Duty-free treatment: specified pharmaceutical active ingredients and products

2010/0214(COD) - 27/07/2010 - Legislative proposal

PURPOSE: to amend Annex I to Council Regulation (EEC) No 2658/87 in order to extend duty-free treatment in the European Union to the above-mentioned pharmaceutical and chemical products.

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

IMPACT ASSESSMENT: no impact assessment was carried out.

LEGAL BASIS: Article 207 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the Record of Discussions of the Trade in Pharmaceutical Products is an arrangement between the most important pharmaceutical producing countries to reduce to zero and on an MFN basis their WTO bindings of duties on certain pharmaceutical products, including active ingredients and intermediates. The Parties to the Agreement are the EU, US, Japan, Canada, Switzerland, Norway and Macao (China).

The arrangement originally covered over six thousand products. However, given that new pharmaceutical products are constantly being developed, the arrangement envisages periodic reviews. The Parties agreed to "meet under the auspices of the Council for Trade in Goods of the WTO, normally at least once every three years, to review the product coverage with a view to including, by consensus, additional pharmaceutical products for tariff elimination." The coverage was first reviewed in 1995-1996 and as a result an extra 465 products received duty free treatment. The second review in 1998 (implemented in July 1999) resulted in an extra 639 products receiving duty free treatment. The third review in 2006 resulted in the addition of 1290 products.

A fourth review of the products covered by the Record was launched in 2009, in accordance with Article 3 of the Record, which requires Participants to review at least once every three years the product coverage with a view to including additional pharmaceutical products for tariff elimination. The EU participated in these technical discussions. In the course of these discussions, Participants concluded that additional INNs and pharmaceutical intermediates used for production and manufacture of finished pharmaceuticals should be granted duty-free treatment and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs should be expanded, thereby adding 718 new substances to the list of products eligible for duty-free treatment.

This proposal invites the Council and Parliament to authorize the addition of 718 supplementary chemical and pharmaceutical products to the existing list of 8619 duty-free products on their imports into the EU.

BUDGETARY IMPLICATION: this proposal has no implications for the EU budget.