Regulation (EU) No 1238/2010 of the European Parliament and of the Council of 15 December 2010 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

REGULATION (EU) No 1238/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 December 2010

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure[(1)],

Whereas:

(1) In the course of the Uruguay Round negotiations, the Community and a number of countries agreed that duty-free treatment should be granted to pharmaceutical products falling within the Harmonised System (HS) Chapter 30 and HS headings 2936, 2937, 2939 and 2941 as well as to designated pharmaceutical active ingredients bearing an 'international non-proprietary name' (INN) from the World Health Organization, specified salts, esters and hydrates of such INNs, and designated pharmaceutical intermediates used for the production and manufacture of finished pharmaceuticals.

(2) The results of the discussions, as set out in the Record of Discussions, were incorporated into the tariff schedules of the participants annexed to the Marrakesh Protocol to the General Agreement on Tariffs and Trade (GATT) 1994.

(3) Participants concluded that representatives of World Trade Organization (WTO) members, party to the Record of Discussions, would 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.

(4) Three such reviews have taken place with the result that a certain number of additional INNs and pharmaceutical intermediates used for the production and manufacture of

finished pharmaceuticals have been granted duty-free treatment, that some of those intermediates have been transferred to the list of INNs, and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs has been expanded.

(5) A fourth review was deemed appropriate and was launched in 2009. It concluded that a certain number of additional INNs and pharmaceutical intermediates used for the production and manufacture of finished pharmaceuticals should be granted duty-free treatment, that some of those intermediates already included in the pharmaceutical sectoral arrangement and its revisions should be transferred to the list of INNs, and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs should be expanded.

(6) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff[(2)] established the Combined Nomenclature (CN) and set out the conventional duty rates of the Common Customs Tariff.

(7) Regulation (EEC) No 2658/87 should therefore be amended accordingly.

(8) In order to ensure that the measures provided for in this Regulation apply from 1 January 2011, it should enter into force on the day following that of its publication,

HAVE ADOPTED THIS REGULATION:

Article 1

Annexes 3, 4 and 6 of Section II of Part Three of Annex I to Regulation (EEC) No 2658/87 (Lists of pharmaceutical substances which qualify for duty-free treatment) are hereby amended as follows:

1. As from 1 January 2011 the Union shall extend duty-free treatment to the INNs listed in Annex I.

2. As from 1 January 2011 the list of prefixes and suffixes which, in combination with the INNs included in the pharmaceutical sectoral arrangement and its revisions, describe the salts, esters or hydrates of INNs which are also eligible for duty-free treatment, on condition that they are classifiable in the same six-digit HS subheading as the corresponding INN, shall be amended as set out in Annex II.

3. As from 1 January 2011 the Union shall extend duty-free treatment to the pharmaceutical intermediates used in the production and manufacture of finished pharmaceuticals, listed in Annex III.

4. As from 1 January 2011 the pharmaceutical intermediates listed in Annex IV shall be withdrawn from the list of such compounds receiving duty-free treatment.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

***Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) No 1238/2010 of the European Parliament and of the Council. (See end of Document for details)*

Done at Strasbourg, 15 December 2010.

For the European Parliament

The President

J. BUZEK

For the Council

The President

O. CHASTEL

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) No 1238/2010 of the European Parliament and of the Council. (See end of Document for details)*

ANNEX I

LIST OF INTERNATIONAL NON-PROPRIETARY NAMES (INNS) TO BE ADDED TO THE LIST OF PRODUCTS RECEIVING DUTY-FREE TREATMENT INCLUDED IN ANNEX 3 TO ANNEX I TO REGULATION (EEC) NO 2658/87

CN code	CAS RN	Name
2842 90 80	119175-48-3	fermagate
2843 90 90	759457-82-4	padeliporfin
2844 40 30	123748-56-1	iodofiltic acid (^{123}I)
2904 10 00	21668-77-9	eprodisate
2906 19 00	199798-84-0	elocalcitol
2909 30 90	24150-24-1	terameprocol
2916 19 95	81485-25-8	peretinoin
2916 39 00	51543-40-9	tarenflurbil
2918 19 98	174022-42-5	bevirimat
2919 90 00	258516-89-1	fospropofol
2920 90 85	163133-43-5	naproxcinod
2921 19 99	3687-18-1	tramiprosate
2922 19 85	68392-35-8	afimoxifene
2922 19 85	753449-67-1	ronacaleret
2922 29 00	433265-65-7	faxeladol
2922 50 00	121524-08-1	amibegron
2922 50 00	329773-35-5	cinaciguat
2922 50 00	643094-49-9	fasobegron
2923 10 00	856676-23-8	choline fenofibrate
2924 29 98	847353-30-4	arbaclofen placarbil
2924 29 98	194785-19-8	bedoradrine
2924 29 98	194085-75-1	carisbamate
2924 29 98	254750-02-2	emricasan
2924 29 98	355129-15-6	eprotirome
2924 29 98	402567-16-2	firategrast
2924 29 98	478296-72-9	gabapentin enacarbil
2924 29 98	15866-90-7	incyclinide
2924 29 98	202844-10-8	indantadol

2924 29 98	96847-55-1	levomilnacipran
2924 29 98	608137-32-2	lisdexamfetamine
2924 29 98	652990-07-3	milveterol
2924 29 98	181816-48-8	ombrabulin
2924 29 98	289656-45-7	senicapoc
2925 19 95	19171-19-8	pomalidomide
2928 00 90	22033-87-0	olesoxime
2928 00 90	2675-35-6	sivifene
2928 00 90	816458-31-8	tecovirimat
2928 00 90	238750-77-1	tosedostat
2928 00 90	149647-78-9	vorinostat
2929 90 00	31645-39-3	palifosfamide
2930 90 99	608141-41-9	apremilast
2930 90 99	216167-92-9	camobucol
2930 90 99	211513-37-0	dalcetrapib
2930 90 99	69819-86-9	darinaparsin
2930 90 99	488832-69-5	elesclomol
2930 90 99	216167-95-2	elsibucol
2930 90 99	168682-53-9	ezatiostat
2930 90 99	58569-55-4	metenkefalin
2930 90 99	887148-69-8	monepantel
2930 90 99	603139-19-1	odanacatib
2930 90 99	162520-00-5	salirasib
2930 90 99	216167-82-7	succinobucol
2930 90 99	125961-82-2	tipelukast
2931 00 99	125973-56-0	amsilarotene
2932 19 00	253128-41-5	eribulin
2932 19 00	186953-56-0	pafuramidine
2932 29 85	195883-06-8	omtriptolide
2932 99 00	664338-39-0	arterolane
2932 99 00	183133-96-2	cabazitaxel
2932 99 00	401925-43-7	celivarone
2932 99 00	461432-26-8	dapagliflozin
2932 99 00	118457-15-1	dexnebivolol