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COVER NOTE

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REPORT FROM THE COMMISSION

Annual Report (2010-2011)

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

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This is the seventh annual report foreseen under Article 11 of Regulation (EC) No 953/2003[1], which is designed to prevent parallel trade in discounted medicines intended for the least developed countries. This report covers the period from 1 January 2010 to 31 December 2011.

As in previous reports, the volume of sales of registered tiered priced medicines has further declined in 2010 and 2011. This is again explained by the fact that eleven voluntary licenses have now been granted by the applicant for the manufacture and supply of medicines for the treatment of HIV/AIDS (ARVs), as opposed to eight in 2009.

In view of the absence of newly registered medicines by (other) pharmaceutical companies since 2004, the European Commission will consider organising a public consultation with stakeholders on the implementation of Regulation 953/2003. The consultation could assist in the evaluation of the role of Regulation 953/2003 in promoting the accessibility of affordable essential medicines to the poorest developing countries.

1. BACKGROUND

In 2000 the UN Millennium Summit adopted eight Millennium Development Goals (MDGs), aimed at freeing humanity from extreme poverty, hunger, illiteracy and disease by 2015. MDG number six aims specifically at halting and reversing the spread of HIV/AIDS, malaria and other major diseases by 2015.

HIV/AIDS, tuberculosis and malaria remain major plagues in many resource-poor countries, particularly in Sub-Saharan Africa. The UNAIDS report on the global AIDS epidemic 2011[2] informs about the steadily decline of the HIV incidence rate by nearly 25% worldwide between 2001 and 2009. However, this global progress masks substantial regional differences. While the incidence rate fell significantly in sub-Saharan Africa and Southern Asia, it remained unchanged in Eastern Asia, Western Europe, Central Europe and North America. Despite the good progress, *Sub-Sahara Africa remains the most heavily affected region*, accounting for 69% of new HIV infections, 68% of all people living with HIV and 72% of AIDS deaths.

Supplying poor and developing countries with medicines at sustainable low prices is one of the key objectives in the fight against these major diseases.[3] In order to achieve this, the European Commission has consistently advocated a policy of "tiered pricing" for medicines, combined with market segmentation between rich and poor countries. The advantage of such

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1 Article 11 of Regulation (EC) No 953/2003 foresees: *"(1) The Commission shall monitor on an annual basis the volumes of exports of tiered priced products listed in Annex I and exported to the countries defined in Article 1 on the basis of information provided to it by pharmaceutical manufacturers and exporters. For this purpose a standard form will be issued by the Commission. Manufacturers and exporters must submit such sales reports annually for each tiered priced product to the Commission on a confidential basis.*
(2) The Commission shall periodically report to the Council on the volumes exported under tiered prices, including on the volumes exported within the framework of a partnership agreement agreed between the manufacturer and the government of a country of destination. The report shall examine the scope of countries and diseases and general criteria for the implementation of Article 3."

2 http://www.undp.org/content/dam/undp/library/MDG/english/MDG_Report_2011_EN.pdf

3 Intellectual property rights on medicines can lead to higher prices by limiting the supply of cheaper generic alternatives. Yet there are also many other important factors that may influence the accessibility of medicines to patients in poor developing countries. Such factors include the lack of national health insurance coverage, import tariffs and taxes on medicines, high distribution mark-ups and inadequate public procurement systems.

a policy is that it encourages manufacturers to distribute the medicines in question in the target countries at the lowest possible ("tiered") price, while at the same time recouping their research and development expenditure with the higher prices charged in developed (OECD) countries. This approach is designed to promote sustainable supplies and continuous distribution of life-saving medicines.

To support tiered pricing, specific safeguards were devised to prevent diversion of medicines from poor developing countries into the European Union. Thus, in May 2003, the EU adopted Council Regulation (EC) No 953/2003 to avoid trade diversion into the European Union of certain key medicines[4] ("the Regulation").

2. COMMISSION REPORTING UNDER REGULATION (EC) NO 953/2003

This report covers the period from 1st January 2010 to 31st December 2011. During the reporting period, no new products were registered by the European Commission under this Regulation.

The report contains the following information:

– The volumes exported under tiered prices for each product registered in annex I of the Regulation;

– The diseases treated with the products in question;

– An assessment of the application of the price formulae in Article 3 of the Regulation in relation to each of the products concerned.

This report is mainly based on the information received from applicants (or applicant companies) under Article 11(1) of the Regulation. The Commission respects the confidentiality of the data provided by applicants and neither guarantees nor questions their accuracy.

In order to keep the public informed of all products registered under the Regulation, their producers, distinctive features, countries of destination, and other relevant details, the Commission has established a website where this information is available:

– http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl

The same website also provides assistance to manufacturers who wish to register a new product.

3. PRODUCTS REGISTERED

There were no new products registered during the reporting period.

The products listed below, aimed at the treatment of HIV/AIDS, were registered in 2004 by GlaxoSmithKline (GSK), Brentford (UK):

[4] OJ L 135, 3.6.2003, pages 5 – 11. The Regulation has last been updated by Commission Regulation 1662/2005 of 11 October 2005 (OJ L 267, 12.10.2005, pages 19 – 21): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:267:0019:0021:EN:PDF

- **EPIVIR 150 mg x 60**
- **COMBIVIR 300/150 mg x 60**
- **EPIVIR Oral Solution 10mg/ml 240 ml**
- **RETROVIR 100 mg x 100**
- **RETROVIR 300 mg x 60**
- **RETROVIR 250 mg x 40**
- **TRIZIVIR 750 mg x 60**
- **ZIAGEN 300 mg x 60**
- **RETROVIR Oral Solution 10 mg/ml – 200 ml**

Price ranges and the prices offered can be found in Annex I, together with the volumes sold in 2010 and 2011 for each product registered under the Regulation.

Under the Regulation, no distinction can be made between purchasers – public or private - for products at these prices in the countries listed. However, it must be noted that these prices are indicative. The actual sales prices have not been reported, as Article 11(1) of the Regulation places no obligation on applicants to do so. It therefore cannot be excluded that in some instances lower prices for the products can be and, indeed have been, negotiated[5].

Over the reporting period, no attempts to illegally re-import tiered-priced products registered under the Regulation back into the EU were reported to the Commission.

4. COUNTRIES OF DESTINATION

Unlike in previous reports, it was not possible to obtain a detailed breakdown of volumes supplied per region in the reporting period. However, the applicant declared that tiered priced products had been supplied to all LDCs, the World Bank's low-income countries, and all of Sub-Saharan Africa. These countries, according to UNITAID, cover 75% of all the people currently living with HIV/AIDS.

5. DISEASES COVERED

HIV/AIDS, malaria and tuberculosis are generally considered the gravest public health concerns for developing countries and a major obstacle to development. This is why EU development policy, including this Regulation, is more specifically focusing on these three diseases. However, only medicines for the treatment of HIV/AIDS have been registered by the applicant, which could be justified by the much higher costs of ARVs as compared to the treatment for malaria and tuberculosis. This is also explained by the fact that the risks of illegal re-importation in the EU of medicines for the treatment of malaria and tuberculosis are fairly limited due to the limited occurrence of these diseases in the EU.] Medicines to treat opportunistic infections associated with HIV/AIDS are also eligible and suitable for coverage under the Regulation, but there have been no applications to

[5] Readers interested in obtaining information on actual sales prices may find it on the website of the Global Fund to Fight AIDS, TB and Malaria. http://bi.theglobalfund.org/analytics/saw.dll?Dashboard&nqUser=PQRExternalUser&PQRLANGUAGE=en&PortalPath=/shared/PQR%20External%20Users/_portal/PQR%20Public&Page=Price%20list

date.Considering that the list of registered products has remained unchanged since 2004, the diseases covered in this report remain identical, i.e. exclusively the treatment of HIV/AIDS.

6. APPLICATION OF PRICE FORMULAE

To date the application of the price formulae provided for in Article 3 of the Regulation has not caused any practical problems. The applicant has not found it necessary to avail itself of the services of an independent auditor in order to protect sensitive business data (a possibility allowed by Article 4(2)(ii) of the Regulation[6]). For seven of the nine products, it proved sufficient to show that the price offered (i.e. the "tiered" price) was less than 25% of the lowest OECD list price. Both the tiered price and the OECD list prices are available to the public.

However, for two products –Epivir oral solution and Retrovir oral solution-, the tiered price was higher than the 25% of the lowest OECD price (Annex 1, pp 9 and 17). The applicant justified the higher percentages by the decreasing volumes of products being sold. The applicant further explained that, as the tiered priced production has decreased –due to the success of the voluntary license strategy-, the cost of these specific packs per unit has increased. In addition, the applicant referred to its tiered pricing policy whereby their medicines are sold according to GDP and burden of epidemic which means that their tiered price as indicated in Annex I of this report and the lowest OECD price may not be far apart if the OECD country has low GDP and a high burden of HIV.

7. EVALUATING THE IMPACT OF THE REGULATION OVER TIME

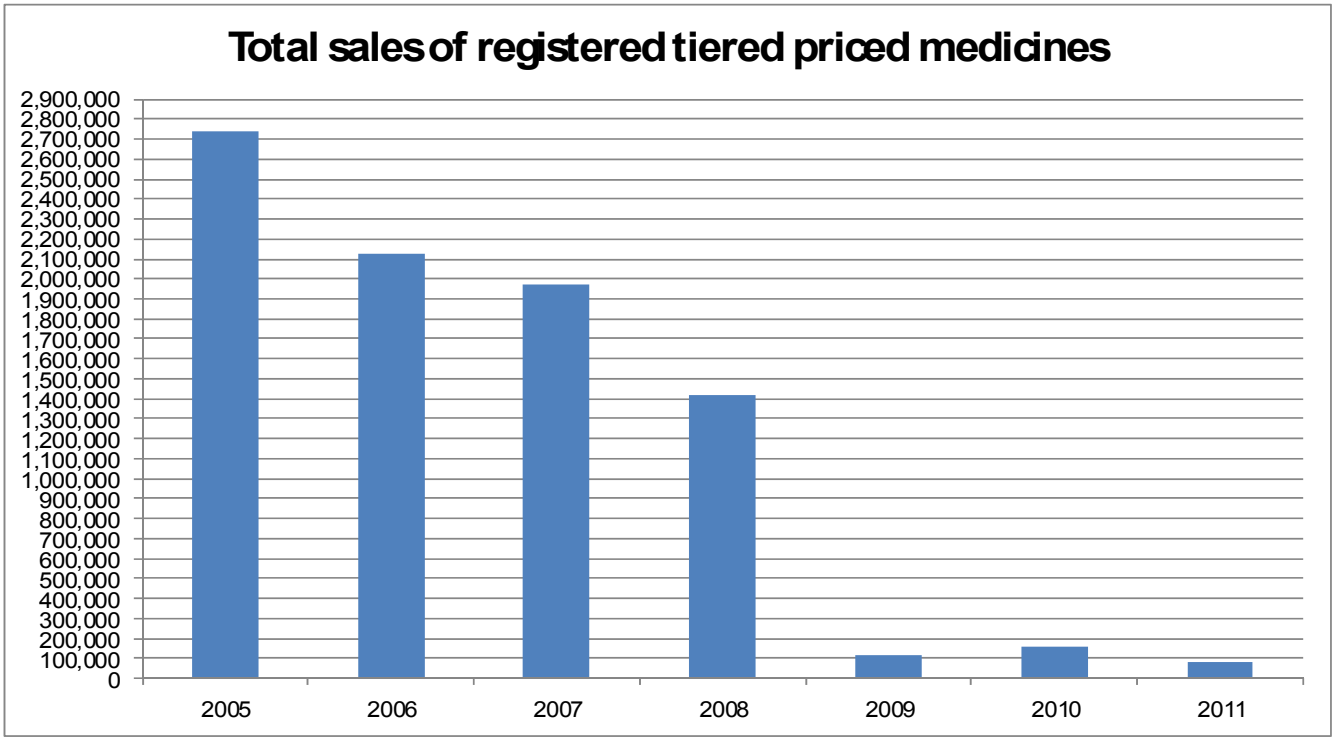
The table below gives some indication of the sales trends per product registered under the Regulation over the last six years:

Figure 1:

Product/unit	2006	2007	2008	2009	2010	2011
Combivir 300/150 mg x 60	397.450	153.793	178.216	66.344	478	8.459
Retrovir 250 mg x 40	585	643	2.700	17.240	0	0
Retrovir 100 mg x 100	132.176	92.467	136.571	10.185	322	385
Trizivir 750 mg x 60	4.903	17.102	7.475	9.895	1.333	140
Retrovir Oral Solution 10 mg	119.807	272.063	13.502	7.305	9.932	1.944
Ziagen 300 mg x 60	40.208	35.884	26.872	5.058	113.591	13.697
Epivir Oral Solution 10mg/ml 240 ml	406.287	155.523	33.311	4.008	24.731	11.571
Epivir 150 mg x 60	975.250	1.125.986	971.689	0	2.605	42.701
Retrovir 300 mg x 60	48.410	118.725	47.682	0	2.335	6.035
Total	**2.125.076**	**1.972.186**	**1.418.018**	***120.035***	***155.327***	***84.932***

Figure 2:

[6] Instead of submitting detailed information on the price offered, the applicant may submit a certificate issued by an independent auditor, stating that the price has been verified and corresponds to one of the criteria set out in Annex III.



As shown in figure 2, the total sales of registered tiered priced medicines has significantly and steadily decreased over the last six years. The total sales of 2011 represent just 3% of the total sales of 2005. This constant drop, which accentuated itself in 2009, could be explained primarily by more customers *purchasing* ARVs from other producers and in particular from generic manufacturers, including those licensed by GlaxoSmithKline through its Royalty Free Voluntary Licenses. ViiV Healthcare, a company established by GlaxoSmithKline and Pfizer to deliver advances in treatment and care for people living with HIV has now granted eleven voluntary licences for the manufacture and supply of ARVs.

In 2011, ViiV Healthcare and its licensees supplied an estimated 717 million of its versions of Epivir and Combivir to African countries. This is the equivalent of approximately 12 months' supply for over a million people living with HIV. This trend is welcome as it improves the availability of affordable ARVs for customers in developing countries and helps to maintain a sustainable supply.

In some cases, the volumes reported in Annex I vary greatly between 2010 and 2011. The explanation provided by the applicant referred to the award process for the supply. The applicant is increasingly asked to respond to requests from governments or non-government organisations to supply medicines in a very short time frame. These are normally requests to respond to a medication out of stock which generic companies cannot supply.

It should also be underlined that, since the creation of this Regulation, available data seem to indicate the absence of cases of illegally re-imported tiered-priced products reported to the Commission.

In view of the data presented above and the absence of newly registered medicines by (other) pharmaceutical companies since 2004, the European Commission will consider the need to organise a public consultation with stakeholders on the implementation of Regulation 953/2003 in order to better evaluate its role in promoting the accessibility of affordable essential medicines to the poorest developing countries.

ANNEX 1: DETAILS OF VOLUMES OF MEDICINES SOLD IN 2010-2011

EPIVIR Oral Solution 10mg/ml – 240 ml **Date of Approval: 19 April 2004**	**Volumes sold (units)[7] - 1 January 2010 to 31 December 2011**

Disease targeted: HIV infection

Active ingredient: lamivudine

Price offered (per unit) 2010: US$ 5.42	**Total no. of packs sold 2010**	**24,731**
Price offered (per unit) 2011: US$ 12	**Total no. of packs sold 2011**	**11,571**

Lowest OECD list price: US$ 29.38

Preferential/lowest OECD list price 2010: 18.5%

Preferential/lowest OECD list price 2011: 40.8%

[7] 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 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: lamivudine

Price offered (per unit) 2010: US$ 5.23	**Total no. of packs sold 2010** **2,605**
Price offered (per unit) 2011: US$ 6.56	**Total no. of packs sold 2011** **42,701**

Lowest OECD list price: US$ 181.42

Preferential/lowest OECD list price 2010: 2.9%

Preferential/lowest OECD list price 2011: 3.6%

COMBIVIR 300/150 mg x 60

Date of Approval: 19 April 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: lamivudine + zidovudine

Price offered (per unit) 2010: US$ 16.19	**Total no. of packs sold 2010**	**478**
Price offered (per unit) 2011: US$ 18.98	**Total no. of packs sold 2011**	**8,459**

Lowest OECD list price: US$ 264.34

Preferential/lowest OECD list price 2010: 6.1%

Preferential/lowest OECD list price 2011: 7.2%

RETROVIR 100 mg x 100

Date of Approval: 19 April 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: zidovudine

Price offered (per unit) 2010: US$ 12.17	**Total no. of packs sold 2010**	**322**
Price offered (per unit) 2011: US$ 18.48	**Total no. of packs sold 2011**	**385**

Lowest OECD list price:US$ 88.75

Preferential/lowest OECD list price 2010: 13.7 %

Preferential/lowest OECD list price 2011: 20.8 %

RETROVIR 300 mg x 60

Date of Approval: 19 April 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: zidovudine

Price offered (per unit) 2010: US$ 13.24	**Total no. of packs sold 2010**	**2,335**
Price offered (per unit) 2011:US$ 24.70	**Total no. of packs sold 2011**	**6,035**

Lowest OECD list price: US$ 133.20

Preferential/lowest OECD list price 2010: 9.9%

Preferential/lowest OECD list price 2011: 18.5%

RETROVIR 250 mg x 40

Date of Approval: 19 April 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: zidovudine

Price offered (per unit) 2010: US$ 11.03	**Total no. of packs sold 2010**	**0**
Price offered (per unit) 2011: US$ 12.03	**Total no. of packs sold 2011**	**0**

Lowest OECD list price: US$ 81.15

Preferential/lowest OECD list price 2010: 13.6%

Preferential/lowest OECD list price 2011: 14.8%

TRIZIVIR 750 mg x 60

Date of Approval: 19 April 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

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

Price offered (per unit) 2010: US$ 53.71	**Total no. of packs sold 2010**	**1,333**
Price offered (per unit) 2011: US$ 53.01	**Total no. of packs sold 2011**	**140**

Lowest OECD list price: US$ 450.31

Preferential/lowest OECD list price 2010: 11.9 %

Preferential/lowest OECD list price 2011: 11.8%

ZIAGEN 300 mg x 60

Date of Approval: 20 September 2004

Volumes sold (units) - 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: abacavir sulphate

Price offered (per unit) 2010: US$ 35.91	**Total no. of packs sold 2010**	**113,591**
Price offered (per unit) 2011: US$ 31.36	**Total no. of packs sold 2011**	**13,697**

Lowest OECD list price: US$ 223.37

Preferential/lowest OECD list price 2010: 16.1%

Preferential/lowest OECD list price 2011: 14%

RETROVIR Oral Solution 10 mg/ml – 200 ml

Date of Approval : 20 September 2004

Volumes sold (units) – 1 January 2010 to 31 December 2011-

Disease targeted: HIV infection

Active ingredient: zidovudine

Price offered (per unit) 2010: US$ 6.35	**Total no. of packs sold 2010**	**9,932**
Price offered (per unit) 2011: US$ 10.38	**Total no. of packs sold 2011**	**1,944**

Lowest OECD list price: US$ 16.22

Preferential/lowest OECD list price 2010: 39.2 %

Preferential/lowest OECD list price 2011: 64%