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PROPOSAL

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 28 May 2014

To: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European
Union

No. Cion doc.: COM(2014) 319 final - Annexes 1 to 7

Subject: ANNEXES to the proposal for a REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL to avoid trade diversion into the
European Union of certain key medicines (codification)

Delegations will find attached document COM(2014) 319 final - Annexes 1 to 7.

Encl.: COM(2014) 319 final - Annexes 1 to 7



EUROPEAN
COMMISSION

Brussels, 28.5.2014
COM(2014) 319 final

ANNEXES 1 to 7

ANNEXES

to the

proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

to avoid trade diversion into the European Union of certain key medicines (codification)

↓ 953/2003

ANNEX I

LIST OF TIERED PRICED PRODUCTS

↓ 1662/2005 Art. 1 and Annex
(adapted)

Product	Manufacturer/ex porter	Country of destination	Distinctive features	Date of approval	CN/TARIC code ¹
TRIZIVIR 750 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Afghanistan Angola Armenia Azerbaijan Bangladesh Benin Bhutan	Distinctive access pack — trilingual text	19.4.2004	30049019
EPIVIR 150 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Botswana Burkina Faso Burundi Cambodia Cameroon Cape Verde Central African Republic	Distinctive access pack — trilingual text — red tablets		30049019
RETROVIR 250 mg × 40	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS	Chad Comoros Congo Côte d'Ivoire ☒ Democratic Republic of the Congo ☒	General export pack (blue) not used in EU. French hospital pack — Francophone markets	19.4.2004	30049019

¹ Only if applicable.

	United Kingdom	Djibouti			
RETROVIR 300 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Equatorial Guinea Eritrea Ethiopia Gambia Ghana Guinea Guinea- Bissau	General export pack (blue) not used in EU. French hospital pack — Francophone markets	19.4.2004	30049019
RETROVIR 100 mg × 100	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Haiti Honduras India Indonesia Kenya Kiribati <input checked="" type="checkbox"/> Kyrgyzstan <input checked="" type="checkbox"/>	General export pack (blue) not used in EU. French hospital pack — Francophone markets	19.4.2004	30049019
COMBIVIR 300/150 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	<input checked="" type="checkbox"/> Laos <input checked="" type="checkbox"/> Lesotho Liberia Madagascar Malawi Maldives Mali Mauritania	Distinctive access pack — trilingual text Bottle (rather than blister pack) 'A22' embossed red tablets		30049019
EPIVIR ORAL SOLUTION 10 mg/ml 240 ml	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Moldova Mongolia Mozambique Myanmar/Burma Namibia Nepal Nicaragua	Distinctive access pack — trilingual text	19.4.2004	30049019

<p>ZIAGEN</p> <p>300 mg × 60</p>	<p>GLAXO SMITH KLINE</p> <p>GSK House</p> <p>980 Great West Road</p> <p>BRENTFORD, MIDDX</p> <p>TW8 9GS</p> <p>United Kingdom</p>	<p>Niger</p> <p>Nigeria</p> <p>☒ North Korea ☒</p> <p>Pakistan</p> <p>Rwanda</p> <p>Samoa</p> <p>São Tomé and Principe</p>	<p>General export pack — not used in EU.</p> <p>French hospital pack — Francophone countries</p>	<p>20.9.2004</p>	<p>30049019</p>
<p>RETROVIR ORAL SOLUTION</p> <p>10 mg/ml</p> <p>200 ml</p>	<p>GLAXO SMITH KLINE</p> <p>GSK House</p> <p>980 Great West Road</p> <p>BRENTFORD, MIDDX</p> <p>TW8 9GS</p> <p>United Kingdom</p>	<p>Senegal</p> <p>Sierra Leone</p> <p>Solomon Islands</p> <p>Somalia</p> <p>South Africa</p> <p>Sudan</p> <p>Swaziland</p> <p>Tajikistan</p> <p>Tanzania</p> <p>☒ Timor- Leste ☒</p> <p>Togo</p> <p>Tuvalu</p> <p>Uganda</p> <p>Vanuatu</p> <p>Yemen</p> <p>Zambia</p> <p>Zimbabwe</p>	<p>Distinctive access pack</p> <p>Trilingual text</p>	<p>20.9.2004</p>	<p>30049019</p>

ANNEX II

COUNTRIES OF DESTINATION

Afghanistan

Angola

Armenia

Azerbaijan

Bangladesh

Benin

Bhutan

Botswana

Burkina Faso

Burundi

Cambodia

Cameroon

Cape Verde

Central African Republic

Chad

China

Comoros

Congo

Côte d'Ivoire

☒ Democratic Republic of the Congo ☒

Djibouti

Equatorial Guinea

Eritrea

Ethiopia
Gambia
Ghana
Guinea
Guinea-Bissau
Haiti
Honduras
India
Indonesia
Kenya
Kiribati
✘ Kyrgyzstan ✘
✘ Laos ✘
Lesotho
Liberia
Madagascar
Malawi
Maldives
Mali
Mauritania
Moldova
Mongolia
Mozambique
Myanmar/Burma
Namibia
Nepal
Nicaragua

Niger
Nigeria
☒ North Korea ☒
Pakistan
Rwanda
Samoa
São Tomé and Príncipe
Senegal
Sierra Leone
Solomon Islands
Somalia
South Africa
Sudan
Swaziland
Tajikistan
Tanzania
☒ Timor-Leste ☒
Togo
Turkmenistan
Tuvalu
Uganda
Vanuatu
Vietnam
Yemen
Zambia
Zimbabwe

ANNEX III

PERCENTAGES REFERRED TO IN ARTICLE 3

Percentage referred to in Article 3(a): 25 %

Percentage referred to in Article 3(b): 15 %

ANNEX IV

SCOPE OF DISEASES

HIV/AIDS, malaria, tuberculosis and related opportunistic diseases

ANNEX V

LOGO



The winged staff of Aesculapius with a coiled serpent, in the centre of a circle formed by 12 stars.





ANNEX VI

Repealed Regulation with list of its successive amendments

Council Regulation (EC) No 953/2003
(OJ L 135, 3.6.2003, p. 5)

Commission Regulation (EC) No 1876/2004
(OJ L 326, 29.10.2004, p. 22)

Commission Regulation (EC) No 1662/2005
(OJ L 267, 12.10.2005, p. 19)

Regulation (EU) No 38/2014 of the European Parliament and of
the Council
(OJ L 18, 21.1.2014, p. 52) Only point 3 of the Annex

ANNEX VII

CORRELATION TABLE

Regulation (EC) No 953/2003	This Regulation
Articles 1, 2 and 3	Articles 1, 2 and 3
Article 4(1)	Article 4(1)
Article 4(2), introductory wording	Article 4(2), introductory wording
Article 4(2)(i)	Article 4(2)(a)
Article 4(2)(ii)	Article 4(2)(b)
Article 4(2)(iii)	Article 4(2)(c)
Article 4(2)(iv)	Article 4(2)(d)
Article 4(2)(v)	Article 4(2)(e)
Article 4(4)	Article 4(3)
Article 4(5)	Article 4(4)
Article 4(6)	Article 4(5)
Article 4(7)	Article 4(6)
Article 4(8)	Article 4(7)
Article 4(9)	Article 4(8)
Article 5	Article 5
Article 5a	Article 6
Article 6	Article 7
Article 7	Article 8
Article 8	Article 9
Article 9	Article 10
Article 10	Article 11
Article 11	Article 12
Article 12	Article 13
-	Article 14

Article 13

Annexes I to V

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Article 15

Annexes I to V

Annex VI

Annex VII
