



Council of the
European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 December 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 737 final - ANNEX 1
Subject:	ANNEX to the REPORT FROM THE COMMISSION Annual Report (2012-2013) on the application of Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines

Delegations will find attached document COM(2014) 737 final - ANNEX 1.

Encl.: COM(2014) 737 final - ANNEX 1



Brussels, 16.12.2014
COM(2014) 737 final

ANNEX 1

ANNEX

to the

REPORT FROM THE COMMISSION

Annual Report (2012-2013)

**on the application of Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid
trade diversion into the European Union of certain key medicines**

ANNEX 1: DETAILS OF VOLUMES OF MEDICINES SOLD IN 2012-2013

EPIVIR Oral Solution 10mg/ml – 240 ml

Date of Approval: 19 April 2004

**Volumes sold (units)¹
- 1 January 2012 to 31
December 2013**

Disease targeted: HIV infection

Active ingredient: lamivudine

	Total no. of packs sold 2012	72
Price offered (per unit) 2012: US\$ 8.74		
Price offered (per unit) 2013: US\$ 7.03	Total no. of packs sold 2013	0

Lowest OECD list price 2012: US\$ 13.95

Lowest OECD list price 2013: US\$ 18.29

Preferential/lowest OECD list price 2012: 62.63 %

Preferential/lowest OECD list price 2013: 38.44 %

¹ In this and the following tables, “units” are the packages in which the products concerned are packed. For example, one “unit” of EPIVIR Oral Solution 10mg/ml – 240 ml is one bottle of 240 ml. One unit of EPIVIR 150 mg x 60 (see following table) is one package containing 60 tablets.

EPIVIR 150 mg x 60

Date of Approval: 19 April 2004

**Volumes sold (units) -
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: lamivudine

**Total no. of packs sold
2012** **0**

Price offered (per unit) 2012: US\$ 3.60

**Total no. of packs sold
2013** **0**

Price offered (per unit) 2013: US\$ 3.85

Lowest OECD list price 2012: US\$ 40.45

Lowest OECD list price 2013: US\$ 40.45

Preferential/lowest OECD list price 2012: 8.90 %

Preferential/lowest OECD list price 2013: 9.52 %

COMBIVIR 300/150 mg x 60

Date of Approval: 19 April 2004

**Volumes sold (units)
- 1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: lamivudine + zidovudine

Price offered (per unit) 2012: US\$ 10.20

Price offered (per unit) 2013: US\$ 7.80

**Total no. of packs sold
2012 3000**

**Total no. of packs sold
2013 0**

Lowest OECD list price 2012: US\$ 158.70

Lowest OECD list price 2013: US\$ 130.20

Preferential/lowest OECD list price 2012: 6.43 %

Preferential/lowest OECD list price 2013: 5.99 %

RETROVIR 100 mg x 100
Date of Approval: 19 April 2004

**Volumes sold (units) -
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: zidovudine

**Total no. of packs sold
2012** **323**

Price offered (per unit) 2012: US\$ 7.00

**Total no. of packs sold
2013** **390**

Price offered (per unit) 2013: US\$ 6.37

Lowest OECD list price 2012: US\$ 99.11

Lowest OECD list price 2013: US\$ 99.11

Preferential/lowest OECD list price 2012: 7.06 %

Preferential/lowest OECD list price 2013: 6.43 %

RETROVIR 250 mg x 40

Date of Approval: 19 April 2004

**Volumes sold (units) -
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: zidovudine

Price offered (per unit) 2012: US\$ 7.20	Total no. of packs sold 2012	0
Price offered (per unit) 2013: US\$ 3.96	Total no. of packs sold 2013	0

Lowest OECD list price 2012: US\$ 51.99

Lowest OECD list price 2013: US\$ 51.99

Preferential/lowest OECD list price 2012: 13.85 %

Preferential/lowest OECD list price 2013: 7.62 %

TRIZIVIR 750 mg x 60

Date of Approval: 19 April 2004

**Volumes sold (units) -
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: abacavir sulphate (300 mg) + lamivudine
(150 mg) + zidovudine (300 mg)

**Total no. of packs sold
2012** **296**

Price offered (per unit) 2012: US\$ 22.80

**Total no. of packs sold
2013** **0**

Price offered (per unit) 2013: US\$ 19.20

Lowest OECD list price 2012: US\$ 442.50

Lowest OECD list price 2013: US\$ 470.14

Preferential/lowest OECD list price 2012: 5.15 %

Preferential/lowest OECD list price 2013: 4.08 %

ZIAGEN 300 mg x 60

Date of Approval: 20 September 2004

**Volumes sold (units) -
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: abacavir sulphate

**Total no. of packs sold
2012** **432**

Price offered (per unit) 2012: US\$ 12.60

**Total no. of packs sold
2013** **90,748**

Price offered (per unit) 2013: US\$ 11.40

Lowest OECD list price 2012: US\$ 95.86

Lowest OECD list price 2013: US\$ 95.86

Preferential/lowest OECD list price 2012: 13.14 %

Preferential/lowest OECD list price 2013: 11.89 %

RETROVIR Oral Solution 10 mg/ml – 200 ml

Date of Approval : 20 September 2004

**Volumes sold (units) –
1 January 2012 to 31
December 2013-**

Disease targeted: HIV infection

Active ingredient: zidovudine

**Total no. of packs sold
2012** **0**

Price offered (per unit) 2012: US\$ 8.37

**Total no. of packs sold
2013** **0**

Price offered (per unit) 2013: US\$ 6.83

Lowest OECD list price 2012: US\$ 10.40

Lowest OECD list price 2013: US\$ 10.40

Preferential/lowest OECD list price 2012: 80.50 %

Preferential/lowest OECD list price 2013: 65.69 %