



EUROPEAN
COMMISSION

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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 Botswana	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	Burkina Faso Burundi Cambodia Cameroon Cape Verde Central African Republic Chad Comoros	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 United Kingdom	Congo Côte d'Ivoire ☒ Democratic Republic of the Congo ☒ Djibouti Equatorial Guinea Eritrea Ethiopia	General export pack (blue) not used in EU. French hospital pack — Francophone markets	19.4.2004	30049019
RETROVIR 300 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD,	Gambia Ghana Guinea Guinea- Bissau Haiti	General export pack (blue) not used in EU. French hospital pack — Francophone markets	19.4.2004	30049019

¹ Only if applicable.

	MIDDX TW8 9GS United Kingdom	Honduras India Indonesia			
RETROVIR 100 mg × 100	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	Kenya Kiribati ☒ Kyrgyzstan ☒ ☒ Laos ☒ Lesotho Liberia Madagascar Malawi	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	Maldives Mali Mauritania Moldova Mongolia Mozambique Myanmar/Burma Namibia	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	Nepal Nicaragua Niger Nigeria ☒ North Korea ☒ Pakistan Rwanda Samoa	Distinctive access pack — trilingual text	19.4.2004	30049019
ZIAGEN 300 mg × 60	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX TW8 9GS United Kingdom	São Tomé and Príncipe Senegal Sierra Leone Solomon Islands Somalia South Africa Sudan Swaziland	General export pack — not used in EU. French hospital pack — Francophone countries	20.9.2004	30049019
RETROVIR ORAL SOLUTION 10 mg/ml 200 ml	GLAXO SMITH KLINE GSK House 980 Great West Road BRENTFORD, MIDDX	Tajikistan Tanzania ☒ Timor- Leste ☒ Togo Tuvalu	Distinctive access pack Trilingual text	20.9.2004	30049019

	TW8 9GS United Kingdom	Uganda Vanuatu Yemen Zambia Zimbabwe			
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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	Article 15

Annexes I to V

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Annexes I to V

Annex VI

Annex VII
