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

2014/0165(COD) - 09/03/2016 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 664 votes to 29, with 4 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines (codified text).

Parliament adopted its position at first reading, taking over the Commission proposal. The proposal in question aims to **codify Council Regulation (EC) No 953/2003** which has been substantially amended several times. The proposal contains a straightforward codification of the existing texts without any change in their substance.

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 on the strict condition 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 proposal 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.

The term ‘tiered-priced product’ shall mean any pharmaceutical product which is used in the prevention, diagnosis or treatment of a disease, referred to in Annex IV, and which is priced in accordance with one of the optional price calculations set out in the Regulation, verified by the Commission or an independent auditor and entered in the list of tiered-priced products set out in Annex I.