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

2014/0165(COD) - 11/05/2016 - Final act

PURPOSE: the codification of Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.

LEGISLATIVE ACT: 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 (codification).

CONTENT: in the interests of legal clarity and transparency, this **Regulation codifies and repeals Council Regulation (EC) No 953/2003** which had been substantially amended several times.

Price segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at heavily reduced prices. Therefore, those heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.

This codified Regulation **prohibits the importation into the European Union** of tiered-priced products.

Derogations are laid down for certain situations under the strict provision that it is ensured that the final destination of the products in question is one of the countries listed in the Regulation's Annex II.

'Tiered-priced products' are any pharmaceutical products used in the prevention, diagnosis or treatment of a disease such as **HIV/AIDS, malaria, tuberculosis and related oppotunistic diseases**, which are priced in accordance with one of the optional price calculations set out in the Regulation, verified by the Commission or an independent auditor, and and entered in the list of tiered-priced products in Annex I of the Regulation.

More specifically, the Regulation sets:

- the criteria for establishing what is a tiered priced product;
- the conditions under which the customs authorities shall take action;
- the measures which shall be taken by the competent authorities in the Member States.

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 of destination. It shall **report biennially to the European Parliament and to the Council** on the volumes exported under tiered prices.

The European Parliament may, within one month of submission of the Commission's report, invite the Commission to an ad hoc meeting of its responsible committee to present and explain any issues related to the application of this Regulation. No later than six months from the date of submission of the report to the European Parliament and to the Council, the Commission shall make the report public.

ENTRY INTO FORCE: 13.6.2016.

DELEGATED ACTS: the Commission may adopt delegated acts to add products to the list of tiered-priced products covered by the Regulation. The power to adopt such delegated acts shall be conferred on the Commission for a period of **5 years from 20 February 2014** (a period that can be tacitly extended for

periods of an identical duration). The European Parliament or the Council may raise objections to a delegated act within three months of notification (which may be extended by three months.) If Parliament or Council raise objections, the delegated act will not enter into force.