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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Report on the application of Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines

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Regulation (EU) 2016/793[1] to avoid trade diversion into the European Union of certain key medicines ("the Regulation"), adopted in May 2016, puts in place safeguards to prevent diversion of medicines from poor developing countries into the European Union. Supplying poor and developing countries with medicines at sustainable low prices is one of the objectives in the fight against the major diseases of HIV/AIDS, malaria and tuberculosis.

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 countries. This approach is designed to promote sustainable supplies and continuous distribution of life-saving medicines.

This is the ninth Report under Article 12(2) of the Regulation which foresees biennially reports by the Commission to the European Parliament and to the Council on the volumes exported under tiered prices registered under the Regulation. The Regulation notes the report shall also examine the scope of countries and diseases and general criteria for the implementation of Article 3.

This report covers the period from 1 January 2014 to 31 December 2015.

Information on products registered under the Regulation, instructions for pharmaceutical companies wishing to register products, [2] and previous reports are available on-line.[3]

1. REFIT EVALUATION OF THE REGULATION

The Regulation was evaluated in 2016 as part of the Commission's regulatory fitness and performance programme (REFIT) including on the scope of countries and diseases and general criteria for the implementation of Article 3. An external contractor, Charles River Associates was commissioned to gather data to support the Commission evaluation of the Regulation[4,5]

The Regulation was evaluated on four criteria: effectiveness, efficiency, coherence and relevance and assessed against the REFIT criteria of being fit for purpose, having delivered on its objectives at minimum cost and whether there is potential for simplification.

[1] OJ L 135, 24.5.2016, p. 39 (replacing Council Regulation (EC) No 953/2003)
[2] http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153992.pdf
[3] http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines
[4] http://trade.ec.europa.eu/doclib/html/154439.htm
http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154442.pdf
[5] http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154437.pdf

The evaluation concluded that the objective of improving access to medicines in the poorest developing countries remains relevant, that tiered pricing still has value, and that in view of the small administrative burden, the benefits that have been realised, the added value of a signal of support for tiered pricing, and its place in the overall context of action targeting major diseases, the Regulation still has a role in the future in the context of the Commission's aim, as stated in the *Trade for all* Communication[6], to promote an ambitious global health agenda and better access to medicines in poor countries.

The Regulation complements other EU actions such as support for the World Trade Organisation's November 2015 Decision to exempt least developed countries from obligations to provide patent protection for pharmaceutical products until at least 2033, so as to support access to medicines.

Other actions include Commission-funded development programmes supporting low- and middle-income countries' public health systems and research and development programmes for medicines needed by these countries. The EU contributes for example to the Global Fund to fight AIDS, tuberculosis and malaria that spends USD 3.5 billion a year in developing countries to which the EU collectively contributes about 50% and the Commission contributed EUR 370 million from the Development Cooperation Instrument and the European Development Fund for 2014-2016.

2. PRODUCTS EXPORTED UNDER TIERED PRICES

One company, GlaxoSmithKline / ViiV Healthcare[7], has medicines registered under the Regulation. These products were registered in 2004 and all aim at the treatment of HIV/AIDS.

The products listed below were exported under tiered prices:

1. COMBIVIR 300/150 mg x 60
2. EPIVIR 150 mg x 60
3. EPIVIR Oral Solution 10mg/ml 240 ml
4. RETROVIR 100 mg x 100
5. ZIAGEN 300 mg x 60
6. RETROVIR Oral Solution 10 mg/ml - 200 ml

Countries of destination during the reporting period were: China, Honduras, Indonesia, Kenya, Moldova, Nigeria, South Africa, and Uganda.

GlaxoSmithKline also registered Retrovir 300 mg x 60, Retrovir 250 mg x 40 and Trizivir 750 mg x 60 under the Regulation in 2004, but there were no sales under tiered prices of these products in the reporting period.

No new products were registered during the reporting period.

3. EVALUATION OF LIST OF COUNTRIES OF DESTINATION

[6] COM(2015)0497 of 14 October 2015.

[7] GSK set up ViiV Healthcare as a joint venture with Pfizer in November 2009. Both companies transferred their HIV assets to the new company.

The analysis of stakeholders' and experts' input by the external contractor found no evidence that there was scope for improving the effectiveness of the Regulation by modifying the list of countries of destination.

4. EVALUATION OF SCOPE OF 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 this Regulation, is more specifically focusing on these three diseases. Only medicines for the treatment of HIV/AIDS have been registered by the manufacturer.

The external study concluded that there was little scope of improving the effectiveness of the Regulation by modifying the lists of "communicable" diseases.

5. GENERAL CRITERIA FOR THE IMPLEMENTATION OF ARTICLE 3

The products were sold to the countries listed at the price of production, with no mark-up, and therefore in accordance with the criteria of Article 3.

The low volumes of products being sold are a consequence of the market becoming supplied with generic products as a result of both the manufacturer's policy of voluntary licensing agreements and expiry of patents.

The manufacturer noted that because the volumes supplied of some products to some countries are very low, the cost of goods increases and the distribution costs for the order(s) then become higher per pack. The access price is based on the cost of producing the product.

6. NOTIFICATIONS UNDER ARTICLE 10

Where there is reason to suspect that, contrary to the prohibition in Article 2, tiered priced products will be imported into the Union, customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the competent authorities on the character of the merchandise. The competent authority shall inform the Commission of all decisions adopted pursuant to the Regulation.

The Commission received no notification pursuant to Article 10 of the Regulation.