COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.12.1996
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96/0268 (ACC)

Proposal for a

COUNCIL REGULATION (EC)

Providing for duty free treatment for specified pharmaceutical active ingredients bearing an "international nonproprietary name" (INN) from the World Health Organisation and specified products used for the manufacture of finished pharmaceuticals and withdrawing duty free treatment as pharmaceutical products from certain INNs whose predominate use is not pharmaceutical.

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Pursuant to the conclusions reached in Uruguay Round Record of Discussions (L/4740 of 25.3.1994) on duty free treatment for pharmaceutical products, the Commission has participated in the first review of the product coverage to include, by consensus, additional products for duty free treatment.

2. The outcome of the review is that 231 pharmaceutical active ingredients bearing an "international nonproprietary name" (INN) from the World Health Organisation and 234 products used for the manufacture of finished pharmaceuticals should be added to the list of products already receiving duty free treatment and also that the list of specified prefixes and suffixes for salts and esters of INNs should be expanded by 84 names.

3. In addition it was concluded that the situation should be rectified in respect of 25 INNs whose use was predominantly non-pharmaceutical by deleting them from the list of INNs receiving duty free treatment.

4. The Commission proposes in line with other countries granting duty free treatment for these additional products as early as possible in 1997 that the duty free treatment shall commence from 1.1.97.

5. For these reasons the Commission proposes that the Council adopt the Regulation contained in the Annex to this communication.

PROPOSAL FOR A COUNCIL REGULATION (EC)

Providing for duty free treatment for specified pharmaceutical active ingredients bearing an "international nonproprietary name" (INN) from the World Health Organisation and specified products used for the manufacture of finished pharmaceuticals and withdrawing duty free treatment as pharmaceutical products from certain INNs whose predominant use is not pharmaceutical

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission,

Whereas, in the course of the Uruguay Round negotiations the Community and a number of countries discussed duty free treatment of pharmaceutical products;

Whereas the participants in those discussions concluded that in addition to products falling in the Harmonised System (HS) chapter 30 and HS Headings 2936, 2937, 2939 and 2941, duty free treatment should be given to designated pharmaceutical active ingredients bearing an "international nonproprietary name" (INN) from the World Health Organisation as well as specified salts, esters and hydrates of such products, and also to designated products used for the production and manufacture of finished products;

Whereas the results of the discussions, as set out in the Record of Discussions[1], were incorporated into the tariff schedules of the participants annexed to the Marrakesh Protocol to GATT 1994;

Whereas they also concluded that representatives of the 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;

Whereas the first such review has taken place with the conclusion that additional INNs and products 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 and esters of INNs should be expanded;

Whereas in the context of the review it was concluded that it was appropriate to rectify the situation with regard to certain INNs whose use was predominantly non-pharmaceutical and which had been inadvertently included among those INNs already receiving duty free treatment.

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[1] GATT Document L/7430

HAS ADOPTED THIS REGULATION:

Article 1

From 1 January 1997 the Community shall also accord duty free treatment for the INNs listed in Annex I as well as the salts, esters and hydrates of such products.

Article 2

From 1 January 1997 the Community shall also accord duty free treatment for the products used in the production and manufacture of pharmaceutical products listed in Annex II.

Article 3

From 1 January 1997 the specified prefixes and suffixes of INNs eligible for duty free treatment shall also include those listed in Annex III.

Article 4

From 1 January 1997 the products listed in Annex IV together with the salts, esters and hydrates of such products shall no longer benefit from duty free treatment.

Article 5

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

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

Done at Brussels,

For the Council

The President

Annex I

Additional INNs to receive duty free treatment

Annex II

Additional pharmaceutical intermediates, ie compounds used for the manufacture of finished pharmaceutical products, to receive duty free treatment.

Annex III

Additions to the list of prefixes and suffixes which, in combination with the INNs, describe salts, esters or hydrates of INNs.

Annex IV

INNs which shall no longer benefit from duty free treatment

FINANCIAL STATEMENT

Section 1. Financial Implications

1. Proposal for a Council Regulation providing duty free treatment for 465 pharmaceutical products and withdrawing duty free treatment from 25 products whose predominant use is not pharmaceutical.

2. Budget heading: (loss of revenue: not known)

3. Legal basis: Article 113

4. Description

   The proposal regulation is a consequence of the agreement reached in the Uruguay Round to undertake a periodic review of the agreement with a view to including, by consensus, additional products for duty free treatment.

5. Type of revenue: Loss of revenue for duties paid on third country imports.

6. Change in level of revenue:

   The withdrawal of duty free treatment from products whose use was predominantly non-pharmaceutical with subsequent revenue gains will offset a large proportion of the revenue loss for duty free treatment being granted to other products. No figures are available for the amounts involved but with this element taken into account the duty loss is likely to be less than 2 MECU.

Annex I

Additional INNs to receive duty free treatment

CN code	CAS RN	Name
2844 40 30	113716-48-6	iolopride (123 I)
	142481-95-6	technetium (99m Tc) furifosmin
2846 90 00	131069-91-5	gadoversetamide
	135326-11-3	gadoxetic acid
	138721-73-0	sprodiamide
2914 40 90	20098-14-0	idramantone
2916 39 00	71109-09-6	vedaprofen
2918 30 00	22161-81-5	dexketoprofen
	112665-43-7	seratrodast
2918 90 90	139403-31-9	pimilprost
2921 49 90	136236-51-6	rasagiline
2922 49 70	6582-31-6	dapabutan
2923 90 00	1794-75-8	laurcetium bromide
2924 10 00	1675-66-7	adelmidrol
	62304-98-7	thymalfasin
	132787-19-0	tradecamide
	129009-83-2	versetamide
2924 29 90	147362-57-0	loviride
	94497-51-5	tamibarotene
2925 19 80	144849-63-8	bisnafide
2925 20 00	137159-92-3	aptiganel
2926 90 80	137109-71-8	balazipone
	147076-36-6	laflunimus
2928 00 90	141579-54-6	fenleuton
2930 90 16	87573-01-1	salnacedin
2930 90 70	90357-06-5	bicalutamide
	112573-72-5	dexecadotril
	107023-41-6	pobilukast
	81110-73-8	racecadotril
2931 00 50	132236-18-1	zifrosilone
2931 00 80	114084-78-5	ibandronic acid
	124351-85-5	incadronic acid
	63132-39-8	olpadronic acid
2932 99 70	105674-77-9	lanproston
2932 99 90	123407-36-3	arteflene
	132017-01-7	bervastatin
	110816-79-0	cromoglicate lisetil
	149494-37-1	ebalzotan
	151581-24-7	iralukast
	113806-05-6	olopatadine
	139110-80-8	zanamivir
2933 29 90	158682-68-9	elisartan
	116684-92-5	galdansetron
	89371-44-8	imidaprilat
	138402-11-6	irbesartan
	118072-93-8	zoledronic acid
2933 39 95	119257-34-0	besipirdine
	118248-91-2	fodipir
	155415-08-0	inogatran
	121750-57-0	itameline
	144412-49-7	lamifiban
	155319-91-8	mangafodipir
	150443-71-3	nicanartine
	29876-14-0	nicotredole
	144035-83-6	piclamilast
	137795-35-8	spiroglumide
	147025-53-4	talsaclidine
	149488-17-5	trovirdine
2933 40 10	127294-70-6	balofloxacin
	143383-65-7	premafloxacin
	143224-34-4	telinavir

2933 40 90	96946-42-8	cisatracurium besilate
2933 40 90	158966-92-8	montelukast
	136668-42-3	quiflapon
2933 59 70	127266-56-2	adatanserin
	106941-25-7	adefovir
	113852-37-2	cidofovir
	150756-35-7	efletirizine
	119687-33-1	iganidipine
	127759-89-1	lobucavir
	140945-32-0	mapinastine
	134208-17-6	mazapertine
	96604-21-6	ocinaplon
	148504-51-2	ripisartan
	115762-17-9	ruzadolane
	118420-47-6	tagorizine
	137234-62-9	voriconazole
	151319-34-5	zaleplon
2933 79 00	148396-36-5	fradafiban
	74436-00-3	geclosporin
	143943-73-1	lirequinil
	106730-54-5	olprinone
	135548-15-1	oxeclosporin
	145733-36-4	tasosartan
	143343-83-3	toborinone
2933 90 95	137882-98-5	abitesartan
	114607-46-4	acitazanolast
	120511-73-1	anastrozole
	134523-00-5	atorvastatin
	128270-60-0	bivalirudin
	139481-59-7	candesartan
	54278-85-2	candocuronium iodide
	105806-65-3	efegatran
	62568-57-4	emideltide
	120081-14-3	goralatide
	142880-36-2	ilomastat
	62732-44-9	ipidacrine
	116287-14-0	lanperisone
	112809-51-5	letrozole
	116644-53-2	mibefradil
	136122-46-8	mipitroban
	144702-17-0	pomisartan
	132036-88-5	ramosetron
	106308-44-5	rufinamide
	144701-48-4	telmisartan
	147059-72-1	trovafloxacin
2934 10 00	149079-51-6	cartasteine
	128312-51-6	cinalukast
	51287-57-1	denotivir
	101001-34-7	pamicogrel
	136433-51-7	tazofelone
	138742-43-5	zankiren
2934 20 90	144665-07-6	lubeluzole
	150915-41-6	perospirone
	146939-27-7	ziprasidone
2934 90 60	130370-60-4	batimastat
	133040-01-4	eprosartan
	135202-79-8	ilonidap
	114686-12-3	imitrodast
	132418-36-1	rocepafant
	132418-35-0	setipafant
2934 90 70	125533-88-2	mofarotene
	127045-41-4	pazufloxacin
2934 90 80	118292-40-3	tazarotene
2934 90 98	151356-08-0	afovirsen

	138298-79-0	alnespirone
	152317-89-0	alniditan
	153420-96-3	atibeprone
	143393-27-5	azalanstat
	149908-53-2	azimilide
	150490-85-0	berupipam
	154361-50-9	capecitabine
	133099-04-4	darifenacin
	137500-42-6	darsidomine
	114030-44-3	dexpemedolac
	115464-77-2	elopiprazole
	141790-23-0	fozivudine tidoxil
	122254-45-9	glenvastatin
	143443-90-7	ifetroban
	82857-82-7	ilepcimide
	104454-71-9	ipenoxazone
	118288-08-7	lafutidine
	138068-37-8	lepirudin
	78994-23-7	levormeloxifene
	116476-16-5	levosemotiadil
	148152-63-0	napitane
	84558-93-0	netivudine
	147432-77-7	ontazolast
	139225-22-2	panamesine
	103255-66-9	pazinaclone
	123447-62-1	prulifloxacin
	131986-45-3	xanomeline
	145781-32-4	zolasartan
2935 00 90	147536-97-8	bosentan
	136817-59-9	delavirdine
	119905-05-4	delequamine
	112966-96-8	domitroban
	125279-79-0	ersentilide
	139133-26-9	lexipafant
	154397-77-0	napsagatran
	139133-27-0	nupafant
	116649-85-5	ramatroban
	133276-80-9	samixogrel
	146623-69-0	saprisartan
	149556-49-0	susalimod
	144494-65-5	tirofiban
	139308-65-9	tolafentrine
	107753-78-6	zafirlukast
2936 29 90	131875-08-6	lexacalcitol
2937 10 10	9002-68-0	follitropin alfa
	152923-57-4	lutropin alfa
2937 22 00	103466-73-5	icometasone enbutate
2937 29 90	144459-70-1	rofleponide
2937 99 00	124478-60-0	aglepristone
	140703-51-1	examorelin
	133107-64-9	insulin lispro
	144743-92-0	teverelix
2939 50 90	151581-23-6	apaxifylline
	132210-43-6	cipamfylline
	100324-81-0	lisofylline
	98833-92-2	stacofylline
2939 90 90	135905-89-4	mirisetron
	117086-68-7	ricasetron
	25775-90-0	zucapsaicin
2940 00 90	133692-55-4	seprilose
2941 90 00	127785-64-2	basifungin
2941 90 00	116853-25-9	cefluprenam
	122841-10-5	cefoselis
	156131-91-8	dimadectin

	123997-26-2	eprinomectin
	149951-16-6	lenapenem
	108852-90-0	nemorubicin
	159445-62-2	orientiparcin
	156769-21-0	sanfetrinem
3001 90 99	120993-53-5	desirudin
3002 10 91	143653-53-6	abciximab
	156227-98-4	afelimomab
	151763-64-3	capromab
	152923-56-3	dacliximab
	145832-33-3	detumomab
	142864-19-5	enlimomab
	152981-31-2	inolimomab
	150631-27-9	nacolomab tafenatox
	159445-64-4	odulimomab
	147191-91-1	priliximab
	153101-26-9	regavirumab
	148189-70-2	votumumab
3002 10 95	143090-92-0	anakinra
	143631-61-2	atexakin alfa
	148637-05-2	cilmostim
	154725-65-2	epoetin epsilon
	148363-16-0	epoetin omega
	102786-52-7	eptacog alfa (activated)
	156679-34-4	lenercept
	124146-64-1	mobenakin
	0-00-0	moroctocog alfa
	148641-02-5	muplestim
	139076-62-3	octocog alfa
3003 39 00	0-00-0	plusonermin
3003 90 90	0-00-0	fuladectin
3507 90 90	143831-71-4	dornase alfa
	154248-97-2	imiglucerase
	149394-67-2	ledismase
	156616-23-8	monteplase
	159445-63-3	nateplase
	155773-57-2	pegorgotein
3911 90 19	95522-45-5	colestilan
	31512-74-0	polixetonium chloride
3913 90 80	39464-87-4	betasizofiran
	0-00-0	certoparin sodium
	0-00-0	minolteparin sodium

Annex II

Additional pharmaceutical intermediates, ie compounds used for the manufacture of finished pharmaceutical products, to receive duty free treatment.

CN code	CAS RN	Name
2843 30 00	12192-57-3	(alpha-D-glucopyranosylthio)gold
2903 69 90	42074-68-0	1-chloro-2-(chlorodiphenylmethyl)benzene
	76283-09-5	alpha,4-dibromo-2-fluorotoluene
2906 29 90	104265-58-9	2-[(1S,2R)-6-fluoro-2-hydroxy-1-isopropyl-1,2,3,4-tetrahydro-2-naphthyl]ethyl p-toluenesulfonate
2907 29 90	700-13-0	2,3,5-trimethylhydroquinone
2909 50 90	63659-16-5	4-[2-(cyclopropylmethoxy)ethyl]phenol
2914 40 90	80-75-1	11-alpha-hydroxypregn-4-ene-3,20-dione
2914 50 00	2107-69-9	5,6-dimethoxyindan-1-one
	24916-90-3	9-beta,11-beta-epoxy-17,21-dihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione
2914 70 90	83881-08-7	21-chloro-9-beta,11-beta-epoxy-17-hydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione
2915 39 90	979-02-2	20-oxopregna-5,16-dien-3-beta-yl acetate
2915 90 20	638-41-5	pentyl chloroformate
2916 39 00	49708-81-8	trans-4-(p-chlorophenyl)cyclohexanecarboxylic acid
2917 19 90	48059-97-8	(E)-oct-4-ene-1,8-dioic acid
	71170-82-6	triethyl 3-bromopropane-1,1,1-tricarboxylate
2917 39 80	27932-00-9	indan-5-yl hydrogen phenylmalonate
2918 13 00	2743-38-6	dibenzoyl-L-tartaric acid
2918 17 00	4358-88-7	ethyl DL-mandelate
2918 19 80	56188-04-6	{(1R,3R,5S)-3,5-dihydroxy-2-[(E)-(3S)-3-hydroxyoct-1-enyl]cyclopentyl}acetic acid
2918 29 90	167678-46-8	3-chloroformyl-o-tolyl acetate
2918 30 00	56105-81-8	(R)-2-(3-benzoylphenyl)propionic acid
	22161-86-0	(RS)-2-(3-benzoylphenyl)propionic acid
	78834-75-0	ethyl 7-chloro-2-oxoheptanoate
	1944-63-4	3-[(3aS,4S,7aS)-7a-methyl-1,5-dioxooctahydro-1H-inden-4-yl]propionic acid
	39562-17-9	methyl 2-(3-nitrobenzylidene)-3-oxobutyrate
2918 90 90	26159-31-9	(RS)-2-(6-methoxy-2-naphthyl)propionic acid
	105560-93-8	methyl (2R,3S)-2,3-epoxy-3-(4-methoxyphenyl)propionate
	40098-26-8	methyl 7-[(3RS)-3-hydroxy-5-oxocyclopent-1-enyl]heptanoate
2921 19 80	4261-68-1	(2-chloroethyl)diisopropylamine hydrochloride
2921 59 90	122-75-8	N,N'-dibenzylethylenediammonium di(acetate)
2922 19 00	126456-43-7	(1S,2R)-1-aminoindan-2-ol
	68047-07-4	4'-[2-(dimethylamino)ethoxy]-2-phenylbutyrophenone
2922 30 00	784-38-3	2-amino-5-chloro-2'-fluorobenzophenone
	156732-13-7	(S)-5-amino-2-(dibenzylamino)-1,6-diphenylhex-4-en-3-one
2922 49 70	37441-29-5	5-amino-2,4,6-triiodoisophthaloyl dichloride
	42854-62-6	benzyl L-alaninate--p-toluenesulfonic acid (1:1)
	39878-87-0	(-)-alpha-(chloroformyl)benzylammonium chloride
	54527-73-0	2-(N-methylbenzylamino)ethyl 3-aminobut-2-enoate
	81677-60-3	methyl (4-nitrophenyl)-L-alaninate
	949-99-5	3-(4-nitrophenyl)-L-alanine
2924 10 00	153758-31-7	(2S)-2-amino-3-hydroxy-N-pentylpropionamide--oxalic acid (1:1)

CN code	CAS RN	Name
	138531-07-4	L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysine
2924 29 90	40188-45-2	3'-acetyl-4'-hydroxybutyranilide
2924 29 90	1149-26-4	N-(benzyloxycarbonyl)-L-valine
	116661-86-0	(2S,3S)-3-(tert-butoxycarbonylamino)-2-hydroxy-4-phenylbutyric acid
	144163-85-9	tert-butyl [(1S,3S,4S)-4-amino-1-benzyl-3-hydroxy-5-phenylpentyl]carbamate
	149451-80-9	tert-butyl [(1S,2S)-1-benzyl-2,3-dihydroxypropyl]carbamate
	98737-29-2	tert-butyl {(S)-alpha-[(S)-oxiranyl]phenethyl}carbamate
	0-00-0	2-chloro-N-[2-(2-chlorobenzoyl)-4-nitrophenyl]acetamide
	125971-96-2	2-[alpha-(4-fluorobenzoyl)benzyl]-4-methyl-3-oxovaleranilide
	32981-85-4	methyl (2R,3S)-3-benzamido-2-hydroxy-3-phenylpropionate
2925 19 80	151860-15-0	meso-N-benzyl-3-nitrocyclopropane-1,2-dicarboximide
	97338-03-9	ethyl (S)-3-(4-aminophenyl)-2-phthalimidopropionate hydrochloride
	94213-26-0	ethyl (S)-3-{4-[bis(2-chloroethyl)amino]phenyl}-2-phthalimidopropionate hydrochloride
2926 90 80	58311-73-2	(Z)-(2-cyanovinyl)trimethylammonium p-toluenesulfonate
	133481-10-4	ethyl (1-cyanocyclohexyl)acetate
	123632-23-5	4-(2,2,3,3-tetrafluoropropoxy)cinnamonitrile
2928 00 90	94213-23-7	(Z)-[cyano(2,3-dichlorophenyl)methylene]carbazamidine
2930 90 16	159453-24-4	N-(benzyloxycarbonyl)-S-phenyl-L-cysteine
2930 90 70	159878-02-1	benzyl (1R,2S)-3-chloro-2-hydroxy-1-(phenylthiomethyl)propylcarbamate
	136511-43-8	ethyl N-{2-[(acetylthio)methyl]-3-(o-tolyl)-1-oxopropyl}-L-methionate
2932 19 00	97148-39-5	ammonium (Z)-2-methoxyimino-2-(2-furyl)acetate
2932 29 80	517-23-7	alpha-acetyl-gamma-butyrolactone
	6559-91-7	4'-demethylepipodophyllotoxin
	39521-49-8	(3aR,4bS,4R,4aS,5aS)-4-(5,5-dimethyl-1,3-dioxolan-2-yl)hexahydrocyclopropa[3,4]cyclopenta[1,2-b]furan-2(3H)-one
	39746-01-5	(3aR,4R,5R,6aS)-4-formyl-2-oxohexahydro-2H-cyclopenta[b]furan-5-yl benzoate
	976-70-5	3-oxopregn-4-ene-21,17-alpha-carbolactone
2932 99 50	32981-86-5	10-deacetylbaccatin III
2932 99 70	7512-17-6	2-acetamido-2-deoxy-beta-D-glucopyranose
	79944-37-9	trans-6-amino-2,2-dimethyl-1,3-dioxepan-5-ol
	125971-94-0	tert-butyl [(4R,6R)-6-(cyanomethyl)-2,2-dimethyl-1,3-dioxolan-4-yl]acetate
	467-55-0	3-beta-hydroxy-5-alpha-spirostan-12-one
	533-31-3	3,4-(methylenedioxy)phenol

CN code	CAS RN	Name
2933 11 90	6150-97-6	magnesium bis[(2,3-dihydro-1,5-dimethyl-3-oxo-2-phenyl-1H-pyrazol-4-yl)methylamino]methanesulfonate
2933 19 90	27511-79-1	3-aminopyrazole-4-carboxamide hemisulfate
2933 29 90	4897-25-0	5-chloro-1-methyl-4-nitroimidazole
2933 39 95	142057-79-2	(RS)-2-[(1-benzyl-4-piperidyl)methyl]-5,6-dimethoxyindan-1-one
	120014-07-5	2-[(1-benzyl-4-piperidyl)methylene]-5,6-dimethoxyindan-1-one
	6935-27-9	benzyl(2-pyridyl)amine
	87848-95-1	6-bromo-2-pyridyl p-tolyl ketone
	32998-95-1	N-(tert-butyl)-3-methylpyridine-2-carboxamide
2933 39 95	84449-80-9	1-[2-(4-carboxyphenoxy)ethyl]piperidinium chloride
	83949-32-0	4-carboxy-4-phenylpiperidinium p-toluenesulfonate
	38092-89-6	8-chloro-6,11-dihydro-11-(1-methyl-4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine
	31255-57-9	3-[2-(3-chlorophenyl)ethyl]pyridine-2-carbonitrile
	107256-31-5	3-[2-(3-chlorophenyl)ethyl]-2-pyridyl 1-methyl-4-piperidyl ketone hydrochloride
	6298-19-7	2-chloro-3-pyridylamine
	5424-11-3	2,2-diphenyl-4-piperidinovaleronitrile
	108555-25-5	1-[2-(4-methoxyphenyl)ethyl]-4-piperidylamine dihydrochloride
	4046-24-6	5-(1-methyl-4-piperidyl)-5H-dibenzo[a,d]cyclohepten-5-ol hydrochloride
	139886-04-7	1-methyl-1,2,5,6-tetrahydropyridine-3-carbaldehyde (E)-O-methyloxime hydrochloride
	70708-28-0	1-(2-pyridyl)-3-(pyrrolidin-1-yl)-1-(p-tolyl)propan-1-ol
	1619-34-7	quinuclidin-3-ol
2933 40 10	105956-96-5	7-[3-(tert-butoxycarbonylamino)pyrrolidin-1-yl]-8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid
	86393-33-1	7-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid
	112811-72-0	1-cyclopropyl-6,7-difluoro-8-methoxy-4-oxo-1,4-dihydroquinoline-3-carboxylic acid
	98349-25-8	ethyl 1-cyclopropyl-6,7-difluoro-4-oxo-1,4-dihydroquinoline-3-carboxylate
2933 40 90	159878-04-3	benzyl (1S,2S)-3-[(3S,4aS,8aS)-3-tert-butylcarbamoylperhydro-2-isoquinolyl]-2-hydroxy-1-(phenylthiomethyl)propylcarbamate
	159989-64-7	(3S,4aS,8aS)-N-(tert-butyl)-2-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-4-(phenylthio)butyl]perhydroisoquinoline-3-carboxamide
	159989-65-8	(3S,4aS,8aS)-N-(tert-butyl)-2-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-4-(phenylthio)butyl]perhydroisoquinoline-3-carboxamide--methanesulfonic acid (1:1)
	120578-03-2	3-[(E)-2-(7-chloro-2-quinolyl)vinyl]benzaldehyde

CN code	CAS RN	Name
	1087-69-0	(9S,13S,14S)-3-methoxymorphinan hydrochloride
	64228-78-0	pentamethylene bis{3-[1-(3,4-dimethoxybenzyl)-6,7-dimethoxy-1,2,3,4-tetrahydro-2-isoquinolyl]propionate}--oxalic acid (1:2)
2933 59 70	75128-73-3	2-[(2-acetamido-6-oxo-6,9-dihydro-1H-purin-9-yl)methoxy]ethyl acetate
	3056-33-5	N-(9-acetyl-6-oxo-6,9-dihydro-1H-purin-2-yl)acetamide
	10310-21-1	2-amino-6-chloropurine
	124832-31-1	2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl N-(benzyloxycarbonyl)-L-valinate
	150378-17-9	(2R,4S)-2-benzyl-5-[2-(tert-butylcarbamoyl)-4-(3-pyridylmethyl)piperazin-1-yl]-4-hydroxy-N-[(1S,2R)-2-hydroxyindan-1-yl]valeramide
2933 59 70	157810-81-6	(2R,4S)-2-benzyl-5-[2-(tert-butylcarbamoyl)-4-(3-pyridylmethyl)piperazin-1-yl]-4-hydroxy-N-[(1S,2R)-2-hydroxyindan-1-yl]valeramide sulfate
	150323-35-6	(3S)-1-(tert-butoxycarbonyl)-3-(tert-butylcarbamoyl)piperazine
	41202-32-8	1-(2-chlorophenyl)piperazine hydrochloride
	13078-15-4	1-(3-chlorophenyl)piperazine hydrochloride
	71-30-7	cytosine
	149062-75-9	1,3-dichloro-6,7,8,9,10,12-hexahydroazepino[2,1-b]quinazoline hydrochloride
	41202-77-1	1-(2,3-dichlorophenyl)piperazine hydrochloride
	56177-80-1	2-ethoxy-5-fluoropyrimidin-4(1H)-one
	112733-45-6	ethyl (7-chloro-2,4-dioxo-1,2,3,4-tetrahydroquinazolin-1-yl)acetate
	59703-00-3	4-ethyl-2,3-dioxopiperazine-1-carbonyl chloride
	64090-19-3	1-(4-fluorophenyl)piperazine dihydrochloride
	147539-21-7	isopropyl[2-(piperazin-1-yl)-3-pyridyl]amine
	35386-24-4	1-(2-methoxyphenyl)piperazine
	5464-78-8	1-(2-methoxyphenyl)piperazine hydrochloride
	145012-50-6	(7RS,9aRS)-perhydropyrido[1,2-a]pyrazin-7-ylmethanol
	2210-93-7	1-phenylpiperazinium chloride
	111641-17-9	4-(piperazin-1-yl)-2,6-bis(pyrrolidin-1-yl)pyrimidine
	68-94-0	purin-6(1H)-one
	70849-60-4	1-(o-tolyl)piperazine hydrochloride
2933 69 80	58909-39-0	tetrahydro-2-methyl-3-thioxo-1,2,4-triazine-5,6-dione
2933 79 00	135297-22-2	(3S,4R)-3-[(R)-1-(tert-butyldimethylsilyloxy)ethyl]-4-[(1R,3S)-3-methoxy-2-oxocyclohexyl]azetidin-2-one
	141646-08-4	1-{[(cyclohexyloxy)carbonyl]oxy}ethyl 1-(1-hydroxyethyl)-5-methoxy-2-oxo-1,2,5,6,7,8,8a,8b-octahydroazeto[2,1-a]isoindole-4-carboxylate
	132127-34-5	(3R,4S)-3-hydroxy-4-phenylazetidin-2-one
	75363-99-4	p-nitrobenzyl (2R,5R,6S)-6-[(R)-1-hydroxyethyl]-3,7-dioxo-1-

CN code	CAS RN	Name
		azabicyclo[3.2.0]heptane-2-carboxylate
	141316-45-2	potassium 1-(1-hydroxyethyl)-5-methoxy-2-oxo-1,2,5,6,7,8,8a,8b-octahydroazeto[2,1-a]isoindole-4-carboxylate
2933 90 60	59467-64-0	[7-chloro-5-(2-fluorophenyl)-2,3-dihydro-1H-1,4-benzodiazepin-2-yl]methylamine
	59469-29-3	[7-chloro-5-(2-fluorophenyl)-2,3-dihydro-1H-1,4-benzodiazepin-2-ylmethyl]ammonium bis(maleate)
	59467-69-5	8-chloro-6-(2-fluorophenyl)-1-methyl-3a,4-dihydro-3H-imidazo[1',5-a][1,4]benzodiazepine
	59469-63-5	7-chloro-5-(2-fluorophenyl)-3-methyl-2-(nitromethylene)-2,3-dihydro-1H-1,4-benzodiazepine 4-oxide
	59467-63-9	7-chloro-5-(2-fluorophenyl)-2-(nitromethylene)-2,3-dihydro-1H-1,4-benzodiazepine
2933 90 95	130404-91-0	N-[(R)-2-({(R)-2-[(2-adamantyloxycarbonyl)amino]-3-(1H-indol-3-yl)-2-methyl-1-oxopropyl}amino)-1-phenylethyl]succinamic acid--1-deoxy-1-methylamino-D-glucitol (1:1)
	122536-48-5	3-[(S)-3-(L-alanylamino)pyrrolidin-1-yl]-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid hydrochloride
	122536-91-8	7-{(S)-3-[(S)-2-(tert-butoxycarbonylamino)-1-oxopropylamino]pyrrolidin-1-yl}-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid
	134575-17-0	tert-butyl meso-3-azabicyclo[3.1.0]hex-6-ylcarbamate
	122536-66-7	tert-butyl {(S)-1-methyl-2-oxo-2-[(S)-pyrrolidin-3-ylamino]ethyl}carbamate
	140629-77-2	tert-butyl [(RS)-pyrrolidin-3-yl]carbamate
	100361-18-0	7-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid
	38150-27-5	5-chloro-2-[3-(hydroxymethyl)-5-methyl-4H-1,2,4-triazol-4-yl]benzophenone
	36916-19-5	5-chloro-2-(3-methyl-4H-1,2,4-triazol-4-yl)benzophenone
	54196-62-2	2',5-dichloro-2-[3-(hydroxymethyl)-5-methyl-4H-1,2,4-triazol-4-yl]benzophenone
	54196-61-1	2',5-dichloro-2-(3-methyl-4H-1,2,4-triazol-4-yl)benzophenone
	141113-28-2	(E)-(+)-2-(2,4-difluorophenyl)-1-{3-[4-(2,2,3,3-tetrafluoropropoxy)styryl]-1H-1,2,4-triazol-1-yl}-3-(1H-1,2,4-triazol-1-yl)propan-2-ol
	141113-41-9	(R)-2-(2,4-difluorophenyl)-3-(1H-1,2,4-triazol-1-yl)propane-1,2-diol
	144034-80-0	dimethyl{2-[5-(1H-1,2,4-triazol-1-ylmethyl)indol-3-yl]ethyl}amine
	122665-86-5	ethyl [3-(cyanomethyl)-4-oxo-3,4-dihydrophthalazin-1-yl]acetate
	41340-36-7	2-(7-ethyl-1H-indol-3-yl)ethanol
	95885-13-5	5-ethyl-4-(2-phenoxyethyl)-4H-1,2,4-triazol-

CN code	CAS RN	Name
		3(2H)-one
	96107-94-7	ethyl 1H-tetrazole-5-carboxylate, sodium salt
	96034-57-0	trans-4-hydroxy-1-(4-nitrobenzyloxycarbonyl)-L-proline
	160194-26-3	2-iodo-4-(1H-1,2,4-triazol-1-ylmethyl)aniline
	66635-71-0	isopropyl 2,3-dihydro-1H-pyrrolizine-1-carboxylate
	4928-88-5	methyl 1H-1,2,4-triazole-3-carboxylate
	0-00-0	1,4,7,10-tetraazacyclododecane-1,4,7-triacetic acid sulfate
	112193-77-8	1,4,7,10-tetraazoniacyclododecane bis(sulfate)
	3641-08-5	1H-1,2,4-triazole-3-carboxamide
	4928-87-4	1H-1,2,4-triazole-3-carboxylic acid
	6969-71-7	1,2,4-triazolo[4,3-a]pyridin-3(2H)-one
2934 10 00	171485-87-3	2-[4-(2-amino-4-oxo-4,5-dihydrothiazol-5-ylmethyl)phenoxymethyl]-2,5,7,8-tetramethylchroman-6-yl acetate
	65872-41-5	(Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetic acid
	64486-18-6	(Z)-2-[2-(chloroacetamido)thiazol-4-yl]-2-(methoxyimino)acetic acid
	76823-93-3	1-{4-[(2-cyanoethyl)thiomethyl]thiazol-2-yl}guanidine
2934 10 00	139340-56-0	{5-[(Z)-3,5-di(tert-butyl)-4-hydroxybenzylidene]-4-oxo-4,5-dihydrothiazol-2-yl}ammonium methanesulfonate
	64485-88-7	ethyl (Z)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetate
	66339-00-2	ethyl 2-(hydroxyimino)-2-[2-(tritylamino)thiazol-4-yl]acetate hydrochloride
	88046-01-9	2-guanidinothiazol-4-ylmethyl carbamimidothioate dihydrochloride
	154212-61-0	N-[2-isopropylthiazol-4-ylmethyl(methyl)carbamoyl]-L-valine
	66215-71-2	(Z)-2-methoxyimino-2-[2-(tritylamino)thiazol-4-yl]acetic acid
	154212-59-6	4-nitrophenyl thiazol-5-ylmethyl carbonate hydrochloride
	38585-74-9	thiazol-5-ylmethanol
	155213-67-5	thiazol-5-ylmethyl (1S,2S,4S)-1-benzyl-2-hydroxy-4-{(2S)-2-[3-(2-isopropylthiazol-4-ylmethyl)-3-methylureido]-3-methylbutyramido}-5-phenylpentylcarbamate
2934 20 50	80756-85-0	S-(benzothiazol-2-yl) (Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminothioacetate
2934 20 90	87691-88-1	1-(1,2-benzisothiazol-3-yl)piperazine hydrochloride
2934 90 50	111974-69-7	2-{2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl)piperazin-1-yl]ethoxy}ethanol
	42399-49-5	(2S,3S)-3-hydroxy-2-(4-methoxyphenyl)-2,3-dihydro-1,5-benzothiazepin-4(5H)-one
2934 90 60	115787-67-2	2-(2-amino-5-nitro-6-oxo-1,6-dihydropyrimidin-4-yl)-3-(3-thienyl)propiononitrile
	117829-20-6	2-amino-7-thenyl-1,7-dihydro-4H-pyrrolo[2,3-d]pyrimidin-4-one hydrochloride

CN code	CAS RN	Name
	112887-68-0	N-{5-[(1,4-dihydro-2-methyl-4-oxoquinazolin-6-ylmethyl)methylamino]-2-thenoyl}-L-glutamic acid
	161005-84-1	(S)-N,N-dimethyl-[3-(2-thienyl)-3-(1-naphthyloxy)propyl]amine--phosphoric acid (1:1)
	104795-66-6	3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide
	104795-67-7	3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide--1H-imidazole (1:1)
	104795-68-8	3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide, sodium salt
	63675-74-1	6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene
	138564-59-7	5-methyl-2-(2-nitroanilino)thiophene-3-carbonitrile
2934 90 70	25229-97-4	2-cyano-3-morpholinoacrylamide
2934 90 80	119221-49-7	5-[(2-aminoethyl)amino]-2-(2-diethylaminoethyl)-2H-[1]benzothiopyrano[4,3,2-cd]indazol-8-ol
	147086-81-5	(4S,6S)-5,6-dihydro-6-methyl-4H-thieno[2,3-b]thiopyran-4-ol 7,7-dioxide
2934 90 98	58-61-7	adenosine
	152305-23-2	(S)-4-(4-aminobenzyl)oxazolidin-2-one
	71420-85-4	7-amino-3-[1-(sulfomethyl)-1H-tetrazol-5-ylthiomethyl]-3-cephem-4-carboxylic acid, sodium salt
	29706-84-1	3'-azido-3'-deoxy-5'-O-tritylthymidine
2934 90 98	51762-51-7	benzhydryl 3-hydroxy-7-(phenylacetamido)cepham-4-carboxylate
	110314-42-6	5-[(benzofuran-2-ylcarbonyl)amino]indole-2-carboxylic acid
	131986-28-2	3-(4-chloro-1,2,5-thiadiazol-3-yl)pyridine
	107452-89-1	omega-conotoxin M VIIA
	126429-09-2	2-(dichloromethyl)-4,5-dihydro-5-(4-mesylphenyl)oxazol-4-ylmethanol
	126813-11-4	(4R,5R)-2-(dichloromethyl)-4,5-dihydro-5-(4-mesylphenyl)oxazol-4-ylmethanol
	4097-22-7	2',3'-dideoxyadenosine
	139264-17-8	(S)-4-{[3-(2-dimethylaminoethyl)-1H-indol-5-yl]methyl}oxazolidin-2-one
	110351-94-5	(S)-4-ethyl-4-hydroxy-7,8-dihydro-1H-pyrano[3,4-f]indolizine-3,6,10(4H)-trione
	140841-32-3	6-[3-fluoro-5-(4-methoxytetrahydropyran-4-yl)phenoxymethyl]-1-methyl-2-quinolone
	94732-98-6	1-(1-{3-[2-(4-fluorophenyl)-1,3-dioxolan-2-yl]propyl}-4-piperidyl)-2,3-dihydro-1H-benzimidazole-2-thione
	125995-03-1	(4R,6R)-6-{2-[2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)pyrrol-1-yl]ethyl}-4-hydroxytetrahydro-2H-pyran-2-one
	131988-19-7	3-(4-hexyloxy-1,2,5-thiadiazol-3-yl)-1-methylpyridinium iodide
	147027-10-9	(1R,2S,5R)-menthyl (2R,5S)-5-(4-amino-2-oxo-1,2-dihydropyrimidin-1-yl)-1,3-oxathiolane-2-

CN code	CAS RN	Name
		carboxylate
	147126-62-3	(1R,2S,5R)-menthyl (2R,5R)-5-hydroxy-1,3-oxathiolane-2-carboxylate
	104218-44-2	3'-O-mesyl-5'-O-tritylthymidine
	27255-72-7	3-methyl-7-(phenylacetamido)-3-cephem-4-carboxylic acid
	0-00-0	(1R,2S,3S,6R)-[(S)-1-phenylethyl]-3,6-epoxytetrahydrophthalimide
	32231-06-4	1-piperonylpiperazine
	55612-11-8	5'-O-tritylthymidine
2935 00 90	151140-66-8	(4-amino-3-iodophenyl)-N-methylmethanesulfonamide
	112101-81-2	5-[(R)-(2-aminopropyl)]-2-methoxybenzenesulfonamide
	120298-38-6	N-(5,6-dihydro-6-methyl-2-sulfamoyl-4H-thieno[2,3-b]thiopyran-4-yl)acetamide 7,7-dioxide
	150975-95-4	5-methanesulfonamidoindole-2-carboxylic acid
	84522-34-9	sodium 4-[2-(5-methylpyrazine-2-carboxamido)ethyl]benzenesulfonamide
2939 10 00	66820-84-6	(RS)-tetrahydropapaverine hydrochloride
2940 00 90	13035-61-5	1,2,3,5-tetraacetyl-beta-D-ribofuranose
3824 90 64	330-95-0	1,3-bis(4-nitrophenyl)urea--4,6-dimethylpyrimidin-2-ol (1:1)
	104832-01-1	(R)-6,7-dimethoxy-2-methyl-1-(3,4,5-trimethoxybenzyl)-1,2,3,4-tetrahydroisoquinoline--dibenzoyl-L-tartaric acid (1:1)
	0-00-0	Intermediate concentrate obtained from a genetically-modified Escherichia coli fermentation medium, containing human granulocyte-macrophage colony-stimulating factor; for use in the manufacture of medicaments of HS No. 3002
3824 90 64	0-00-0	Intermediate concentrate obtained from a genetically-modified Escherichia coli fermentation medium, containing human interferon alpha-2b; for use in the manufacture of medicaments of HS No. 3002
	0-00-0	Intermediate concentrates obtained from a Micromonospora inyoensis fermentation medium used for the manufacture of the antibiotics sisomicin (INN) and netilmicin (INN)
	0-00-0	Intermediate concentrates obtained from a Micromonospora purpurea fermentation medium used for the manufacture of the antibiotics gentamicin sulfate (INNM) and isepamicin (INN)
3824 90 95	0-00-0	ethyl 7-chloro-2-oxoheptanoate, in the form of a solution in toluene
3911 90	162430-94-6	1,6-hexanediamine, polymer with 1,10-dibromodecane
3913 90 80	83513-48-8	danaparoid sodium

Annex III

Additions to the list of prefixes and suffixes which, in combination with the INNs, describe salts, esters or hydrates of INNs.

ACETURATE
N-ACETYLGLYCINATE
ACISTRATE
ACOXIL
AMSONATE
BENZATHINE
BEZOMIL
BUCICLATE
BUNAPSILATE
BUTEPRATE
BUTYL ESTER
CARBESILATE
p-CHLOROBENZENESULFONATE
p-CHLOROBENZENESULPHONATE
CICLOTATE
CIPIONATE
CLOSILATE
CLOSYLATE
CROBEFATE
CROMACATE
CROMESILATE
CYCLOPENTANEPROPIONATE
CYCLOTATE
CYPIONATE
DAPROPATE
DEANIL
DECIL
DIBUDINATE
DIBUNATE
DIETHANOLAMINE
DIGOLIL
N,N-DIMETHYL-beta-ALANINE
DIOLAMINE
DOCOSIL
DOFOSFATE
EDAMINE
EDISYLATE
EPOLAMINE
ERBUMINE
ETABONATE
ETHANOLAMINE
ETHYLENEDIAMINE
FARNESIL
FENDIZOATE
FOSTEDATE
HIBENZATE
HYBENZATE
HYCLATE
o-(4-HYDROXYBENZOYL)BENZOATE
ISOCAPROATE
LAURIL
LAURILSULFATE
LAURILSULPHATE
LAURYL
LAURYLSULFATE
LAURYLSULPHATE
MEGALLATE
METEMBONATE
4-METHYLBICYCLO[2.2.2]OCT-2-ENE-1-CARBOXYLATE
MOFETIL
OCTIL
OLAMINE
OXOGLURATE
PENDETIDE

PIVOXETIL
PROXETIL
1-PYRROLIDINEETHANOL
SODIUM LAURIL SULFATE
SODIUM LAURIL SULPHATE
SODIUM LAURYL SULFATE
SODIUM LAURYL SULPHATE
STEAGLATE
TENOATE
TEPROSILATE
TETRADECYL HYDROGEN PHOSPHATE
TOFESILATE
TRICLOFENATE
TRIETHANOLAMINE
TRIFLUTATE
TROLAMINE
TROMETAMOL
TROMETHAMINE
TROXUNDATE
XINAFOATE

Annex IV

INNs which shall no longer benefit from duty free treatment

CN code	CAS RN	Name
2903 22 00	79-01-6	trichloroethylene
2903 30 10	811-97-2	norflurane
2903 51 10	58-89-9	lindane
2906 21 00	100-51-6	benzyl alcohol
2915 29 00	82279-57-0	zinc acetate, basic
2922 41 00	56-87-1	lysine
2922 42 90	56-86-0	glutamic acid
2922 49 10	56-40-6	glycine
2922 50 00	72-19-5	threonine
2923 10 10	67-48-1	choline chloride
2928 00 90	79-17-4	pimagedine
2930 90 20	111-48-8	thiodiglycol
2933 90 95	73-22-3	tryptophan
3102 70 10	156-62-7	calcium carbimide
3904 61 10	9002-84-0	politef
3906 90 90	54182-57-9	carbomer
3907 20	0-00-0	macrogol ester
3907 20 12	25322-68-3	macrogol
3907 20 21	25301-02-4	tyloxapol
3907 60 10	25038-59-9	pegoterate
3908 10 00	25038-54-4	policapram
3910 00 00	9006-65-9	dimeticone
3912 20 11	9004-70-0	pyroxylin
3912 31 00	9000-11-7	carmellose
3912 39 80	8063-82-9	hypromellose

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