Basic information

2010/0214(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Duty-free treatment: specified pharmaceutical active ingredients and products **Subject** 4.20.04 Pharmaceutical products and industry 6.20.01 Agreements and relations in the context of the World Trade Organization (WTO) 6.20.04 Union Customs Code, tariffs, preferential arrangements, rules of origin 6.20.05 Multilateral and plurilateral economic and trade agreements and relations	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
INTA International Trade	MOREIRA Vital (S&D)	29/09/2010

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	3057	2010-12-10

European Commission

Commission DG	Commissioner
Trade and Economic Security	DE GUCHT Karel

Key events

Date	Event	Reference	Summary
27/07/2010	Legislative proposal published	COM(2010)0397	Summary
07/09/2010	Committee referral announced in Parliament, 1st reading		
26/10/2010	Vote in committee, 1st reading		Summary
11/11/2010	Committee report tabled for plenary, 1st reading	A7-0316/2010	
23/11/2010	Decision by Parliament, 1st reading	T7-0411/2010	Summary
23/11/2010	Results of vote in Parliament		
10/12/2010	Act adopted by Council after Parliament's 1st reading		
15/12/2010	Final act signed		
15/12/2010	End of procedure in Parliament		
31/12/2010	Final act published in Official Journal		

Technical information

Procedure reference	2010/0214(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the European Union TFEU 207
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	INTA/7/03532

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE450.762	20/10/2010	
Committee report tabled for plenary, 1st reading/single reading		A7-0316/2010	11/11/2010	
Text adopted by Parliament, 1st reading/single reading		T7-0411/2010	23/11/2010	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00059/2010/LEX	15/12/2010	

European Commission

Document type	Reference	Date	Summary

Legislative proposal	COM(2010)0397	27/07/2010	Summary

Additional information		
Source	**Document**	**Date**
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Regulation 2010/1238 OJ L 348 31.12.2010, p. 0036	Summary

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.

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.

Duty-free treatment: specified pharmaceutical active ingredients and products

2010/0214(COD) - 23/11/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 639 votes to 3, with 19 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council providing for duty-free treatment for specified pharmaceutical active ingredients bearing an "international non-proprietary name" (INN) from the World Health Organisation and specified products used for the manufacture of finished pharmaceuticals and amending Annex I to Regulation (EEC) No 2658/87.

Parliament adopted its position at first reading under the ordinary legislative procedure (former co-decision procedure) taking over the Commission proposal.