Council Regulation (EC) No 713/2005 of 10 May 2005 imposing a definitive countervailing duty on imports of certain broad spectrum antibiotics originating in India

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2026/97 of 6 October 1997 on protection against subsidised imports from countries not members of the European Community[(1)] (the basic Regulation), and in particular Articles 18 and 19 thereof,

Having regard to the proposal submitted by the Commission after consulting the Advisory Committee,

Whereas:

A. PROCEDURE

I. Previous investigation and existing measures

(1) The Council, by Regulation (EC) No 2164/98[(2)], imposed a definitive countervailing duty on imports of certain broad spectrum antibiotics, namely amoxicillin trihydrate, ampicillin trihydrate and cefalexin not put up in measured doses or in forms or packings for retail sale (the product concerned) falling within CN codes ex 2941 10 10, ex 2941 10 20 and ex 2941 90 00 originating in India. The measures took the form of an ad valorem duty ranging between 0 and 12 % imposed on imports from individually named exporters with a residual duty rate of 14,6 % imposed on imports from other exporters.

II. Request for a combined expiry and interim review

(2) Following the publication of a notice of impending expiry[(3)] of the definitive measures in force, the Commission received a request for the initiation of a combined expiry and interim review of Regulation (EC) No 2164/98 pursuant to Articles 18(2) and 19(2) of the basic Regulation, from related Community producers of the like product, Sandoz GmbH, Austria, and Sandoz Industrial Products SA, Spain, (the applicants). The applicants represent a major proportion, in this case over 40 %, of the total Community production of certain broad spectrum antibiotics.

(3) The request was based on the grounds that the expiry of the measures would be likely to result in the continuation or recurrence of subsidisation and injury to

Changes to legislation: *There are currently no known outstanding effects for the Council Regulation (EC) No 713/2005. (See end of Document for details)*

the Community industry and that the level of the measures in force was allegedly inappropriate to counteract the subsidisation which was causing the injury.

(4) Prior to the initiation of the combined expiry and interim review, and in accordance with Articles 22(1) and 10(9) of the basic Regulation, the Commission notified the Government of India (the GOI) that it had received a properly documented review request. The GOI was invited for consultations with the aim of clarifying the situation as regards the contents of the request and arriving at a mutually agreed solution. The GOI declined the Commission's invitation to have consultations.

III. Initiation of a combined expiry and interim review

(5) The Commission examined the evidence submitted by the applicants and considered it sufficient to justify the initiation of a review in accordance with the provisions of Articles 18(2) and 19(2) of the basic Regulation. After consultation of the Advisory Committee, the Commission initiated, by a notice published in the *Official Journal of the European Union*[(4)], a combined expiry and interim review of Council Regulation (EC) No 2164/98.

IV. Investigation period

(6) The investigation covered the period from 1 April 2002 to 31 March 2003 (the review investigation period or IP). The examination of trends in the context of injury covered the period from 1 January 1999 up to the end of the review investigation period (the period considered).

V. Parties concerned by the investigation

(7) The Commission officially informed the applicants, other known Community producers, exporting producers, importers, upstream suppliers, users and the GOI of the initiation of the investigation. Interested parties had the opportunity to make their views known in writing and to request a hearing. The written and oral comments submitted by the parties were considered and, where appropriate, taken into account.

(8) In view of the apparently large number of exporting producers of the product concerned in India which were named in the request, the use of sampling techniques for the investigation of subsidisation was envisaged in accordance with Article 27 of the basic Regulation.

(9) However, only a limited number of exporting producers made themselves known and provided the information requested for sampling. Therefore, the use of sampling techniques was not considered necessary.

(10) The Commission sent questionnaires to all parties known to be concerned who made themselves known within the deadlines set in the notice of initiation. Replies were received from five Community producers, seven exporting producers, one importer, two up-stream suppliers and the GOI.

(11) The Commission sought and verified all information it deemed necessary for the determination of subsidisation and injury as well as to determine whether there

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is a likelihood of continuation or recurrence of subsidisation and injury and whether maintaining or amending the measures would not be against the Community interest. Verification visits were carried out at the premises of the following interested parties:

1. Community producers

   DSM Anti-Infectives BV, Delft (The Netherlands), which also replied to the Commission's questionnaire on behalf of DSM Anti-Infectives Deretil SA, Almeria, (Spain) and DSM Anti-Infectives Chemferm SA, Santa Perpetua de Mogoda, (Spain). These three companies are hereafter jointly referred to as 'DSM'.

   Sandoz GmbH (formerly Biochemie GmbH), Kundl (Austria), which also replied to the Commission's questionnaire on behalf of Sandoz Industrial Products SA (formerly Biochemie SA), Barcelona (Spain). Both companies are hereafter jointly referred to as 'Sandoz'.

2. Government of India

   Ministry of Commerce, New Delhi.

3. Exporting producers in India

   KDL Biotech Ltd (formerly Kopran Ltd), Mumbai,

   Orchid Pharmaceuticals and Chemicals Ltd, Chennai,

   Nectar Lifesciences Ltd, Chandigarh,

   Nestor Pharmaceuticals Ltd, New Delhi,

   Ranbaxy Laboratories Ltd, New Delhi,

   Torrent Gujarat Biotech Ltd, Ahmedabad,

   Surya Pharmaceutical Ltd, Chandigarh.

VI. Disclosure and comments on procedure

(12) The GOI and the other interested parties were informed of the essential facts and considerations upon which it was intended to propose the continuation of measures. They were also given a reasonable time to comment. Certain parties presented their comments in writing. In addition, the GOI and three exporting producers presented their positions in post-disclosure hearings followed up by post-hearing submissions summarizing their positions. All submissions and comments were taken duly into consideration as set out below.

(13) The GOI and one exporting producer pointed out during a post-disclosure hearing that the applicants did not produce one type of the like product, i.e. cefalexin, and claim that therefore in respect of this type the initiation of the investigation should be made void.

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(14) In response to this submission, it should be recalled that already in the original investigation it was established that all types of the product under investigation (see below under Section B) constitute one single category of product[(5)]. All types belong to the same category, i.e. bulk semisynthetic broad spectrum antibiotics, and have the same use, that of being incorporated into finished dosage forms which are effective in treating a variety of infectious diseases. Thus, since all types form one product for the purpose of this proceeding, which is produced by the applicants, this argument has to be refuted.

(15) The GOI and one exporting producer contended that the non-confidential questionnaire replies of the Community producers were not sufficiently detailed and not filed in accordance with Article 29 of the basic Regulation. It was alleged, that a lack of information in the non-confidential questionnaire replies denied cooperating exporters an effective opportunity to defend their interests in relation to the injury and causal link analysis.

(16) In this context, it should be noted that, as set out in section E, the Community industry in the present investigation consists of only two parties, i.e. Sandoz and DSM. In addition, one party produced only amoxicillin trihydrate and ampicillin trihydrate, whereas the other produced cefalexin as well. These particular circumstances with regard to the Community industry increased the confidential nature of certain data provided during the investigation. In any event, the file available for inspection by interested parties contains the non-confidential replies to the questionnaire of both cooperating Community producers, where confidential data have been provided in index form in order to permit a reasonable understanding of the substance of the information submitted in confidence. Therefore, the non-confidential questionnaire replies of the Community producers are still considered in line with the provisions of Article 29 of the basic Regulation. In addition, it is pertinent to note, that the indexed injury data as disclosed and set out in section F of this Regulation provided all interested parties with a sufficiently precise picture on the injury and causality situation, so as to be able to assess the analysis and defend their interests.

B. PRODUCT CONCERNED AND LIKE PRODUCT

I. Product concerned

(17) The product covered by this review is the same product as the one concerned by Council Regulation (EC) No 2164/98, namely amoxicillin trihydrate, ampicillin trihydrate and cefalexin not put up in measured doses or in forms or packings for retail sale falling within CN codes ex 2941 10 10, ex 2941 10 20 and ex 2941 90 00 originating in India (the product concerned).

II. Like product

(18) During the post-disclosure hearing the GOI and one exporting producer have drawn attention to the fact that one Community producer mentioned certain differences in ‘stability, purity, assay, galenical properties etc.’ when comparing the

product concerned and the like product. In addition, the only cooperating importer mentioned differences with regard to water solubility.

(19) However, both the product concerned and the like product have to correspond to the same international pharmacopoeias with certain specifications. Thus, though not alike in all respects, they closely resemble each other as required by Article 1(5) of the basic Regulation.

(20) Consequently, the investigation confirmed that the amoxicillin trihydrate, ampicillin trihydrate and cefalexin produced and sold in the Community by the Community producers had identical or closely resembling physical characteristics and uses to the product concerned and were thus a like product within the meaning of Article 1(5) of the basic Regulation.

C. SUBSIDIES

I. Introduction

(21) On the basis of the information contained in the review request and the replies to the Commission's questionnaire, the following schemes, which allegedly involve the granting of subsidies, were investigated:

1. Nationwide schemes

(a) Advance licence scheme,

(b) Duty entitlement passbook scheme,

(c) Special economic zones/Export oriented units scheme,

(d) Export promotion capital goods scheme,

(e) Income tax schemes,

— Export income tax exemption scheme,

— Income tax incentive for research and development,

(f) Export credit scheme.

(22) The schemes (a) to (d) specified above are based on the Foreign Trade (Development and Regulation) Act 1992 (No 22 of 1992) which entered into force on 7 August 1992 (Foreign Trade Act). The Foreign Trade Act authorises the GOI to issue notifications regarding the export and import policy. These are summarised in 'Export and Import Policy' documents, which are issued by the Ministry of Commerce every five years and updated regularly. One Export and Import Policy document is relevant to the review investigation period of this case; i.e. the five-year plan relating to the period 1 April 2002 to 31 March 2007 (EXIM-policy 02-07). In addition, the GOI also sets out the procedures governing the EXIM-policy 02-07 in a 'Handbook of Procedures – 1 April 2002 to 31 March 2007, Volume I' (HOP I 02-07)[6]. The Handbook of Procedures is also updated on a regular basis.