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

2014/0165(COD) - 28/05/2014 - Legislative proposal

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

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Council Regulation (EC) No 953/2003 has been substantially amended several times. On 1 April 1987, the Commission decided to instruct its staff that all acts should be codified after no more than ten amendments, stressing that this is a minimum requirement. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this, stressing the importance of codification.

The European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

CONTENT: in the interests of clarity and transparency of Union law, the purpose of this proposal is to undertake a codification of Council Regulation (EC) No 953/2003 to avoid trade diversion into the European Union of certain key medicines.

The new Regulation will supersede the various acts incorporated in it; it fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

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.

The proposed codified Regulation serves the purpose of **preventing tiered priced products from being imported into the Union**. Exemptions 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 Annex II. More specifically, the proposed Regulation lays down:

- 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.