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HARMONIZED SYSTEM COMMITTEE
-
28th Session
-

NC0507E1

O. Eng.

Brussels, 5 November 2001.

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

(Item 1 on the Additional List)

I. BACKGROUND

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

2. In its reply, the Secretariat asked this administration to submit detailed information concerning the composition of the product and the presentation form, preferably with a sample, to enable the Secretariat to prepare a working document.

3. 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.

II. NOTE FROM THE JORDANIAN ADMINISTRATION

4. "We are undecided on the classification of the product at issue. However, we are considering two HS headings :

(1) Heading 30.04, because of the therapeutic use of these pellets and in accordance with example (a) of Section (D) of the Explanatory Notes on page 241 (Exclusion from Chapter 28).

(2) Heading 30.06, as bone reconstruction cements because these pellets help in bone formation (and given that there is no further explanation of bone reconstruction cements in the Explanatory Notes)."

File No. 2887

Product description (excerpts from the catalogue)

5. OSTEOSET® pellets offer a framework into which a patient's bone can grow. The pellets are resorbed at a rate consistent with the new bone growth (an average of 4-8 weeks).

6. OSTEOSET® pellets were cleared by the Food and Drug Administration in June 1996 and received CE mark later the same year. Since those clearances, OSTEOSET® has been used in thousands of cases and proven to be safe, predictable, and effective.

7. OSTEOSET® T pellets are made of medical grade calcium sulfate containing 4 % tobramycin sulfate.

8. OSTEOSET® T is a bone graft substitute made from medical grade calcium sulfate with the incorporation of tobramycin. *In vitro* and *in vivo* elution tests have shown sustained release of therapeutic levels of tobramycin locally with low to undetectable systemic levels. The results of the pre-clinical canine studies and clinical case presentations reported here demonstrate excellent bone healing response and biocompatibility of OSTEOSET® T pellets. Thus, OSTEOSET® T pellets have been shown to be effective in treating bone voids and provide therapeutic local levels of tobramycin for extended periods.

III. SECRETARIAT COMMENTS

9. Due to the late arrival of the request, the Secretariat has reproduced only the relevant parts of the comments of the Jordanian Administration and excerpts from the catalogue describing the product in question without making any comments of its own. A copy of the catalogue will be available for examination by delegates during the meeting.

IV. CONCLUSION

10. The Committee is invited to examine the question raised by the Administration of Jordan, taking into account the limited information provided.

11. In view of the late publication of this document and the nature of the question, the Committee may wish to ask the Scientific Sub-Committee for its views on the nature of the OSTEOSET® product.