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COVER NOTE

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

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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

TABLE OF CONTENTS

This is the eighth annual report foreseen under Article 11 of Regulation (EC) No 953/2003, which is designed to prevent parallel trade in discounted medicines intended for the least developed countries. This report covers the period from 1 January 2012 to 31 December 2013.

As in previous reporting periods, the volume of sales of registered tiered priced medicines has further declined in 2012 and 2013. With a historic low sales volume in 2012. This is explained by the fact that currently fourteen licenses have been granted by the applicant for the manufacture and supply of medicines for the treatment of HIV/AIDS (ARVs), as opposed to nine in 2011.

As part of the REFIT exercise[1], the European Commission will evaluate the Regulation by 2015.

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. In 2011 there was a UN Political Declaration supporting the achievement of MDG 6 which sets forth a series of ambitious targets and elimination commitments for 2015.[2]

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 2013[3] informs about the historic declines in AIDS-related deaths and new HIV infections in low- and middle-income countries. According to the report, as of December 2012, an estimated 9.7 million people in low- and middle- income countries were receiving antiretroviral therapy. This is a historic increase of 1.6 million over 2011. Hence, the goal of the 2011 UN Political Declaration to reach 15 million people living with HIV with lifesaving antiretroviral treatment by 2015 is approaching. However, access to treatment varies considerably within and between countries and regions. The 9.7 million people worldwide receiving antiretroviral therapy in low- and middle-income countries represent only 34% of the 28.6 million people eligible under the WHO 2013 guidelines.

Supplying poor and developing countries with medicines at sustainable low prices is one of the key objectives in the fight against these major diseases. 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 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.

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1 For more info consult: http://ec.europa.eu/smart-regulation/refit/index_en.htm

2 General Assembly Resolution 65/277. *Political Declaration on HIV and AIDS: Intensifying our efforts to eliminate HIV and AIDS, A/*RES/65/277 (10 June 2011), available from undocs.org/A/RES/65/277.

3 UNAIDS Global Report 2013, available from http://www.unaids.org/en/resources/campaigns/globalreport2013/globalreport/

To support tiered pricing, specific safeguards were devised to prevent diversion of medicines from poor developing countries into the European Union.

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

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 the applicant under Article 11(1) of the Regulation.

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.ec.europa.eu/cgi-bin/antitradediversion/index.pl

The same website also provides information for 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):

- **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**

[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

- **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 2012 and 2013 for each product registered under the Regulation, with the exception of RETROVIR 300 mg x 60. ViiV Healthcare has discontinued the supply of this medicine.

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

Countries of destination during the reporting period were: Kenia, Laos, South Africa and Uganda.

5. DISEASES COVERED

The Regulation allows for the registration of medicines treating HIV/AIDS, malaria and tuberculosis. These diseases 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. Only medicines for the treatment of HIV/AIDS have been registered by the applicant. 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

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. Retrovir oral solution has not been supplied during the reporting period.

The applicant justified the higher percentages by the decreasing volumes of products being sold as a consequence of their licensing policy of the last years. The commercial price is also low in the OECD country and the access price is based on the cost of producing the product. Oral solutions are also more expensive to manufacture. This has led to a situation where the commercial selling price is close to the actual cost of the good, which is reflected in the access price.

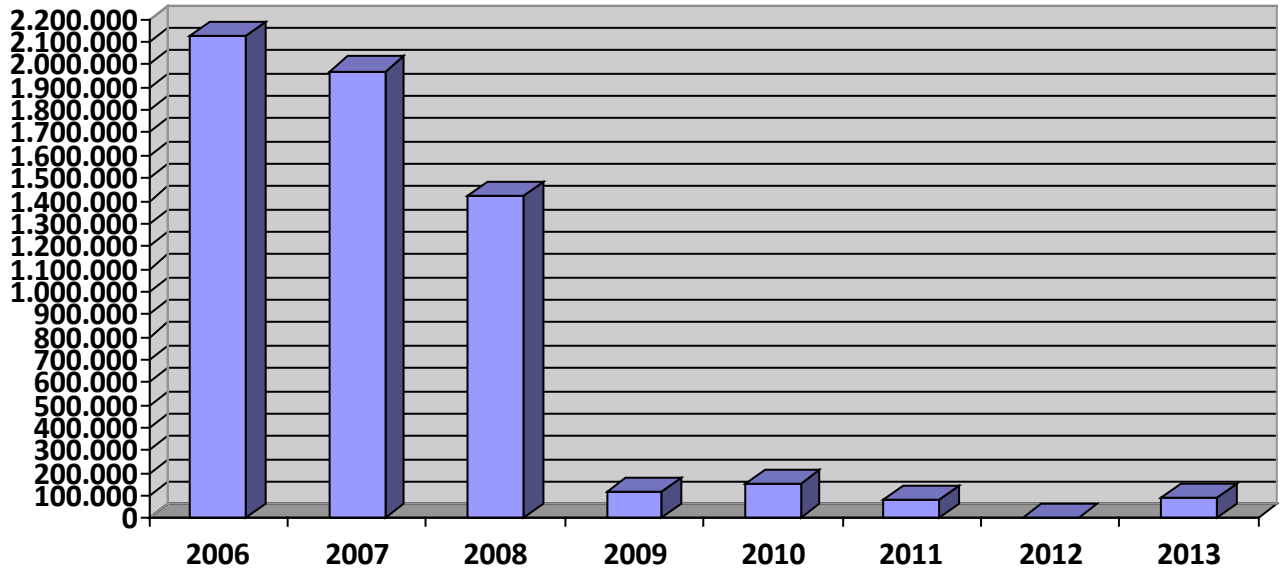
7. EVALUATING THE IMPACT OF THE REGULATION OVER TIME

The table below gives the sales trends per product registered under the Regulation over the last eight years:

Figure 1:

Product/unit	2006	2007	2008	2009	2010	2011	2012	2013
Combivir 300/150 mg x 60	397.450	153.793	178.216	66.344	478	8.459	3.000	0
Retrovir 250 mg x 40	585	643	2.700	17.240	0	0	0	0
Retrovir 100 mg x 100	132.176	92.467	136.571	10.185	322	385	323	390
Trizivir 750 mg x 60	4.903	17.102	7.475	9.895	1.333	140	296	0
Retrovir Oral Solution 10 mg	119.807	272.063	13.502	7.305	9.932	1.944	0	0
Ziagen 300 mg x 60	40.208	35.884	26.872	5.058	113.591	13.697	432	90.748
Epivir Oral Solution 10mg/ml 240 ml	406.287	155.523	33.311	4.008	24.731	11.571	72	0
Epivir 150 mg x 60	975.250	1.125.986	971.689	0	2.605	42.701	0	0
Retrovir 300 mg x 60	48.410	118.725	47.682	0	2.335	6.035	642	NA
Total	**2.125.076**	**1.972.186**	**1.418.018**	***120.035***	***155.327***	***84.932***	***4.765***	***91.138***

Figure 2:



As shown in figure 2, the total sales of registered tiered priced medicines has significantly and steadily decreased over the last eight years. 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 licenses. ViiV Healthcare, a company established by

GlaxoSmithKline and Pfizer, has now granted fourteen licences for the manufacture and supply of ARVs.

Over the two year period (2012-2013), some 95.000 packages of ARVs were exported to LDC under the Regulation. There was a major decline in 2012 with a sales volume of no more than 4.765 packages which fell under the Regulation. This concerned mostly the export of Combivir 300/150 mg x 60 to Uganda. In 2013 the sales volume increased, due to the sales of Ziagen tablets to South Africa (around 90.000 packages).