



HARMONIZED SYSTEM
COMMITTEE

-
26th Session
-

NC0322E1
(+ Annex)
O. Eng.

Brussels, 19 October 2000.

REVIEW OF THE CLASSIFICATION OF CERTAIN INN PRODUCTS

(Item VII.23 on Agenda)

Reference documents :

42.193 (SSC/14)	NC0090E2, Annexes E/1 and M/1 (HSC/23.- Report)
42.825 (SSC/14)	NS0005E1 (SSC/15)
42.850, Annexes A/3 and C/1 (SSC/14 – Report)	NS0014E2, Annexes A/4 and B/1 (SSC/15 – Report)
NC0016E1 (HSC/23)	NC0181E1 (HSC/25)
NC0078E1 (HSC/23)	NC0250E/2, Annexes E and P/1 (HSC/25 –Report)

I. BACKGROUND

1. On 9 August 2000, the Secretariat received a note from the Canadian Administration indicating two classification errors with regard to INN products, namely Midaxifylline (INN List 79) and Corifollitropin alfa (INN List 80), the classification of which was decided at previous HS Committee sessions.

II. SECRETARIAT COMMENTS

Midaxifylline

2. In Doc. 42.193 (SSC/14), the Secretariat proposed subheading 2933.59 for the classification of Midaxifylline. The Scientific Sub-Committee examined this document at its 14th Session and in its report (Annexes A/3 and C/1 to Doc. 42.850) the classification of Midaxifylline was indicated as "2939.50" in the English text and as "2933.50" in the French text. The Harmonized System Committee at its 23rd Session approved these classifications agreed upon by the Scientific Sub-Committee without noticing the error. Accordingly, this error was reflected in Annex M/1 to Doc. NC0090B2 (HSC/ 23 - Report).
3. Midaxifylline was described as an adenosine receptor antagonist in the WHO Drug Information, Proposed INN List 79 (see Annex hereto). The Secretariat proposed subheading 2933.59 based on the presence of a pyrimidine (hydrogenated) ring in the structure of the product. However, though there is no reason indicated in the report, it

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appears that the Scientific Sub-Committee classified the product in subheading 2939.50 as a theophylline derivative.

4. In view of the error reflected in the French text (2933.50), the Committee may wish to refer this item back to the Scientific Sub-Committee for re-examination of the classification of Midaxifylline.

Corifollitropin alfa

5. The Harmonized System Committee, at its 25th Session, approved the classification of Corifollitropin alfa in subheading 2934.40. However, as pointed out by Canada, subheading 2934.40 does not exist. Upon examining the relevant background documents the Secretariat noticed that this error originated from a letter received from the Canadian Administration, recommending subheading 2934.40 as the classification for Corifollitropin alfa. The Secretariat did not notice this error at that time and indicated this recommended subheading along with the Secretariat's proposal for classifying this item in subheading 2937.99. This was reflected in Doc. NS0005E1 for examination at the 15th Session of the Scientific Sub-Committee in January 2000. The Sub-Committee decided not to classify this product in subheading 2937.99 (proposed by the Secretariat), but decided to accept the Canadian recommendation of subheading 2934.40 without noticing the error. This classification was finally adopted by the Harmonized System Committee at its 25th Session as reflected in Annex P/1 to Doc. NC0250B2.

6. In studying the relevant correspondence with respect to Corifollitropin alfa (INN List 80), the Secretariat noticed that according to the WHO Drug Information, Proposed INN List 80 and Recommended INN List 42, Corifollitropin alfa was described as a "follicle-stimulating hormone" (see the Annex hereto). However, when further information was requested by the Secretariat from the WHO, as to whether this product could be considered as a hormone or immunological product etc., the WHO by fax of 24 June 1999 indicated that this product was a "follicle-stimulating hormone analogue".

7. According to the present HS Nomenclature, hormone analogues are not covered by HS heading 29.37. The Secretariat has therefore requested the WHO to again clarify whether Corifollitropin alfa should be considered to be a hormone or a hormone analogue. By the time of the preparation of this document the Secretariat had not yet received a reply from the WHO.

8. The Committee may therefore wish to refer the classification question of Corifollitropin alfa to the Scientific Sub-Committee for further examination.

III. CONCLUSION

9. The Committee is requested to decide on the course of action to be taken in order to rectify the classification errors with regard to the classification of Midaxifylline and Corifollitropin alfa, as pointed out by Canada, taking note of the Secretariat's comments in paragraphs 2 to 8 above.

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midaxifyllinum

midaxifylline

8-(1-aminocyclopentyl)-1,3-dipropylxanthine
adenosine receptor antagonist

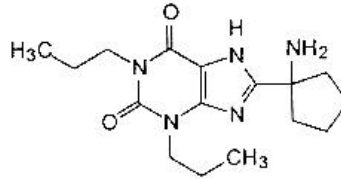
midaxifylline

8-(1-aminocyclopentyl)-1,3-dipropyl-3,7-dihydro-1*H*-purine-2,6-dione
antagoniste de récepteur adenosine

midaxifilina

8-(1-aminociclopentil)-1,3-dipropilxantina
*antagonista del receptor adenosina*C₁₆H₂₅N₅O₂

151159-23-8

**corifollitropinum alfa**

corifollitropin alfa

follicle-stimulating hormone (human α -subunit reduced), complex with follicle-stimulating hormone (human β -subunit reduced) fusion protein with 118-145-chorionic gonadotropin (human β -subunit)
hormone

corifollitropine alfa

hormone folliculostimulante modifiée formée de deux sous-unités α et β
sous-unité α : gonadotropine chorionique (partie protéique réduite de la sous-unité α humaine) sous-unité β : hormone folliculostimulante (partie protéique réduite de la sous-unité β humaine)-112-139-gonadotropine chorionique (partie protéique réduite de la sous-unité β humaine)
hormone

corifollitropina alfa

Hormona estimulante del folículo modificada, formada por dos subunidades α y β : Subunidad α : gonadotropina coriónica (fracción proteica reducida de la subunidad α humana) Subunidad β : hormona estimulante del folículo (fracción proteica reducida de la subunidad β humana)-112-139-gonadotropina coriónica (fracción proteica reducida de la subunidad β humana)
hormona

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APDVQDCPEC	TLQENPFFSQ	PGAPILQCMG	CCFSRAYPTP
LRSKKTMLVQ	K [•] NVTSESTCC	VAKSYNRVTV	MGGFKVENHT
AHCSTCY [•] YH	K [•] S		
NSCELT [•] NITI	AIEKEECRFC	ISINTTWCAG	YCYTRDLVYK
DPARPKIQKT	CTFKELVYET	VRVPGCAHHA	DSLTYTPVAT
QCHCGKCDSD	STDCTVRGLG	PSYC [•] SFGEMK	ESSS [•] SKAPPP
SLPSP [•] RLPG	P [•] SDTPILP [•] Q		

- * glycosylation sites
- * sites de glycosylation
- * posiciones de glicosilación