenthal GmbH, Stolberg, Germany	5 ampoules with 2 mL of solution, supplied in a box		YES	YES					
Tramal 50 mg solution for injection	solution for injection	Grünenthal GmbH, Stolberg, Germany	5 ampoules with 1 mL of solution, supplied in a box		YES	YES					
Tramal suppositories	suppositories	Grünenthal GmbH, Stolberg, Germany	5 suppositories in a strip, supplied in a box		YES	YES					
Tramal drops 96 mL	solution, oral drops	Grünenthal GmbH, Stolberg, Germany	96 mL of solution in an amber glass bottle with a metering pump, supplied in a box		YES	YES					
Tramal kapi, solution for oral drops	solution, oral drops	Grünenthal GmbH, Stolberg, Germany	10 mL of solution in an amber glass bottle, supplied in a box		YES	YES					
Tramal capsules	capsules	Grünenthal GmbH, Stolberg, Germany	20 (2x10) capsules in a blister, supplied in a box		YES	YES					
Tramal retard tablets 100 mg	film coated tablets with prolonged-release	Grünenthal GmbH, Stolberg, Germany	Box with 30 tablets in a blister		YES	YES					
Tramal retard tablets 150 mg	film coated tablets with prolonged-release	Grünenthal GmbH, Stolberg, Germany	Box with 30 tablets in a blister		YES	YES					
Tramal 200 mg retard tablets	prolonged-release film coated tablets	Grünenthal GmbH, Stolberg, Germany	30 tablets in a blister, supplied in a box		YES	YES					
Tramundin retard	prolonged release tablets	Mundipharma Gm.b.H., Limburg, Germany and Mundipharma GES.m.b.H., Vienna, Austria	50 (5x10) tablets in a blister (PVC/Al) , supplied in a box		YES		YES				
Transtec 35 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4 patches in a carton box		YES	YES				YES	
Transtec 35 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 16 patches in a carton box		YES	YES				YES	
Transtec 52.5 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen,	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4		YES	YES				YES	

		Germany	patches in a carton box								
Transtec 70 µg/h	transdermal patch	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	One transdermal patch in a multilayer bag (paper/PE/Al/surlin), 4 patches in a carton box		YES	YES				YES	
Travatan 40 µg/mL eyel drops, solution	eye drops	Alcon Couvreur N.V., Rijksweg 14, Puurs, Belgium; Alcon Cusi S.A., Camil Fabra 58, El Masnou, Barcelona, Spain	2.5 mL of solution in a polypropylene bottle with dropper attachment, in foil, supplied in a box		YES	YES					
Travocort cream	cream	Intendis Manufacturing S.p.A., Segrate, Milano, Italy	15 g of cream in an Al tube		YES	YES					
Trental 400 mg tablets	modified-release film-coated tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	20 (2x10) tablets in a blister, supplied in a box		YES	YES					
Tricor 145 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	33 (3x10) film coated tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES		YES		YES	
Tricor 160 mg	film coated tablets	Laboratoires Fournier S.A., Fontaine Les Dijon, France	34 (3x10) film coated tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES		YES		YES	
Triderm cream	cream	Schering-Plough Labo N.V. Industrepark 30, Heist-op-den-Berg, Belgium	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Triderm ointment	ointment	Schering-Plough Farma, Lda, Casal do Colaride, Agualva Cacem, Portugal	15 g of cream in an aluminum tube, supplied in a box		YES	YES					
Trileptal 150 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES				YES	
Trileptal 300 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES				YES	
Trileptal 60 mg/mL oral suspension	oral suspension	Novartis Pharma S.A.S., Huningue Cedex, France	250-mL of oral suspension in an amber glass bottle with plastic temper-proof closure, 10-mL plastic syringe for administration of oral suspension and a plastic bottle attachment, supplied in a box		YES	YES				YES	
Trileptal 600 mg film coated tablets	film coated tablets	Novartis Farma S.p.A., Torre Annunziata (Napoli), Italy	50 (5x10) tablets in a blister (PVC/PE/PVDC/Al), supplied in a box		YES	YES				YES	
Trinitrosan 5 mg	concentrate for solution for infusion	Merck KGaA, Frankfurter Straße 250, Darmstadt, Germany	1-mL of concentrate for the solution for infusion in a glass ampoule, 5 ampoules in a box		YES	YES					
Trinovum tablets	tablets	Cilag AG, Schaffhausen, Switzerland	21 (1x21) tablets (7 white, 7 pink and 7 orange) in a blister (PVC/Al), supplied in a box		YES	YES					
Triquilar	coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	21 coated tablets (6 red-brown, 5 white and 10 dar yellow) in blister (PVC/Al), supplied in a box		YES	YES					
Trisequens	film coated tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	28 (12 blue, 10 white, 6 red) tablets in a plastic calendar dial pack (dispenser with		YES	YES					

			marked days of the week), supplied in a box									
Tritace 1.25	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritace 2.5	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritace 5	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a blister, supplied in a box		YES	YES						
Tritazide 2.5 mg/12.5 mg	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a green blister (PVC/Al), supplied in a box		YES	YES						
Tritazide 5 mg/25 mg	tablets	Aventis Pharma S.p.A., S.S. 17 KM 22, Scoppito, Italy	28 (2x14) tablets in a green blister (PVC/Al), supplied in a box		YES	YES						
Trusopt eye drops	eye drops	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	5 mL of solution in a plastic container OCUMETER PLUS, supplied in a box		YES	YES						
Tuberkulin PPD RT 23 SSI 10 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 1.5 mL of tuberculin of 10 T.U./0.1 mL		YES							
Tuberkulin PPD RT 23 SSI 2 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 1.5 mL of tuberculin of 2 T.U./0.1 mL		YES							
Tuberkulin PPD RT 23 SSI 2 T.U./0.1 mL	solution for intradermal use	Statens Serum Institut, Copenhagen, Denmark	Box with 1 glass bottle containing 5 mL of tuberculin of 2 T.U../0.1 mL		YES							
Tulip 10 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES		YES					
Tulip 10 mg film coated tablets	film-tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	60 tablets (6x10) in a blister, supplied in a box		YES		YES					
Tulip 20 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister, supplied in a box		YES		YES					
Tulip 20 mg film coated tablets	film-tablets	Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Republic of Slovenia	60 tablets (6x10) in a blister, supplied in a box		YES		YES					
Tulip 40 mg film coated tablets	film coated tablets	Lek farmacevtska družba d.d., Ljubljana, Republic of Slovenia	30 (3x10) tablets in a blister (Al/PVC//PVC//Al), supplied in a box		YES		YES					
Tusidil sugar coated tablets	sugar coated tablets	AD JAKA 80 Radoviš, Radoviš, FYROM	20 (1x20) sugar-coated tablets in a A-PVC blister, supplied in a box		YES		YES					
Tusidil syrup for children	syrup	AD JAKA 80 Radoviš, Radoviš, FYROM	60 mL of syrup in an amber glass bottle, supplied in a box		YES		YES					
Tusifan syrup 1 mg/mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in a dark brown plastic bottle, supplied in a box	YES			YES				YES	
Tusifan syrup 3 mg/mL	syrup	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	150 mL of syrup in a dark brown plastic bottle, supplied in a box	YES			YES				YES	
TWINRIX Adult	suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de lInstitut 89,	Pre-filled glass syringe containing a single dose of the vaccine (1 mL of		YES							

		Rixensart, Belgium	suspension) with plunge stopper and needle, supplied in a carton box								
TWINRIX Paediatric	suspension for injection	GlaxoSmithKline Biologicals s.a., Rue de IInstitut 89, Rixensart, Belgium	Pre-filled glass syringe containing a single dose of the vaccine (0.5 mL of suspension) with plunge stopper and needle, supplied in a carton box		YES						
TYPHIM Vi, thyphoid polysaccharide vaccine, purified	solution for intramuscular and subcutaneous use	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Box with 1 glass syringe containing 1 dose of vaccine (0.5 mL) and a needle with a needle protection		YES						
Ulfamid tablets 20 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Ulfamid tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	10 (1x10) tablets in a blister, supplied in a box		YES		YES				
Ultop capsules 20 mg	gastric-resistant capsules, hard	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 capsules in a plastic (HDPE) bottle with plastic PP cap and desiccant, supplied in a box		YES		YES				
Ultop capsules 20 mg	gastric-resistant capsules, hard	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 capsules in a plastic (HDPE) bottle with plastic (PP) closure and desiccant, supplied in a box		YES		YES				
Ultop capsules 40 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	14 capsules in a plastic bottle (with desiccant), supplied in a box		YES		YES				
Ultop powder for solution for infusion 40 mg	powder for solution for infusion	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	Colourless glass bottle with lyophilisate (closed with a rubber stopper and Al ring), supplied in a box		YES		YES				
Ultop S capsules 10 mg	capsules	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 capsules in a plastic bottle (with desiccant), supplied in a box		YES		YES				
Ultraproct suppositories	suppositories	Intendis Manufacturing SpA, Segrate, Milano, Italy	10 suppositories in a strip (Al/LDPE foil), supplied in a box		YES	YES					
Ultraproct oitment	rectal ointment	Intendis Manufacturing SpA, Segrate, Milano, Italy	30 g of ointment in an aluminium tube with a plastic applicator, supplied in a box		YES	YES					
Ultravist 240 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 50 mL of solution, supplied in a box		YES	YES					
Ultravist 300 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 100 mL of solution, supplied in a box		YES	YES					
Ultravist 300 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 50 mL of solution, supplied in a box		YES	YES					
Ultravist 300 solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 ampoules each containing 20 mL of solution, supplied in a box		YES	YES					
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 infusion bottles each with 100 mL of solution, supplied in a box		YES	YES					
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	200 mL in a glass bottle for infusion, 10 bottles in a box		YES	YES					
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-178, Berlin, Germany	500 mL of solution in a glass infusion bottle, 8 bottles in a box		YES	YES					
Ultravist 370 solution for infusion	solution for infusion	Schering AG, Muellerstrasse 170-	10 infusion bottles each with 50 mL of solution, supplied in		YES	YES					

		178, Berlin, Germany	a box									
Ultravist 370 solution for injection	solution for injection	Schering AG, Muellerstrasse 170-178, Berlin, Germany	10 ampoules each containing 30 mL of solution, supplied in a box		YES	YES						
Ulzol	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (2x7) capsules in a blister, supplied in a box	YES			YES					
UPFEN 200 mg film coated tablets	film coated tablets	Bristol-Myers Squibb, 304, avenue du Dr Jean Bru, Agen, France	20 (2x10) film coated tablets in a PVC-Al blister, supplied in a box		YES		YES					YES
UPFEN 200 mg effervescent tablets	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	2 plastic tubes each with 10 effervescent tablets, supplied in a box (desiccant in the plastic cap)		YES		YES					YES
UPSARIN plus vitamin C	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube (desiccant in polyethylene cap), supplied in a box		YES		YES					YES
Upsavit vitamin C 1000 mg	effervescent tablets	Bristol-Myers Squibb, 304, avenue du Dr. Jean Bru, Agen, France; Bristol-Myers Squibb, 979 Avenue des Pyrenees, Le Passage, France	10 effervescent tablets in a polypropylene tube (desiccant in polyethylene cap), supplied in a box		YES		YES					YES
Uromitexan injection	solution for intravenous injection	Baxter Oncology GmbH, Kantstrasse 2, Halle, Germany	15 (3x5) ampoules with 4 mL of solution, supplied in a box		YES	YES						
Urosal M plus capsules	capsules, soft	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	30 (3x10) capsules in a PVC/Al blister, supplied in a box	YES								YES
Ursofalk capsules	capsules	dr. Falk Pharma GmbH, Freiburg, Germany	100 (4 x 25) tablets in PVC//Al blister, supplied in a box		YES		YES					
Urutal 8 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	Bottle with 100 tablets, supplied in a box	YES			YES					
Urutal forte 16 mg tablets	tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	60 (3x20) tablets in a PVC/PVDC/Al blister, supplied in a box	YES			YES					
UTROGESTAN 100 mg capsules	capsules, soft	Laboratoires Besins International, Montrouge, France; Besins International Belgique S.A., Drogenbos, Belgium	30 (2x15) capsules in a PVC/Al blister, supplied in a box		YES		YES					
Uvin H Forte tea blend	tea blend	Cedevita d.o.o., Zagreb, Republic of Croatia	Polypropylene bag with 50 g, supplied in a carton box	YES								YES
Uvin H Forte tea blend in filter bags	tea blend in filter bags	Cedevita d.o.o., Zagreb, Republic of Croatia	25 filter bags (microcrystal cellulose) each with 1.5 g of tea blend, supplied in a box	YES								YES
Uvin H Forte granules	granules	Cedevita d.o.o., Zagreb, Republic of	14 bags (paper/Al/PE) each containing 5 g of granules,	YES								YES

		Croatia	supplied in a box								
Vagifem	vaginal tablets	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark	15 (3x5) applicators each with one vaginal tablet, in blister packs, supplied in a box		YES	YES					
Vagisan	vaginal tablets	Dr. August Wolff GmbH & Co. Arzneimittel, Bielefeld, Germany	7 vaginal tablets in a strip, supplied in a box		YES		YES				
Vaira 10 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a blister, supplied in a box	YES			YES				
Vaira 5 mg tablets	film coated tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (1x28) tablets in a blister, supplied in a box	YES			YES				
Valcyte 450 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	60 tablets in a plastic (HDPE) bottle, supplied in a carton box		YES	YES				YES	
Vaqta 25 IU/0.5 mL (purified, inactivated hepatitis A vaccine)	suspension for injections	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Box with 1 glass bottle containing 0.5 mL of suspension		YES						
Vaqta 50 IU/1 mL (purified, inactivated hepatitis A vaccine)	suspension for injections	Merck Sharp & Dohme B.V., Waarderweg 39, Postbus 581, Haarlem, the Netherlands	Box with 1 glass bottle containing 0.5 mL of suspension		YES						
Vasilip film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	30 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES				
Vasilip 10 mg film-coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES				
Vasilip film coated tablets 20 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	31 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES				
Vasilip 20 mg film-coated tablets	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES				
Vasilip film coated tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	32 (3x10) tablets in a PVC/PE/PVDC//Al blister, supplied in a box		YES		YES				
Vasilip film coated tablets 40 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister PVC/PE/PVDC/PE/PVC//Al), supplied in a box		YES		YES				
Vasoflex 1 mg	tablets	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	30 tablets in an amber glass bottle, supplied in a box		YES		YES				
VAXIGRIP - inactivated vaccine against influenza (fragmented)	suspension for injection	Sanofi Pasteur S.A., Lyon, France	Pre-filled glass syringe (glass type I) with a needle and a chlorobromobutyl or chlorobutyl stopper, containing single dose (0.5 mL) of suspension for injection, supplied in a box		YES						
VAXIGRIP inactivated vaccine against influenza (fragmented)	suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Pre-filled glass syringe with a needle containing a single dose (0.5 mL) of the suspension for injection, supplied in a box		YES						

VAXIGRIP Pediatric use - inactivated vaccine against influenza (fragmented) for children	suspension for injection	Sanofi Pasteur S.A., 2 avenue Pont Pasteur, Lyon, France	Pre-filled glass syringe with needle containing a single dose (0.25 mL) of suspension for injection, supplied in a box		YES						
Velafax tablets 37.5 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Velafax tablets 75 mg	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a blister, supplied in a box	YES			YES				
Velafax XL capsules 150 mg	prolonged-release capsules, hard	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) capsules in a transparent blister (PVC/Al) , supplied in a box	YES			YES				
Velafax XL capsules 75 mg	prolonged-release capsules, hard	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) capsules in a transparent blister (PVC/Al) , supplied in a box	YES			YES				
Velcade powder for solution for injection	powder for solution for injection	Janssen Pharmaceutica NV, Turnhouseweg 30, Beerse, Belgium	10-mL glass vial containing 38.5 mg of powder for solution for injection, supplied in a box		YES	YES			YES		
Venofer 100 mg/5 mL solution for intravenous injection	solution for injection	Vifor International Inc., St. Gallen, Switzerland for Lek farmacevtska družba d.d. Ljubljana, Republic of Slovenia	5 ampoules each with 5 mL of solution, supplied in a box		YES		YES				
VENTAVIS 10 µg/mL solution for atomizer	solution for atomizer	Schering AG, Berlin, Germany and BERLIMED S.A., Alcala de Henares, Madrid, Spain	3-mL glass ampoule containing 2 mL of solution for nebulizer, 100 ampoules in a box		YES	YES			YES		
Ventolin inhalation solution	nebulisation solution	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	10 mL of solution in an amber glass bottle with plastic cap, supplied in a box	YES			YES				
Ventolin syrup	syrup	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	200 mL of syrup in an amber glass bottle with aluminum cap and plastic measuring spoon, supplied in a box	YES			YES				
Ventolin tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	60 (2x30) tablets in a blister (PVC/Al), supplied in a box	YES			YES				
Vepesid injection 100 mg/5 mL	solution for injection (for preparation of i.v. infusion)	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	5 mL of solution in a glass bottle, supplied in a box (10 boxes in a collective carton packaging)		YES	YES					
Vepesid capsules 100 mg	capsules	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	10 capsules in an amber glass bottle, supplied in a box		YES	YES					
Vepesid capsules 50 mg	capsules	Bristol-Myers Squibb S.r.l., Sermoneta, Latina, Italy	20 capsules in an amber glass bottle, supplied in a box		YES	YES					
Verbinaf 125 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				
Verbinaf 250 mg ablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				

Vermox 100 mg/5 mL oral suspension	oral suspension	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	30 mL of suspension in an amber glass bottle with a 5 mL plastic measuring spoon, supplied in a box		YES		YES				
Vermox tablets 100 mg	tablets	Krka d.d., Novo mesto, Republic of Slovenia in cooperation with Janssen Pharmaceutica, Beerse, Belgium	6 (1x6) tablets in a strip (Al/PE), supplied in a box		YES		YES				
Verolax Senna	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	23 (2x10) tablets in a PVC/PVD//Al) blister, supplied in a box		YES						YES
Vesanoid soft capsules 10 mg	soft capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	100 soft capsules in a brown plastic bottle, supplied in a box		YES	YES					
VFEND 200 mg powder for solution for infusion	powder for solution for infusion	Pfizer PGM, Pocé-sur-Cisse, France	One glass vial with rubber cap and aluminum ring, containing powder, supplied in a box		YES	YES			YES		
VFEND 40 mg/mL powder for oral suspension	powder for oral suspension	Pfizer PGM, Pocé-sur-Cisse, France	45 g of powder for oral suspension in a plastic bottle with a temper-evident stopper, a plastic measuring cup for solvent (23 mL), a plastic attachment for bottle neck and a plastic syringe for administration of oral suspension, supplied in a box		YES	YES			YES		
VFEND tablets 200 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES		
VFEND tablets 50 mg	film coated tablets	Heinrich Mack Nachf. GmbH & Co., Illertissen, Germany	28 (2x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Viagra tablets 100 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Viagra tablets 25 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/Al) supplied in a box		YES	YES			YES		
Viagra tablets 50 mg	film coated tablets	Pfizer PGM, Poce-sur-Cisse, France	One (1x1) film coated tablet in a blister (PVC/Al) supplied in a box		YES	YES			YES		
Videx capsules 125 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/Al blister, supplied in a carton box		YES	YES		YES		YES	
Videx capsules 250 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/Al blister, supplied in a carton box		YES	YES		YES		YES	
Videx capsules 400 mg	gastric-resistant capsules, hard	Bristol-Myers Squibb, Meymac, France	30 (3x10) capsules in a PVC/PE/ACLAR/Al blister, supplied in a carton box		YES	YES		YES		YES	
Vilpin 10 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in an orange PVC/PVDC//Al, supplied in a box	YES			YES				
Vilpin 5 mg tablets	tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	30 (3x10) tablets in a blister (orange PVC/PVDC//Al) , supplied in a box	YES			YES				

Vincristine injection 1 mg	solution for injection (for intravenous use)	Pfizer (Perth) Pty Limited, Bentley WA, Australija	1-mL of solution for injection in a plastic bottle, 5 bottles in a box		YES	YES					
VIRACEPT 250 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	270 film-coated tablets in a plastic (HDPE) bottle with child resistant closure, supplied in a box		YES	YES			YES		
Viramune tablets 200 mg	tablets	Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany and Boehringer Ingelheim Ellas A.E., Atika, Greece	60 (6x10) tablets in a blister (PVC/Al), supplied in a box		YES	YES			YES		
Virolex cream	cream	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	5 g of cream in a tube, supplied in a box		YES		YES				
Virolex lyophilisate for preparation of infusion solution	lyophilisate for preparation of solution for infusion	Krka d.d., Novo Mesto, Republic of Slovenia in cooperation with Glaxo SmithKline	5 glass bottles each with 250 mg of lyophilisate, supplied in a box		YES		YES				
Virolex eye ointment	eye ointment	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	4.5 g of ointment in a tube, supplied in a box		YES		YES				
Virolex tablets	tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	20 (2x10) tablets in a blister, supplied in a box		YES		YES				
Visipaque 270 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Gass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 50 mL of solution, 10 ampoules in a box		YES	YES					
Visipaque 270 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Gass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 100 mL of solution, 10 ampoules in a box		YES	YES					
Visipaque 270 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 50 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES					
Visipaque 270 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 100 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 100 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Glass bottle (with rubber stopper, aluminum ring and plastic cap) containing 200 mL of solution, 6 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork,	Glass bottle (with rubber stopper, aluminum ring and plastic protective cap)		YES	YES					

		Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	containing 100 mL of solution, 10 ampoules in a box								
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Glass bottle (with rubber stopper, aluminum ring and plastic protective cap) containing 50 mL of solution, 10 ampoules in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 500 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 6 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 200 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 50 mL of solution with a rubber stopper and plastic (polypropylene) closure with protective ring and cap, 10 bottles in a box		YES	YES					
Visipaque 320 mgI/mL	solution for injection	GE Healthcare Republic of Ireland, Carrigtwohill, Co. Cork, Republic of Ireland; GE Healthcare AS, Nydalen, Oslo, Norway	Plastic (polypropylene) bottle containing 20 mL of solution, with a plastic twist-off cap, 10 bottles in a box		YES	YES					
Vistagan Liquifilm 0.5 % eye drops	eye drops, solution	Allergan Pharmaceuticals Republic of Ireland, Castlebar Road, Westport, Co Mayo, Republic of Ireland	5 mL of solution in a plastic bottle with a dropper, supplied in a box		YES	YES					
Visudyne	powder for solution for infusion	Novartis Pharma S.A.S., Huningue Cedex, France	One glass vial containing powder with rubber stopper and aluminum ring, supplied in a box		YES	YES			YES		
Vitamin B12 Krka solution for injection 100 µg/1 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 ampoules with 1 mL of solution, supplied in a box		YES		YES				
Vitamin B12 Krka solution for injection 500 µg/1 mL	solution for injection	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	100 ampoules with 1 mL of solution, supplied in a box		YES		YES				
Vitopril 10 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	30 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box		YES		YES				
Vitopril 20 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	31 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box		YES		YES				
Vitopril 5 mg	tablets	STADA Arzneimittel AG, Stadtstraße 2-18, Bad Vilbel, Germany	32 (3x10) tablets in a PVC/PVdC/Alu blister, supplied in a box		YES		YES				
Vizol eyel drops solution	eye drops, solution	Jadran - Galenski laboratorij d.d., Pulac bb, Rijeka, Republic of Croatia	10 mL of nasal drops in a clear plastic (PE) bottle with a dropper attachment, supplied in a box	YES			YES				YES
Water for Injection, Alkaloid	diluent for parenteral use	Alkaloid AD - Skopje, Bulevar Aleksandar Makedonski 12, Skopje, FYROM	50 colourless glass ampoules with 5 mL of water for injection, supplied in a box		YES		YES				

Water for Injections Viaflo	diluent for parenteral use	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	20 plastic Viaflo bags with 500 mL of infusion solution, in a protective bag, supplied in a box		YES		YES				
Water for Injection, Viaflo	diluent for parenteral use	Baxter S.A., Belgium; Baxter Healthcare Ltd, Great Britain; Bieffe Medital Sabinanigo, Spain; Baxter Healthcare S.A., Republic of Ireland	30 plastic Viaflo bags with 250 mL of water for injection in a protective bag, supplied in a box		YES		YES				
Voltaren Emulgel 1 %	gel	Novartis Consumer Health S.A., Route de l' Etraz, Nyon, Switzerland Novartis Pharma Produktions GmbH, Oflinger Strasse 44, Wehr, Germany	50 g of gel in an aluminium tube, supplied in a box		YES	YES					YES
Voltaren forte	film coated tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	Box with 20 tablets (blister, 2x10 tbl.)	YES			YES				
Voltaren injection	solution for injection	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	5 ampoules each with 3 mL of solution for injection, supplied in a box	YES			YES				
Voltaren rapid	coated tablets	Pliva Croatia Ltd., Zagreb, Republic of Croatia in cooperation with Novartis Pharma AG, Basel, Switzerland	10 (1x10) film coted tablets in a PVC//Al ili PVC/PE/PVDC//Al blister, supplied in a box	YES			YES				
Voluven 6% solution for infusion	solution for infusion	Fresenius Kabi Deutschland GmbH, Germany	500 mL of solution in a transparent plastic bag (Freeflex), 15 bags in a box		YES		YES			YES	
Voluven 6% solution for infusion	solution for infusion	Fresenius Kabi Deutschland GmbH, Germany	500 mL of solution in a glass bottle, 10 bottles in a box		YES		YES			YES	
Xalacom	eye drops, solution	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	2.5 mL of solution in a 5 mL plastic (LDPE) bottle with dropper attachment and plastic (HDPE) temper-proof closure, supplied in a box		YES	YES				YES	
Xalatan	eye drops, solution	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium	2.5 mL eye drops, solution in a 5 mL plastic bottle with dropper attachment, supplied in a box		YES	YES					
Xanax SR 0.5 mg tablets	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia; s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	30 (3x10) tablets in a PA/Al//Al blister, supplied in a box		YES	YES					
Xanax SR 1 mg tablets	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia; s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	31 (3x10) tablets in a PA/Al//Al blister, supplied in a box		YES	YES					
Xanax SR tablets 2 mg	modified release tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium;	33 (3x10) tablets in a PVC/Al blister , supplied in a box		YES	YES					

		Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy									
Xanax tablets 0.25 mg	tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	31 (3x10) tablets in a PVC/Al blister , supplied in a box		YES	YES					
Xanax tablets 0.5 mg	tablets	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium; Pfizer Italia s.r.l. Localita Marino del Tronto, Ascoli Piceno, Italy	32 (3x10) tablets in a PVC/Al blister , supplied in a box		YES	YES					
XELODA 150 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	60 (6x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
XELODA 500 mg film coated tablets	film coated tablets	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	120 (12x10) tablets in a blister (PVC/PE/PVDC//Al), supplied in a box		YES	YES		YES	YES		
Xenical	capsules	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	42 (2x21) capsules in a blister, supplied in a box		YES	YES					
Xigris 20 mg powder for solution for infusion	powder for solution for infusion	Lilly Pharma Fertigung und Distribution GmBH & Co. KG, Giessen, Germany	One glass vial with 20 mg of medicinal product, supplied in a box		YES	YES					
Xigris 5 mg powder for solution for infusion	powder for solution for infusion	Lilly Pharma Fertigung und Distribution GmBH & Co. KG, Giessen, Germany	One glass vial with 5 mg of medicinal product, supplied in a box		YES	YES					
Xolair 150 mg	powder and diluent for solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass vial with powder and one glass ampoule with 2 mL of Water for Injection, supplied in a box		YES	YES			YES		
Xolair 75 mg	powder and diluent for solution for injection	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	One glass vial with powder and a glass ampoule with 2 mL of Water for Injection, supplied in a box		YES	YES			YES		
Xorimax 125 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/Al/PE//Al blister or an Al/PE strip, supplied in a box		YES		YES			YES	
Xorimax 250 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/Al/PE//Al) blister or an Al/PE strip , supplied in a box		YES		YES			YES	
Xorimax 500 mg film coated tablets	film coated tablets	Sandoz GmbH, Kundl, Austria	10 (1x10) film coted tablets in a PA/Al/PE//Al) blister or an Al/PE strip , supplied in a box		YES		YES			YES	
XYZAL 0.5 mg/mL oral solution	oral solution	UCB Pharma S.p.A., Pianezza, Italy	200 mL of oral solution in a glass bottle with temper-proof closure and a 10-mL plastic nebulizer, supplied in a box		YES	YES				YES	
Xyzal 5 mg film coated tablets	film coated tablets	UCB Pharma S.p.A., Via Praglia 15, I-10044 Pianezza (TO), Italy	10 (1x10) tablets in a Al/Al blister, supplied in a box		YES	YES				YES	

Yasmin film tablets	film coated tablets	Schering AG, Muellerstrasse 170-178, Berlin, Germany	21 (1x21) film-coated tablets in a blister, supplied in a box		YES	YES				YES	
Yasnal film coated tablets 10 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister (OPA/Al/PVC//Al), supplied in a box		YES		YES				
Yasnal film coated tablets 5 mg	film coated tablets	Krka d.d., Šmarješka cesta 6, Novo mesto, Republic of Slovenia	28 (4x7) tablets in a blister (PVC/Al/OPA//Al), supplied in a box		YES		YES				
Zaditen	eye drops, solution	EXCELVISION, Annonay, France	5 mL of solution in a white plastic (LDPE) bottle with a dropper and a plastic (HDPE) stopper with a safety ring, supplied in a box		YES	YES					YES
Zaditen SDU	eye drops, solution	EXCELVISION, Annonay, France	20 (5x4) single-dose plastic (LDPE) containers with 0.4 mL of solution in a protective package (PVC/Al/PA-Al/papir), supplied in a box		YES	YES					YES
Zalasta 10 mg tablets	tablets	Jadran-Galenski laboratorij d.d., Rijeka, Hrvatska in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC-Al blister , supplied in a box	YES			YES				
Zalasta 5 mg tablets	tablets	Jadran-Galenski laboratorij d.d., Rijeka, Hrvatska in cooperation with Krka d.d., Novo mesto, Republic of Slovenia	28 (4x7) tablets in a OPA/Al/PVC-Al blister , supplied in a box	YES			YES				
Zalasta Q-Tab 10 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Zalasta Q-Tab 15 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Zalasta Q-Tab 20 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Zalasta Q-Tab 5 mg	orodispersible tablets	Krka Farma d.o.o., Radnička cesta 48, Zagreb, Republic of Croatia	28 (4x7) tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES				
Zaldiar 37.5 mg/325 mg	film coated tablets	Grünenthal GmbH, Zieglerstrasse 6, D-52078 Aachen, Germany	10 tablets in a blister, supplied in a box		YES	YES					
Zan 10 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
Zan 5 mg capsules	capsules	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	7 capsules in a PVC/PVDC/Al blister, supplied in a box	YES			YES				
Zeffix tablets	film coated tablets	Glaxo Operations UK Ltd. (trading as Glaxo Wellcome Operations), Hertfordshire, Great Britain, GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	28 (2x14) tablets in a blister (PVC/PA/Al), supplied in a box		YES	YES		YES	YES		

ZELDOX 20 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 40 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 60 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
ZELDOX 80 mg capsules	capsules	Heinrich Mack Nachf. GmbH & Co. (Pfizer grupa), Illertissen, Germany	Box with 30 capsules (blister, 3x10 capsules)		YES	YES						
Zemplar 5 µg/mL solution for injection	solution for injection	Abbott S.p.A., Via Pontina 52, I-04010 Campoverde di Aprilia (Latina), Italy	5 glass ampoules each with 1 mL of solution, supplied in a carton box		YES	YES				YES		
Zenafluk capsules 100 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/Al blister, supplied in a box	YES			YES					
Zenafluk capsules 150 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	One capsule in a PVC/Al blister, supplied in a box	YES			YES					
Zenafluk capsules 200 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/Al blister, supplied in a box	YES			YES					
Zenafluk capsules 50 mg	capsules	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	7 capsules in a PVC/Al blister, supplied in a box	YES			YES					
Zenapax	concentrate for infusion solution	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, Basel, Switzerland	Bottle with 5 mL of concentrate, supplied in a box		YES	YES			YES			
Zerit capsules 30 mg	capsules	Bristol-Myers Squibb, Meymac, France	56 (4x14) capsules in a blister, supplied in a box		YES	YES						
Zerit capsules 40 mg	capsules	Bristol-Myers Squibb, Meymac, France	56 (4x14) capsules in a blister, supplied in a box		YES	YES						
Ziagen tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	60 (6x10) tablets in a blister, supplied in a box		YES	YES						
Zinnat suspension 125 mg/5mL	granules for oral suspension	Glaxo Wellcome Operations, Greenford, Great Britain	Granules for 100 mL of suspension in a glass bottle, with a plastic spoon and a measuring device, supplied in a box		YES	YES						
Zinnat 125 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						
Zinnat 250 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						
Zinnat 500 mg tablets	film coated tablets	Glaxo Wellcome Operations, Greenford, Great Britain	10 tablets in a blister, supplied in a box		YES	YES						
Zipantola tablets 20 mg	gastric-resistant tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	28 (2x14) tablets in a OPA/Al/PVC//Al blister, supplied in a box	YES			YES					

Zipantola 40 mg tablets	gastric-resistant tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	14 (1x14) tablets in a blister, supplied in a box	YES			YES				
Zofran injection 4 mg	solution for intravenous injection	GlaxoSmithKline S.p.A., Parma, Italy	5 ampoules with 2 mL of solution, supplied in a box		YES	YES					
Zofran injection 8 mg	solution for intravenous injection	GlaxoSmithKline S.p.A., Parma, Italy	5 ampoules with 4 mL of solution, supplied in a box		YES	YES					
Zofran 4 mg tablets	tablets	Glaxo Wellcome S.A., Aranda de Duero, Spain; GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	10 tablets in a blister, supplied in a box		YES	YES					
Zofran 8 mg tablets	tablets	Glaxo Wellcome S.A., Aranda de Duero, Spain; GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	10 tablets in a blister, supplied in a box		YES	YES					
Zoladex 3.6 mg	subcutaneous implant	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	Implant for s.c. administration in a syringe with a safety system (SafeSystem TM), in a sterile protective casing, supplied in a carton box		YES	YES					
Zoladex LA 10.8 mg	subcutaneous implant	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	Implant for s.c. administration in a syringe with a safety system (SafeSystem TM), in a sterile protective casing, supplied in a carton box		YES	YES					
Zoloft tablets 100 mg	film coated tablets	Pfizer Italia S.r.l., Borgo San Michele, Latina, Italy	28 (2x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Zoloft tablets 50 mg	film coated tablets	Pfizer Italia S.r.l., Borgo San Michele, Latina, Italy	28 (2x14) tablets in a blister (PVC/Al), supplied in a box		YES	YES					
Zoltex 20 mg tablets	gastric-resistant tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	28 (2x14) tablets in a blister (PA/Al/PVC//Al), supplied in a box	YES			YES				
Zoltex 40 mg tablets	gastric-resistant tablets	Belupo, lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Republic of Croatia	14 (2x7) tablets in a PA/Al/PVC//Al blister, supplied in a box	YES			YES				
Zometa 4 mg/5 mL concentrate for solution for infusion	concentrate of solution for infusion	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, Switzerland	5 mL of solution concentrate in a plastic bottle, supplied in a box		YES	YES					
Zomig Rapimelt	orodispersible tablets	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, Great Britain	6 (1x6) tablets in a blister (PVC/Al-Al/paper), supplied in a box		YES	YES					
Zomig tablets 2.5 mg	film coated tablets	Astra Zeneca UK Limited, Great Britain	3 (1x3) tablete in a blister (Alu/PA-Alu/PVC), supplied in a box		YES	YES					
Zonadin 10 mg tablets	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Zonadin 5 mg tablets	film tablets	Pliva Croatia Ltd., Ulica grada Vukovara 49, Zagreb, Republic of Croatia	20 (2x10) tablets in a blister, supplied in a box	YES			YES				
Zorac 0.05% gel	gel	Pierre Fabre Medicament	15 g of gel in an aluminum tube, supplied in a box		YES	YES					

		Production, France									
Zorac 0.1 % gel	gel	Pierre Fabre Medicament Production, France	15 g of gel in an aluminum tube, supplied in a box		YES	YES					
Zovirax	cream	Glaxo Operations UK Ltd, Durham, Great Britain	2 grams of cream in an aluminum tube with plastic cap, supplied in a box		YES	YES					YES
Zyban	prolonged release tablets	GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, Poznan, Poland	60 (6x10) tablets in an Al/Al blister, supplied in a box		YES	YES					
Zyllt film coated tablets 75 mg	film coated tablets	KRKA FARMA d.o.o., DPC Jastrebarsko, Cvetkovići bb, Jastrebarsko, Republic of Croatia	14 (2x7) tablets in a blister, supplied in a box	YES			YES				
Zyprexa 10 mg injection	powder for solution for injection	Lilly Pharma Fertigung und Distribution GmbH & Co. KG, Giessen, Germany	5-mL glass vial with powder for solution for injection, supplied in a box		YES	YES					
Zyprexa 10 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 15 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 2.5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a Alu/Alu blister, supplied in a box		YES	YES					
Zyprexa 7.5 mg coated tablets	film coated tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	56 (8x7) tablets in an Al/Al blister, supplied in a box		YES	YES					
Zyprexa Velotab 10 mg orodispersible tablets	orodispersible tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a blister, supplied in a box		YES	YES					
Zyprexa Velotab 5 mg orodispersible tablets	orodispersible tablets	Eli Lilly and Company Limited, Basingstoke, Hampshire, Great Britain	28 (4x7) tablets in a blister, supplied in a box		YES	YES					
Zyvoxid granules for oral suspension 20 mg/mL	granules for oral suspension	Pharmacia & Upjohn Company, Michigan, USA and Pfizer Manufacturing Belgium NV, Puurs, Belgium	66 g granules in an amber glass bottle of 240 mL with a plastic temper-evident stopper and a plastic measuring spoon (2.5 mL/5 mL), supplied in a box		YES	YES				YES	
Zyvoxid 2 mg/mL solution for infusion	solution for infusion	Fresenius Kabi Norge, Halden, Norway	300 mL of solution in a plastic infusion bag, in a protective aluminium casing. 10 bags per box.		YES	YES				YES	
Zyvoxid tablets 600 mg	film coated tablets	Pharmacia & Upjohn Company, Michigan, USA and Pfizer Manufacturing Belgium NV, Puurs, Belgium	10 (1x10) tablets in a PVC/Al blister, supplied in a box		YES	YES				YES	