



HARMONIZED SYSTEM
COMMITTEE

-
31st Session
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NC0674E1
(+ Annex)

O. Eng.

Brussels, 14 March 2003.

AMENDMENT OF THE EXPLANATORY NOTES WITH A VIEW TO DISTINGUISHING
BETWEEN MEDICATED BONE GRAFT SUBSTITUTES AND
BONE RECONSTRUCTION CEMENTS

(Item VII.3 on Agenda)

Reference documents :

NC0507E1 (HSC/28)	NC0562E1 (HSC/29)
NC0510E2, Annex H/21 (HSC/28 – Report)	NC0590E2, Annex H/4 (HSC/29)
NS0059E1 (SSC/17)	NC0622E1 (HSC/30)
NS0060E2, Annex A/15 (SSC - 17 – Report)	NC0655E2, Annexes G/12 and L/1 (HSC/30 - Report)

I. BACKGROUND

1. At its 29th Session, the Harmonized System Committee examined the classification of a medicated bone graft substitute called "OSTEOSET[®]T". The Committee unanimously agreed to classify this product in heading 30.04 (subheading 3004.20), by application of GIRs 1 and 6.
2. In order to reflect this decision, and at the request of the Jordanian Administration, the Committee instructed the Secretariat to prepare a draft Classification Opinion for examination by the following presessional Working Party (Classification Opinion 3004.20/1 was adopted at the 30th Session).
3. Furthermore, the Committee instructed the Secretariat to prepare a draft text of amendments to the relevant part of the Explanatory Notes for examination at its 30th Session, with a view to clarifying how to distinguish between medicated bone graft substitutes and the bone reconstruction cements classifiable in heading 30.06. In this regard, it was pointed out that the text should reflect the contents of paragraphs 2 and 3 of Annex A/15 to Doc. NS0060E2, which are reproduced below. Administrations were also invited to submit their proposals in this connection to the Secretariat as soon as possible.

Note : Shaded parts will be removed when documents are placed on the WCO documentation database available to the public.

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- "2. Certain delegates were of the view that the product should be classified in heading 30.06 as a bone reconstruction cement, since the product had two functions, i.e., as a filling and as a medicament, and by virtue of Note 4 to Chapter 30, heading 30.06 took priority over any other heading of the Nomenclature. Furthermore, they noted that according to the Explanatory Note to heading 30.06 on page 576, the addition of medicinal substances was allowed.
3. The majority of the Sub-Committee, however, agreed with the Secretariat's opinion in paragraph 23 of Doc. NS0059E1, that classification in heading 30.06 would not be appropriate taking into account the nature of the product. The product could not be considered to be a "cement".

4. At the 30th Session, the **US** Delegate explained that the **United States** had recently submitted a non-paper with alternative texts regarding the Explanatory Notes to headings 30.04 and 30.06, in order to provide for a clearer distinction between medicated bone graft substitutes of heading 30.04 and bone reconstruction cements of heading 30.06. The Committee agreed to examine the amendments to the Explanatory Notes on the basis of the **US** alternative texts. In this connection, the Director noted that although the term "adsorbed" appeared in the Secretariat text, the term "absorbed" was used in the **US** text.
5. The Committee felt that in addition to the above there appeared to be certain textual questions to be studied and agreed to send this issue to the next preessional Working Party. The Secretariat was therefore instructed to prepare a new working document on the basis of the **US** texts, for consideration, in the first instance, by the next preessional Working Party.
6. The **US** texts, which were placed in square brackets, are reproduced in the Annex to this document.

II. SECRETARIAT COMMENTS

7. With respect to the use of the term "adsorbed" or "absorbed", according to scientific literature (Hawley's Condensed Chemical Dictionary, 12th Edition), the term "absorption" means that "the penetration of one substance into the inner structure of another, as distinguished from adsorption, in which one substance is attracted to and held on the surface of another."
8. With respect to the term "absorption" in French, the "Grand Larousse Universel", Volume 1, page 31 states as follows :

"Chim. phys. Propriété que présentent les solides et les liquides de retenir certaines substances (gaz ou liquides) dans la totalité de leur volume. (De façon plus générale, il y a absorption quand un système hétérogène évolue de sorte que toutes les phases disparaissent à l'exception d'une seule qui capte les autres." (Original texts)

"Chemistry. Physics. Property whereby solids and liquids retain certain substances (gases or liquids) in their total volume. (More generally speaking, absorption occurs when a heterogeneous system develops in such a way that all the phases disappear, apart from a single phase taking up all the others." (Translation of the original language)

The Secretariat considers that French and English scopes of the term "absorption" are the same.

9. The Secretariat used the term “adsorbed” in the Annex to Doc. NC0622E1 since the US Patent and Trademark Office Web site (www.uspto.gov) referred to this product stating that calcium sulfate has been utilised as a filler for bone cavities as it is spontaneously adsorbed and replaced by bone (emphasis added) (see paragraph 14 of Doc. NS0059E1). (Only English is available in the Web site).
10. The producer’s brochure, however, has not used the term “adsorbed” nor “absorbed” and it reads “the pellets are resorbed at a rate consistent with the new bone growth” (emphasis added) (see paragraph 5 to Doc. NC0507E1). The French brochure also uses the term “résorption”. According to the Concise Oxford Dictionary, the term “resorb” means “*Physiology* remove (cells, tissues, etc.) by gradual breakdown into component materials and dispersal in the circulation”.
11. According to “Grand Larousse Universel”, Volume 13, page 8920, the term “résorption” in French means :
- “Méd. Disparition par absorption ou atrophie progressive d’un épanchement pathologique, d’un tumeur, d’un corps étranger, d’un organe.” (Original text)
- “Medicine. Disappearance by absorption or progressive atrophy of a pathological effusion, tumour, foreign body or organ.” (Translation of the original language)
- The Secretariat considers that the French and English scopes of the above-mentioned terms are the same.
12. Taking the above into consideration, the Secretariat is of the view that the term “resorbed” in English (“résorbe” in French) is the most appropriate among the options since the term “resorbed” is used in the producer’s brochure and reflects the characteristics of the product. The Secretariat, however, leaves this question to the HS Committee to decide. The Secretariat has placed the alternative term “resorbed” in the proposed texts in square brackets.
13. The proposed amendments to the Explanatory Notes are set out in the Annex to this document.

III. CONCLUSION

14. The Committee is invited to approve the draft amendments to the Explanatory Notes set out in the Annex (taking into account the Secretariat comments above) once they have been finalised by the presessional Working Party.

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