COMMISSION DECISION

of 25 October 2000

suspending the examination procedure concerning obstacles to trade in pharmaceutical products on the market of the Republic of Korea

(notified under document number C(2000) 3098)

(2000/679/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], as amended by Regulation (EC) No 356/95 [2], and in particular Article 11(2)(a) thereof,

After consulting the Advisory Committee,

Whereas:

A. PROCEDURAL BACKGROUND

(1) On 15 June 1999 (EFPIA (European Federation of Pharmaceutical Industries and Associations) lodged a complaint under Article 4 of Council Regulation (EC) No 3286/94 (hereinafter the Regulation) on behalf of those of its members which have an interest to market their products in Korea.

(2) The complainant alleged that Community sales of pharmaceutical products in Korea are hindered by a number of obstacles to trade within the meaning of Article 2(1) of the Regulation, i.e. 'a practice adopted or maintained by a third country and in respect of which international trade rules establish a right of action'. The alleged obstacles to trade were:

— discrimination in pricing and reimbursement practices,

— excessive regulatory requirements,

— intellectual property issues.

The complainant also claimed a general lack of transparency of the Korean regulatory system.

(3) At the time the complaint was logded the Korean regulatory system governing pharmaceuticals was undergoing a period of change. This made it difficult to assess whether there was sufficient evidence in the complaint of the existence of WTO violations in respect of some of the issues. However, the Commission decided that the complaint contained sufficient evidence to justify the initiation of an examination procedure on the grounds of discrimination in pricing and reimbursement practices. In order to make a proper assessment of the new legal and regulatory environment the Commission decided that it would also take into account any information discovered during the investigation that related to other issues raised in the complaint. A corresponding notice was published in the *Official Journal of the European Communities* [3].

B. REACTION OF THE KOREAN GOVERNMENT TO THE INITIATION OF THE EXAMINATION PROCEDURE

(4) Following the initiation of the investigation a note verbale was sent to the Korean authorities requesting that they respond to a questionnaire on the alleged barriers to trade in pharmaceutical products. The Korean Governement replied by note verbale informing the Commission of the changes and planned changes to the Korean legislation governing the pharmaceuticals sectors. The changes concerned all the issued contained in EFPIA's complaint.

C. THE FINDINGS OF THE INVESTIGATION

Pricing and reimbursement issues

(5) The complaint alleged discrimination against foreign products regarding both the method for determining reimbursement prices and the system for reimbursement. The rules introduced during the investigation appear to have eliminated the discriminatory elements previously existing. Imported products were admitted for the first time on the list of reimbursable pharmaceuticals (i.e. those pharmaceutical products that are eligible for reimbursement by the State health care system) on 1 July 1999. Imported products are now reimbursed according to the same rules as domestic products and the unfavourable treatment of innovative products should have been removed by the new rules for price calculation agreed upon by the task force for pricing.

[1] OJ L 349, 31.12.1994, p. 71.
[2] OJ L 41, 23.2.1995, p. 3.
[3] OJ C 218, 30.7.1999.

(6) Furthermore, on 15 November 1999 the Korean authorities introduced the actual transaction price (ATP) system of reimbursement for pharmaceutical products. This is intended to eliminate the discounts previously demanded by the purchaser of pharmaceuticals, which represented a problem for international industry as it was claimed that domestic producers had an advantage as their products were reimbursed at a price level that allowed them to offer substantial discounts. The system includes the introduction of a complex electronic data exchange system.

(7) However, both on the issue of reimbursement at actual transaction price and on the pricing of innovative products the new rules have entered into force very recently and have not yet been fully implemented.

Regulatory requirements

(8) New rules on clinical trials for newly marketed products entered into force on 1 January 2000. The new regulation governing marketing of new pharmaceuticals has abolished the obligation to carry out clinical trials in Korea but maintains the requirement for the applicant to submit a so-called bridging study with data obtained on Koreans. However, the legislation lacks detail as to the circumstances in which a bridging study will be considered sufficient and this leaves the industry with some concerns that they may be required to carry out clinical trials in Korea on all new products. As regards the other regulatory issue, that is, the possibiltiy for foreign producers to subcontract production to a local manufacturer without transferring the product licence, the rules introduced on 1 January 2000 only allow it between companies with manufacturing licences in Korea. However, no violation of WTO rules has been found on this issue.

Intellectual property issues

(9) On data protection, although it appears that the system still does not guarantee full protection to data submitted to obtain marketing authorisation, no case of unfair use of confidential data was reported in the context of the investigation.

As for the issue of patent term restoration the change in the rules concerning clinical trials has been taken into account in the latest amendment to the Regulation on patent term extension. That text says that, for medicines developed abroad and exempt from clinical trials in Korea, the extension period includes both the period spent in clinical trials abroad and the time taken by KFDA to examine the file and give approval to the new medicine. That now removes the scope for discrimination of foreign products.

Transparency

(10) It is true that it is not easy, even for the industry on the spot, to understand which is the latest regulation governing a certain matter due to the continuous developments in the system and to the difficulties of translation of this very technical matter. However, the legislation governing the system has been published and generally made available.

D. **RECOMMENDATIONS**

(11) The Commission considers that the system ruling pharmaceutical products in Korea has undergone substantial change since the lodging of the complaint under the Regulation and that these changes have improved the possibility for the Community industry to enter the Korean market. However, most of the new legislation introduced has not yet been implemented and there are indications that implementation may be delayed or that the legislation may be interpreted in a trade restrictive way. These concerns are confirmed by the latest developments.

(12) The industry's main concerns lay with the implementation of the ATP reimbursement system. During the investigation the Korean authorities informed the Commission services that the full implementation of the ATP system would be completed by 1 May 2000. However, subsequently the Korean authorities have stated that this will not take place until May 2001 as the electronic exchange of data, essential for the operation of the system, foreseen for the reporting of the transaction prices will not be fully in place until that date. This will become an even greater concern after 1 July 2000 if the planned introduction of separation of prescribing and dispensing of pharmaceutical products takes place. There are approximately 20 000 pharmacies that would then be required to report on the prices of pharmaceuticals and the delay in introduction of the electronic reporting system makes it likely that no accurate assessment of prices can take place.

(13) The Commission considers therefore that it would be appropriate to monitor the effect of the changes in the Korean legislation for a period of not less than six months from the date of entry into force of this Decision given that some of the changes have not been fully introduced and others have not yet been introduced. Such monitoring would give an indication whether the changes have in fact improved the situation with regard to the barriers to trade in pharmaceutical products in Korea alleged in the complaint.

(14) The examination procedure concerning the Korean regime governing the pharmaceuticals sector should therefore be suspended and the Commission should supervise the situation in accordance with Article 11(2)(b) of the Regulation.

(15) A report on the enforcement of the new regulations will be issued after six months from the date of the suspension. Any further action which might appear necessary will be proposed on the basis of that report.

HAS DECIDED:

Sole Article

The examination procedure concerning obstacles to trade in pharmaceutical products on the market of the Republic of Korea is hereby suspended.

Done at Brussels, 25 October 2000.

For the Commission

Pascal LAMY

Member of the Commission