

**Notice of initiation of an examination procedure concerning obstacles to trade within the meaning of Council Regulation (EC) No 3286/94, consisting of measures imposed by the Republic of Korea affecting trade in pharmaceutical products**

(1999/C 218/03)

On 16 June 1999, the Commission received a complaint under Article 4 of Council Regulation (EC) No 3286/94<sup>(1)</sup> (hereinafter 'the Regulation').

### 1. Complainant

The complaint was lodged by EFPIA (European Federation of Pharmaceutical Industries and Associations) on behalf of Community member firms exporting or wishing to export to the Republic of Korea the products covered by the complaint. EFPIA is a non-profit making association whose functions are to promote the pharmaceutical industry and to act for it in pursuit of its scientific, technical, economic and legal objectives.

### 2. Products

The products concerned are pharmaceutical products covered by OECD Standard International Trade classification (SITC) heading 54 (medicinal products and specific active substances produced by the pharmaceutical industry), falling under the following Combined Nomenclature headings: 29.36, 29.37, 29.38, 29.39, 29.41, 3001 to 3006.

However, the examination which the Commission is initiating may also cover other products, particularly those which interested parties making themselves known within the time limits mentioned below (see Section 8) can show are affected by the alleged practices.

### 3. Subject

The complaint concerns obstacles to trade allegedly caused by Korean practices involving discrimination in pricing and reimbursement practices, excessive regulatory requirements and intellectual property issues. The complainant also claims a lack of transparency of the Korean system regulating trade in pharmaceuticals.

### 4. Allegations of obstacles to trade

EFPIA claims that the Korean practices referred to in Section 3 constitute obstacles to trade within the meaning of Article 2(1) of the Regulation.

<sup>(1)</sup> Council Regulation (EC) No 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organisation (WTO) (OJ L 349, 31.12.1994, p. 71). Regulation last amended by Regulation (EC) No 356/95 (OJ L 41, 23.2.1995, p. 3).

#### (a) Discriminatory regime for the determination of reimbursement prices

The complaint alleges that there exists in the Republic of Korea discrimination in law and practice concerning reimbursement prices for pharmaceutical products, including unfavourable treatment of innovative products (which are in most cases non-Korean) compared to generic products (generally Korean) and privileges in the reimbursement regime reserved for Korean products.

EFPIA claims that these practices are in breach of Articles III(4) of GATT 1994. Article III(4) stipulates that products of a WTO member country imported into the territory of another member are not to be accorded less favourable treatment than that accorded to similar products of domestic origin as regards the sale, putting up for sale or distribution of those products on the market of the importing country.

In the light of the information available, the Commission considers that there is sufficient *prima facie* evidence that the Korean system for the reimbursement of pharmaceutical products discriminates against imported products and therefore is contrary to Article III(4) of GATT 1994.

#### (b) Other alleged obstacles to trade

The other alleged obstacles to trade are: excessive requirements for the registration and marketing for new product; the prohibition of contract manufacturing between a foreign producer not established in Korea and a Korean manufacturer, and, as regards intellectual property, the discrimination of foreign producers concerning patent terms.

The complainant has not at this stage presented sufficient evidence of the existence of WTO violations in respect of these other issues. However, if further information concerning these issues or others arising from the changing legal and regulatory environment in Korea is submitted, the Commission may also take it into account in connection with any decision taken in this case.

### 5. Allegation of adverse trade effects

EFPIA claims that its members are suffering adverse trade effects within the meaning of Article 2(4) of the Regulation and they are in danger of being more adversely affected in the near future.

The main evidence of adverse trade effects of the Korean discriminatory legislation and practices in the low and falling share held by the European pharmaceutical industry on the Korean market. Sales of pharmaceuticals by EU companies to the top 50 countries in 1997 show that, in all but two industrialised markets, one of which is Korea, EU products hold a market share of more than 20 %; in Korea this is just 10,8 %. This appears to indicate that the practices described above effectively impede the establishment and consolidation of Community pharmaceutical producers on the Korean market. In addition, in 1997, the Korean pharmaceuticals market was the tenth largest in the world and had been growing at a rate of 10 to 15 % annually. However, the annual rate of growth of Community exports to Korea fell from 20 % in 1994 to 8 % in 1997.

The complaint has been lodged by an association representing the entire Community industry, which would appear to imply a material impact on the economy of the Community within the meaning of Article 2(4) of the Regulation.

#### 6. Community interest

The pharmaceutical industry is a major employer in the EU: in 1996 it employed almost 500 000 people. Exports represent an important component in the industry's turnover, around 19 %.

In this respect, it appears essential to safe guard the equal treatment of EU pharmaceuticals to fast growing third country markets such as Korea by removing obstacles to trade. Furthermore, it is also important as a matter of principle to ensure that EU's trade partners fully comply with their obligations under the WTO Agreements.

In view of the above, it is considered to be in the Community's interest to initiate a TBR examination procedure.

#### 7. Procedure

Having decided, after consultation of the Advisory Committee established by the Regulation, that there is sufficient evidence to justify initiating an examination procedure for the purpose of considering the legal and factual issues involved, and that this is in the interest of the Community, the Commission has commenced an examination in accordance with Article 8 of the Regulation.

Interested parties may make themselves known and make known their views in writing on specific issues raised by the complaint, providing supporting evidence.

Furthermore, the Commission will hear the parties who so request in writing when they make themselves known, provided that they are fundamentally concerned by the result of the procedure.

This notice is published in accordance with Article 8(1)(a) of the Regulation.

#### 8. Time Limit

Any information relating to the matter and any request for a hearing should reach the Commission not later than 30 days following the date of publication of this notice and should be sent to:

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Directorate-General I — External Relations: Commercial Policy  
and Relations with North America, the Far East, Australia and  
New Zealand,  
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