Duty-free treatment: specified pharmaceutical active ingredients and products

2010/0214(COD) - 15/12/2010 - Final act

PURPOSE: to extend the provision of duty-free treatment for specified pharmaceutical active ingredients bearing an ‘international non-proprietary name’ (INN) from the World Health Organization and specified products used for the manufacture of finished pharmaceuticals.

LEGISLATIVE ACT: Regulation (EU) No 1238/2010 of the European Parliament and of the Council amending Annex I to Council Regulation (EEC) No 2658/87 as regards the provision of duty-free treatment for specified pharmaceutical active ingredients bearing an ‘international non-proprietary name’ (INN) from the World Health Organization and specified products used for the manufacture of finished pharmaceuticals.

CONTENT: following a first-reading agreement with the European Parliament, the Council adopted a regulation on the provision of duty-free treatment for specified pharmaceutical active ingredients bearing an ‘international non-proprietary name’ (INN) from the World Health Organization and specified products used for the manufacture of finished pharmaceuticals.

At the WTO Uruguay Round, an arrangement was concluded 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. Reviews took place in 1995-1996, 1998 and 2006 (Pharma I, II, and III reviews), and resulted in the addition of almost 2400 products.

The fourth review (Pharma IV) was launched in 2009. In the course of these discussions, participants concluded that additional INNs (international non-proprietary names) 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.

Consequently, this Regulation authorises the addition of 718 supplementary chemical and pharmaceutical products to the existing list of 8619 duty-free products on their imports into the EU.

ENTRY INTO FORCE AND APPLICATION: from 01/01/2011.