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HARMONIZED SYSTEM COMMITTEE
-
29th Session
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NC0562E1
(+ Annex)

O. Eng.

Brussels, 4 April 2002.

CLASSIFICATION OF A MEDICATED BONE GRAFT SUBSTITUTE CALLED "OSTEOSET®T"

(Item VIII.4 on Agenda)

Reference documents :

NC0507E1 (HSC/28)
NC0510E2, Annex H/21 (HSC/28 – Report)
NS0059E1 (SSC/17)
NS0060E2, Annex A/15 (SSC-17 – Report)

I. BACKGROUND

1. On 10 September 2001, the Secretariat received a request from the Jordanian Administration, together with a copy of a catalogue prepared by a US manufacturer, asking the Secretariat to submit the question of the classification of a medicated bone graft substitute called "OSTEOSET® T" to the Harmonized System Committee at its 28th Session.

2. In its reply, the Secretariat asked the Jordanian Administration to submit detailed information concerning the composition of the product and its presentation, preferably together with a sample, to enable the Secretariat to prepare a working document. On 7 October 2001, the Secretariat received a reply from the Jordanian Administration, stating that a sample was not available and that the catalogue mentioned above should be used as a basis for the working document (see paragraphs 5 to 9 of Doc. NS0059E1).

3. At its 28th Session, in view of the technical nature of this question, the Committee decided to send it to the Scientific Sub-Committee for its views on the nature of the product, i.e., whether it should be considered to be a medicament or bone reconstruction cement.

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

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II. DISCUSSIONS AT THE 17TH SESSION OF THE SCIENTIFIC SUB-COMMITTEE

4. The Scientific Sub-Committee, at its 17th Session, first examined whether the product would fall in heading 30.06 or outside that heading.

5. 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.

6. 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".

7. On the basis of the above, the Sub-Committee considered the appropriate heading for the classification of the product in question. One delegate questioned whether or not calcium sulfate, which was the main ingredient of the product, could be considered to be a medicament, indicating that the calcium sulfate pellets might be used alone as mentioned in paragraph 17 of Doc. NS0059E1.

8. However, the majority of the delegates considered that the product should be classified in heading 30.03 or 30.04, depending on the presentation of the product since the product would be spontaneously adsorbed and replaced by bone, thus being used for therapeutic purposes.

9. In this regard, several delegates expressed doubts as to whether the product at issue could be regarded as being put up in measured doses, since the product was in the form of pellets (to avoid dust) and the dosage did not have the normal degree of precision.

10. Other delegates were however of the view that even if it was difficult to regard the product as being put up in measured doses, it appeared that the product was put up in packings for retail sale and therefore it could fall in heading 30.04, by virtue of the second part of the text of heading 30.04. At subheading level, it was pointed out that since the product contained tobramycin, it should be classified in subheading 3004.20.

11. Finally, the Secretariat was asked to check whether the product was in fact traded in packings put up for retail sale for purposes of the discussion of this question at the next session of the HS Committee.

III. SECRETARIAT COMMENTS

"OSTEOSET® T" pellets

12. "OSTEOSET®T" pellets are a bone graft substitute made from medical grade calcium sulfate containing 4 % tobramycin sulfate. According to the Web site of the manufacturer (www.wmt.com), calcium sulfate has been found to completely resorb and aid significantly in bone repair. By engineering the shape and size of the hemihydrate crystal,

the resorption rate of the final product could be controlled (see paragraphs 12 to 18 of Doc. NS0059E1). "OSTEOSET® T" pellets offer a biological framework into which new bone can form, and are resorbed at a rate consistent with natural bone formation.

13. The Secretariat also notes that "OSTEOSET® T" pellets are not to be taken orally and are to be inserted inside a cavity of the fractured bone by using "OSTEOSET® T" injectors (see the Annex).

14. Concerning the question as to whether the product is in fact traded in packings put up for retail sale (see paragraphs 8 to 11 above), the Secretariat has obtained a technical monograph presented by the manufacturer with respect to the pellets. According to this literature, "OSTEOSET® T" is presented in the form of uniformly shaped cylindrical pellets (4.8 mm in diameter), put up for sale in 5cc, 10cc and 20cc sterile bottles.

Classification

15. As mentioned in paragraph 8 above, the majority of the Scientific Sub-Committee took the view that the product should be classified in heading 30.03 or 30.04 rather than heading 30.06. The Secretariat also shares this view.

16. Furthermore, on the basis of paragraph 14 above, it is clear that "OSTEOSET® T" pellets would be regarded as a product put up in measured doses and traded in packings put up for retail sale. Therefore, classification in heading 30.03 should be ruled out and that product should be classified in heading 30.04.

17. As for the classification at subheading level, although there is no detailed information about the composition of the product, it appears that since it contains antibiotics (4% of tobramycin sulfate; see paragraph 12 above), it should be classified in subheading 3004.20.

IV. CONCLUSION

18. The Committee is invited to examine the classification of a medicated bone graft substitute called "OSTEOSET® T", taking into account the discussions at the 17th Session of the Scientific Sub-Committee and the Secretariat comments above.

A bone graft substitute made from medical grade calcium sulfate containing 4 % tobramycin sulfate. This product is in the form of uniformly shaped cylindrical pellets (4.8 mm in diameter), put up for sale in 5cc, 10cc and 20cc sterile bottles.

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