Avoiding trade diversion into the EU of certain key medicines. Codification

2014/0165(COD) - 09/12/2016 - Follow-up document

The Commission presented a report on the application of Regulation (EU) 2016/793 of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines.

The Regulation 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.

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

Evaluation: the Regulation was evaluated on four criteria: effectiveness, efficiency, coherence and relevance. It was 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.

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.

Exported products: one company, GlaxoSmithKline / ViiV Healthcare, has medicines registered under the Regulation. These products were registered in 2004 and all aim at the treatment of HIV/AIDS.

During the reference period, **six products** were exported under tiered prices to China, Honduras, Indonesia, Kenya, Moldova, Nigeria, South Africa, and Uganda.

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 the Regulation.