



SCIENTIFIC SUB-COMMITTEE

-
15th Session
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NS0005E1
(+ Annexes I, II and III)

O. Eng.

Brussels, 8 December 1999.

CLASSIFICATION OF CERTAIN INN PRODUCTS
AND PHARMACEUTICAL INTERMEDIATES

(Item II.4 on Agenda)

Reference documents :

42.193 (SSC/14)
42.825 (SSC/14)
42.850, Annexes A/3 and C/1 (Report – SSC/14)
NC0078E1 (HSC/23)
NC0090E2, Annex E/4 (Report – HSC/23)
Letters 98.N.1297 - and 99NL1054 - Go/FI

1. The Sub-Committee has been examining the classification of INN products and pharmaceutical intermediates for the purposes of the WTO Agreement on Trade in Pharmaceuticals. This document deals with the classification of certain pending cases and that of new products proposed to be included in the WTO Agreement.

I. INN LIST 80

2. Since the working document (Doc. 42.825) concerning INN List 80 had only been published immediately prior to the meeting, the Sub-Committee at its 14th Session agreed to follow the same procedure that it had applied to INN List 78. Accordingly, delegates were requested to submit comments on the proposed classifications in the Annex to Doc. 42.825 to the Secretariat as soon as possible, in order to enable the Secretariat to submit the agreed classifications to the 23rd Session of the Harmonized System Committee for decision, after receiving the approval of the Chairman of the Scientific Sub-Committee.
3. As of 24 March 1999, the Secretariat had received comments from Canada, Japan, Switzerland and the United Kingdom. Taking into account the comments from these Administrations, the Secretariat prepared a list of INNs with regard to which there appeared to be consensus as to classification. The Secretariat forwarded the proposed classifications

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to the Chairman of the Scientific Sub-Committee for approval. On 1 April 1999, the Secretariat received a reply from the Chairman of the Scientific Sub-Committee, conveying his approval of the agreed classifications.

4. Consequently, the Secretariat prepared a working document (Doc. NC0078E1) for the 23rd Session of the Harmonized System Committee. Those agreed classifications were listed and identified in the Annex to Doc. NC0078E1 as "Agreed classification" in the remarks column (49 cases). This Annex also incorporated a list of products on which there were different views as to classification (27 cases). The proposed classifications in these cases were placed in square brackets.
5. The Harmonized System Committee, at its 23rd Session, adopted the classifications of 48 INN products out of the 49 listed as "Agreed classifications" (see Doc. NC0078E1 and Annexes E/4 and M/5 to Doc. NC0090E2). Since one delegate indicated that Volpristin should be classified in heading 29.41 as an antibiotic rather than in heading 29.34, the Harmonized System Committee agreed to submit this product along with other 27 products whose classifications were placed in square brackets to the next session of the Scientific Sub-Committee for examination.
6. During the intersession, the Secretariat obtained further information from the World Health Organization (WHO) on certain products. Based on the information and the comments received from administrations, the Secretariat has proposed HS codes for these 28 products as set out in Annex 1 to this document.
7. The Sub-Committee is invited to discuss the classification of the remaining 28 products from INN List 80 set out in Annex 1 to this document.

II. NEW INN LIST 81

8. On 4 August 1999, the Secretariat also received from the WHO the latest INN List (81), which contains 43 products. These products are listed in Annex II to this document along with the Secretariat's proposals concerning the classification of these products. In respect of certain products, the Secretariat has proposed more than one classification (placed in square brackets) in the absence of sufficient information. The Sub-Committee is invited to examine the classification of the products covered by INN List 81.

III. PENDING CLASSIFICATIONS

INN Lists

9. The Sub-Committee, at its 14th Session, postponed action on the classification of 11 INNs (see Annex C/1, (C/1/1, C/1/2/Rev. and C/1/3/Rev.) to Doc. 42.850) for lack of adequate technical information concerning these products. During the intersession, the Secretariat obtained some additional information from the WHO on these products. Details as to these products, along with the information obtained from the WHO and the Secretariat's comments on their classification are set out in Annex III to this document. The Sub-Committee is invited to discuss the classification of these 11 INN products.

EC list of Pharmaceutical Intermediates

10. Finally, the Sub-Committee at its 14th Session, postponed action on the classification of three pharmaceutical intermediates, of the list of 367 substances received from the EC in November 1998. In respect of these three pharmaceutical intermediates namely, GM2-KLH conjugate (ID. 609), QS-21 adjuvant (ID. 610) and KLH/reductive amination (ID. 613), the Sub-Committee needed further information from the manufacturers. As soon as it becomes available, the Secretariat will publish another document for consideration of the Sub-Committee.
11. As regards the chemical structures of the above-mentioned products, the Secretariat sent administrations necessary information with letters .

IV. CONCLUSIONS

12. Taking into account of the Secretariat's comments above, the Sub-Committee is invited to :
- (i) examine the classification of 28 products from INN List 80 set out in Annex I;
 - (ii) examine the classification of 43 products from INN List 81 set out in Annex II; and
 - (iii) re-examine the classification of 11 INN products listed in Annex III.

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INN LIST 80

INN	Comments from Administrations	New information from the WHO	Proposed HS code
Alitretinoin	Derivative of retinol (Swiss)	Retinol derivative. USAN Council, USA (Allergan Ligand Retinoid Therapeutics (ALRT))	2936.21
Anecortave	Need for more information as to whether it is a hormone (Canada, UK). 2915.39 (Canada)	Adrenocortical hormone analogue. USAN Council, USA (Alcon Laboratories, Inc.)	2937.99
Avasimibe	2935.00 (Canada)		2929.90
Caspofungin	Need for more information as to whether it is an antibiotic (Swiss, UK). 2941.90 (Canada)	Antibiotic with antifungal properties. USAN Council, USA (Merck & Co., Inc.)	2941.90
Corifollitropin alfa	2934.40 (Canada)	Follicle-stimulating hormone analogue. N.V. Organon, the Netherlands	2937.99
Darbufelone	2934.90 (Canada)		2934.10
Depreotide	2933.90 (Japan, UK)		2933.90
Deracoxib	2937.99, inhibitor of cyclooxygenase-2 (Swiss)	Cyclooxygenase-2 inhibitor, non-steroidal anti-inflammatory and analgesic USAN Council, USA (G.D. Searle & Co.)	2935.00
Desmoteplase	Need for more information as to whether it is an enzyme (UK). 3507.90 (Canada)	Enzyme, tissue-type-plasminogenactivator. Schering AG, Berlin, Germany	3507.90
Dexbudesonide	2914.40 (Canada)		2932.99
Hemoglobin glutamer	3913.90 (Canada)	Hemoglobin analogue, blood substitute. USAN Council, USA (Biopure Corp.)	3002.10
Insulin detemir	2934.90 (Canada)	Insulin analogue (pancreas hormone analogue) Novo Nordisk A/S, Denmark	2937.99
Itavastatin	2933.90 (Canada)		2933.40

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Leridistim	2934.90 (Canada). 29.37, need for more information as to whether it is a hormone (UK)	Immunomodulator, colony stimulating factor. USAN Council, USA (G.D. Searle & Co.)	3002.10
Lusupultide	2933.29 ((Canada) 2933.90 (Japan, UK)		2933.29
Nesiritide	2934.90 (Canada, Japan, Swiss) 2933.90 (UK) 3002.10 (Swiss) Need for more information as to whether it is a modified immunological product.	Human natriuretic factor analogue, vasodilator/diuretic. USAN Council, USA (Biochemie GmbH (Austria))	2934.90
Olmesartan	2933.29 (Canada)		2934.90
Pegacaristim	Need for more information as to whether it is a pituitary or similar hormone etc. 3913.90 (Canada)	Immunomodulator, colony stimulating factor (megakaryocyte growth factor). USAN Council, USA (Amgen Inc.)	3002.10
Pegnartograstim	29.34 (UK). 3913.90 (Canada)	Immunomodulator, granulocyte colony stimulating factor (G-CSF) type substance. F.Hoffmann-La Roche, Switzerland	3002.10
Satraplatin	2942.00 (Canada)		2843.90
Semparatide	2933.29 (Canada)		2933.29
Simeticone	3003.90 (Canada) 3824.90 (Swiss) 3910.00 (UK), 39 (Swiss)	Dimethyl poly siloxane, dimethyl silicone (synonyms)	3910.00
Tabimorelin	2937.99 (Swiss)	Growth hormone release-stimulating peptide. USAN Council, USA (Triangle Pharms)	2924.29
Tositumomab	All "momabs" in current ECICS are 3002.10 (UK)		3002.10
Travoprost	29.37 (UK)	Prostaglandin (intercellular messengers that are found in high concentrations at sites of chronic inflammation). USAN Council, USA (Alcn Labs)	2918.90
Vangatalcite	2838.99 (Canada)		2842.90
Vepalimomab	All "momabs" in current ECICS are 3002.10 (UK)	Immunomodulator (immunoglobulin). BioTie Therapies Ltd., Finland	3002.10

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Volpristin	29.41 (Suggested at HSC/23)	Antibiotic, pristinamycin derivative. French Pharmacopoeia Commission (Rhone-Poulenc Rorer, France)	2941.90
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INN LIST 81

INN	Proposed HS code	Remarks
Abetimus	2930.90	
Caloxetic acid	2931.00	
Anidulafungin	[2941.90] [2933.90]	Need for more information as to whether it is an antibiotic
Artenimol	2932.99	
Bexlosteride	2933.79	
Cadroxifloxacin	[2941.90] [2933.90]	Need for more information as to whether it is an antibiotic
Cefmatilen	2941.90	
Cilengitide	[2933.90] [3002.10]	Need for more information as to whether it is a modified immunological product
Cipemastat	2933.39	
Clamikalant	2935.00	
Esketamine	2921.49	
Etanercept	3002.10	
Exatecan	2934.90	
Falnidamol	2933.39	
Finrozole	2933.90	
Fosfructose	2940.00	
Frakefamide	2924.29	
Ganstigmine	2934.90	

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Gemifloxacin	[2941.90] [2933.90]	Need for more information as to whether it is an antibiotic
Ibritumomab tiuxetan	3002.10	
Idremcinal	2932.99	
Ilodecakin	3002.10	
Izonsteride	2934.90	
Lasofloxifene	2933.90	
Liatermin	2937.99	
Licarbazepine	2933.90	
Mepolizumab	3002.10	
Olanexidine	[2925.19] [2941.90]	Need for more information as to whether it is an antibiotic
Pibrozelesin	2933.90	
Pimecrolimus	2934.90	
Prazarelix	2933.39	
Ranpirnase	3507.90	
Rasburicase	3507.90	
Rovelizumab	3002.10	
Sarakalim	2934.90	
Selamectin	2932.99	
Sbrotuzumab	3002.10	
Siramesine	2934.90	

Talnetant	2933.90	
Tesmilifene	2922.19	
Tezosentan	2935.00	
Tocladesine	[3002.10] [2934.90]	Need for more information as to whether it is a modified immunological product
Troxacitabine	2934.90	

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INN PRODUCTS WHOSE CLASSIFICATION WAS
POSTPONED AT THE PREVIOUS SESSION

INN	New information from WHO	HS code	Secretariat's comments
Denileukin diffitox	Immunomodulator, recombinant fusion protein consisting of diphtheria toxin and human interleukin elements. USAN Council, USA (Seragen, Inc.)	3002.10	
Thyrotropin alfa	Growth hormone releasing hormone. USAN Council, USA (Genzyme Corporation)	[2937.10] [2937.90] [2934.90]	The original technical information received from the WHO indicates that it is a thyrotropin releasing hormone (<i>TRH</i>) analog. The Secretariat doubts whether it could be classified as a hormone
Tremacamra	Antiviral, inhibitor of viral attachment to host cells. USAN Council, USA (Boehringer Ingelheim Corp.)	3504.00	
Calcobutrol	Heterocyclic compound with nitrogen atoms only. Schering AG, Berlin, Germany	2933.90	
Defoslimod	Glycoside derivative. Laboratories OM S.A., Switzerland	2938.90	
Fondaparin sodium	Glycoside derivative (pentasaccharide). Sanofi Winthrop, Brussels, Belgium	2938.90	
Olamufloxacin	Synthetic antibacterial (nalidixicacid derivative). Society of Japanese Pharmacopoeia, Japan (Hokuriku Seiyaku Co. Ltd.)	2933.40	
Sardomozide	Urea azine (can be regarded as hydrazine derivative). Novartis Pharma Inc., Switzerland	2928.00	
Valrubicin	Antibiotic with antineoplastic properties. USAN Council, USA (Anthra Pharmaceuticals, Inc.)	2941.90	

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Tasonermin	Polypeptide. Boehringer Ingelheim, Germany	2934.90	
Macrogol ester	Polymer, pharmaceutical aid. Various manufacturers	[3402.13] [3404.20] [3907.20]	Since information regarding specific products is not available it is not possible to determine whether the products are polymers (Note 3(c) to Chapter 39) or organic surface-active agents (Note 3 to Chapter 34).