Council Regulation (EC) No 129/2007 of 12 February 2007 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

COUNCIL REGULATION (EC) No 129/2007

of 12 February 2007

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission,

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 Organisation, specified salts, esters or hydrates of such INNs, and designated intermediates used for the production and manufacture of finished products.

(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 GATT 1994.

(3) Participants concluded that representatives of the WTO members, party to the record of discussions, would meet under the auspices of the WTO Council for Trade in Goods, 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) In the course of three such reviews it was concluded that a certain number of additional INNs and intermediates used for production and manufacture of finished pharmaceuticals should be granted duty-free treatment, that certain of these intermediates 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.

(5) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff[(1)] established the Combined

Changes to legislation: *There are currently no known outstanding effects for the Council Regulation (EC) No 129/2007. (See end of Document for details)*

Nomenclature (CN) and set out the conventional duty rates of the Common Customs Tariff.

(6) Regulation (EEC) No 2658/87 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

As from 1 January 2007 the Community shall extend duty-free treatment to the INNs listed in Annex I.

Article 2

As from 1 January 2007 the list of prefixes and suffixes which, in combination with the INNs, 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 replaced by the list in Annex II.

Article 3

As from 1 January 2007 the Community shall extend duty-free treatment to the intermediates used in the production and manufacture of pharmaceutical products listed in Annex III.

Article 4

As from 1 January 2007 the intermediates listed in Annex IV shall no longer benefit from duty-free treatment.

Article 5

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) shall be amended accordingly.

Article 6

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

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

Done at Brussels, 12 February 2007.

For the Council

The President

F.-W. STEINMEIER

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 Commission Regulation (EC) No 1549/2006[(2)]

ID No	CN code	CAS RN	Name
696	2842 90 80	12539-23-0	vangatalcite
572	2843 90 90	129580-63-8	satraplatin
413	2843 90 90	141977-79-9	miriplatin
223	2843 90 90	146665-77-2	eptaplatin
682	2843 90 90	172903-00-3	triplatin tetranitrate
504	2843 90 90	181630-15-9	picoplatin
807	2843 90 90	274679-00-4	padoporfin
629	2844 40 30	131608-78-1	technetium (99mTc) nitridocade
628	2844 40 30	225239-31-6	technetium (99mTc) fanolesomab
711	2844 40 30	476413-07-7	yttrium (90Y) tacatuzumab tetraxetan (yttrium (90Y) tacatuzumab)
738	2845 90 10	474641-19-5	deutolperisone
283	2846 90 00	193901-90-5	gadofosveset
284	2846 90 00	227622-74-4	gadomelitol
281	2846 90 00	280776-87-6	gadocoletic acid
282	2846 90 00	544697-52-1	gadodenterate
761	2903 39 90	354-92-7	perflisobutane
497	2903 39 90	355-25-9	perflubutane
495	2903 39 90	355-42-0	perflexane
498	2903 39 90	76-19-7	perflutren
496	2903 47 00	307-43-7	perflubrodec
328	2906 19 00	163217-09-2	inecalcitol
727	2906 19 00	524067-21-8	becocalcidiol
21	2907 29 00	57-91-0	alfatradiol
464	2909 49 90	128607-22-7	ospemifene
66	2909 49 90	302904-82-1	atocalcitol

Changes to legislation: *There are currently no known outstanding effects for the Council Regulation (EC) No 129/2007. (See end of Document for details)*

270	2909 49 90	341524-89-8	fispemifene
592	2909 50 90	3380-30-1	soneclosan
335	2914 40 90	158440-71-2	irofulven
803	2914 70 00	274925-86-9	nebicapone
56	2915 90 80	185517-21-9	arundic acid
87	2916 39 00	153559-49-0	bexarotene
640	2918 19 85	121009-77-6	tenivastatin
659	2918 19 85	156965-06-9	tisocalcitate
750	2918 19 85	54845-95-3	icomucret
677	2918 99 90	157283-68-6	travoprost
744	2918 99 90	161172-51-6	etalocib
294	2918 99 90	183293-82-5	gemcabene
643	2918 99 90	251565-85-2	tesaglitazar
757	2918 99 90	476436-68-7	naveglitazar
436	2921 30 99	219810-59-0	neramexane
153	2921 49 80	186495-49-8	delucemine
124	2921 49 80	226256-56-0	cinacalcet
367	2921 49 80	33817-09-3	levmetamfetamine
234	2922 19 80	119618-22-3	esoxybutynin
611	2922 19 80	146376-58-1	talibegron
596	2922 19 80	148717-90-2	squalamine
266	2922 19 80	162359-55-9	fingolimod
683	2922 19 80	186139-09-3	trodusquemine
193	2922 19 80	190258-12-9	edronocaine
709	2922 19 80	207916-33-4	xidecaflur
391	2922 19 80	36144-08-8	mantabegron
644	2922 19 80	98774-23-3	tesmilifene
626	2922 29 00	148717-54-8	tecalcet
619	2922 29 00	175591-23-8	tapentadol
440	2922 29 00	90060-42-7	nolomirole
230	2922 39 00	33643-46-8	esketamine
198	2922 49 95	176199-48-7	eglumetad (eglumegad)
310	2922 49 95	198022-65-0	icofungipen

386	2922 49 95	220991-20-8	lumiracoxib
554	2922 49 95	220991-32-2	robenacoxib
103	2922 50 00	135306-78-4	caloxetic acid
72	2922 50 00	187219-95-0	axomadol
278	2922 50 00	193901-91-6	fosveset
589	2922 50 00	252920-94-8	solabegron
551	2922 50 00	255734-04-4	ritobegron
752	2922 50 00	269079-62-1	isalmadol
261	2922 50 00	286930-03-8	fesoterodine
238	2922 50 00	37178-37-3	etilevodopa
399	2922 50 00	7101-51-1	melevodopa
161	2922 50 00	93413-62-8	desvenlafaxine
110	2924 19 00	1188-38-1	carglumic acid
632	2924 19 00	250694-07-6	teglicar
692	2924 19 00	92262-58-3	valrocemide
603	2924 29 95	112522-64-2	tacedinaline
36	2924 29 95	119363-62-1	amiglumide
195	2924 29 95	131179-95-8	efaproxiral
528	2924 29 95	133865-88-0	ralfinamide
567	2924 29 95	133865-89-1	safinamide
735	2924 29 95	147497-64-1	davasaicin
71	2924 29 95	156740-57-7	axitirome
434	2924 29 95	163000-63-3	neboglamine (nebostinel)
26	2924 29 95	173334-57-1	aliskiren
347	2924 29 95	175481-36-4	lacosamide (erlosamide)
332	2924 29 95	181872-90-2	iosimenol
568	2924 29 95	183990-46-7	salcaprozic acid
279	2924 29 95	188196-22-7	frakefamide
601	2924 29 95	193079-69-5	tabimorelin
462	2924 29 95	196618-13-0	oseltamivir
349	2924 29 95	209394-27-4	ladostigil
828	2924 29 95	220847-86-9	valategrast
614	2924 29 95	228266-40-8	taltobulin