COMMISSION COMMUNICATION

Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted

(OJ No C 115 of 6. 5. 1982, p. 5)

In order progressively to establish the free movement of proprietary medicinal products, the Council has adopted four Directives ([1]) essentially relating to the conditions in which the Member States deliver marketing authorizations for these products.

Furthermore, in the 'De Peijper' case ([2]), the Court of Justice of the European Communities, to which the matter was referred under Article 177 of the EEC Treaty, has delivered a judgment on parallel imports of medicinal products. This judgment gives the Commission interpretative rulings enabling it to exercise more stringent checks on the application of the rules of the Treaty on free movement of goods, in particular the provision of Articles 30 to 36 of the EEC Treaty.

Following this judgment, the Commission considered it necessary to supplement the existing Directives by transmitting to the Council on 2 June 1980 a proposal for a Directive ([3]) relating to parallel imports of proprietary medicinal products.

The Commission has taken note of the objections raised by the Economic and Social Committee to the proposal relating to parallel imports and the negative vote taken on that proposal by the European Parliament on 16 October 1981.

The Commission has therefore decided to withdraw its proposal, especially as its adoption by the Council appears improbable in the present circumstances.

The Commission is not, however, abandoning its responsibility to ensure that full effect is given to the provisions of the Treaty relating to the free movement of goods.

The Parliament stressed during its discussion and in the text of its resolution its attachment to the principle of free movement. This is why the Commission wishes to indicate, on the occasion of this withdrawal, the way in which it intends to apply, under its own responsibility, the rules embodied in the Treaty as interpreted by the Court of Justice, in order to preserve the unity of the Community's internal market.

In case 104/75, the Court had to give a ruling on a set of health regulations relating to the marketing of medicinal products that prevented the marketing of a medicinal product introduced as a parallel import.

([1]) Directive 65/65/EEC of 26 January 1965 (OJ No 22 of 9. 2. 1965); Directive 75/318/EEC of 20 May 1975 (OJ No L 147 of 9. 6. 1975); Directive 75/319/EEC of 20 May 1975 (OJ No L 147 of 9. 6. 1975); Directive 78/25/EEC of 12 December 1977,(OJ No L 11 of 14. 1. 1978.

([2]) CJEC 20 May 1976, Case 104/75, 1976 Report, p. 613.

([3]) Proposal dated 2 June 1980 for a Directive amending Directives 65/65/EEC and 75/319/EEC (OJ No C 143 of 12. 6. 1980).

The Court first of all established that national rules or practices which result in imports being channelled in such a way that only certain traders can effect these imports, whereas others are prevented from doing so, are caught by the prohibition set out in Article 30 of the EEC Treaty.

The Court went on to reaffirm the Member States' right, in pursuance of Article 36 of the EEC Treaty, to decide, subject to the limitations imposed by the Treaty, on the level of protection they wish to afford for the health and life of persons, in particular the stringency of the checks to be carried out.

It nevertheless immediately stressed the general context in which this competence of the Member States was to be exercised:

National rules or practices which do restrict imports of pharmaceutical products or are capable of doing so are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans.

National rules or practices do not fall within the exception specified in Article 36 if the health and life of humans can be as effectively protected by measures which do not restrict intra-Community trade so much.

In particular Article 36 cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required.

In the case in point the competent national authorities intended to prevent a parallel importer from marketing a medicinal product that was similar to a medicinal product which had already been authorized and was produced by the same manufacturer for two reasons.

First, the parallel manufacturer was not able to provide the authorities with the complete file (1) relating to the quality, efficacy and safety of the product in general, which the manufacturer's authorized importer had already supplied to those same authorities with a view to obtaining a marketing authorization for that medicinal product.

Secondly, the parallel importer could not, unlike the authorized importer, obtain from the manufacturer the reports on checks made on each manufacturing batch.

In the judgment on the 'De Peijper' case, the Court ruled that 'national rules or practices which make it possible for a manufacturer of the pharmaceutical product in question and his duly appointed representative, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner …'

(1) This file comprises *inter alia* a description of the manufacturer's production and control methods and the results of the analytical, toxico-pharmacological and clinical tests conducted on the medicinal product in general.

'It is only if the information or documents to be produced by the manufacturer or his duly appointed importer show that there are several variants of the medicinal preparation and that the differences between these variants have a therapeutic effect that there would be any justification for treating the variants as different medicinal preparations, for the purpose of authorizing them to be placed on the market and as regards producing the relevant documents …'

The Commission, in its role as guardian of the Treaty, will ensure that the rules and practices applied by Member States to parallel imports of medicinal products, and in particular proprietary medicinal products which account for the majority of intra-Community trading operations in medicinal products, will remain within limits compatible with Articles 30 to 36.

In particular, such measures must:

— be strictly necessary from the health standpoint,

— obstruct intra-Community trade as little as possible,

— require Member States to adopt an active and vigilant attitude towards pharmaceutical companies.

The Commission points out that the competent authorities in the Member States are not entitled to oppose the marketing of any medicinal product, the subject of parallel importation, that already has a marketing authorization, on the grounds that the parallel importer is not able to obtain documents which only the manufacturer or his approved representative can have at their disposal.

In the absence of any harmonized rules governing the system of parallel imports, it is up to the Commission, in accordance with the procedure under Article 169, and to the interested parties, in accordance with the means of redress which they have at their disposal, to ensure that parallel imports of medicinal products are made possible under the conditions laid down by the rulings of the Court.

After consulting senior experts in public health matters from the Member States' administrations meeting in the Pharmaceutical Committee ([1]), the Commission had proposed a uniform system for parallel imports of proprietary medicinal products. Despite the withdrawal of its proposal, the Commission considers it useful to indicate safe ways of monitoring parallel imports which, subject to the rulings of the Court, seem to it to be justified for the purpose of protecting the health and life of humans pursuant to Article 36 of the Treaty.

The Commission points out that the competent authorities of the Member States already have at their disposal two important safeguards for health in the case of parallel imports of proprietary medicinal products.

On the one hand, the national rules governing the activities of importers, wholesalers and, where applicable, manufacturers of proprietary medicinal products apply equally to parallel importers. These rules usually cover professional competence and responsibilities, the technical premises and equipment required and the rules for the operation of such establishments, in particular the procedures relating to the preservation of documents to facilitate official checks and inspections.

([1]) Set up by Council Decision 75/320/EEC of 20 May 1975, OJ No L 147 of 9. 6. 1975.

On the other hand, the authorities competent to issue marketing authorizations for proprietary medicinal products already, as a rule, possess the dossier relating to the quality, efficacy and safety of the medicinal products in general, which has been supplied by the manufacturer or his approved importer and which states, in pursuance of Article 4 (11) of Directive 65/65/EEC, the authorizations already obtained for the product in any other Member State. According to the Court, the competent administration of the importing Member State is clearly entitled to require the manufacturer, or his duly appointed importer, to state whether the manufacturer, or the group of manufacturers to which he belongs, produces several variants of the same medicinal product for different Member States. If this is so, it is only if the documents submitted by the manufacturer show that there are differences having a therapeutic effect that there would be any justification for treating the variants as different medicinal products for the purpose of marketing authorization.

In addition to these safeguards, the authorities have a legitimate interest in being able to verify, at all times and beyond doubt, whether the batches of imported medicinal products are in conformity with the particulars contained in the dossier.

The Commission concedes that the parallel importer may be required to supply the competent authorities in the Member State into which the product is imported with certain information readily accessible to him when he wants to market for the first time a proprietary medicinal product already marketed by the manufacturer or his duly appointed representative.

This information must allow the competent authorities in the Member State into which the product is imported to check, within a reasonable period, that the proprietary medicinal product that is the subject of parallel importation is effectively covered by the marketing authorization already granted to the manufacturer or his duly appointed representative. In the Commission's view, this period should not exceed 45 days from the time the parallel importer gives the following information to the competent authorities:

a) name of the proprietary medicinal product in the Member State into which it is imported and in the Member State from which it comes;

b) name or corporate name and permanent address of the person responsible for placing the product on the market in the Member State into which it is imported and in the Member State from which it comes, and where appropriate, of the manufacturer(s);

c) name or corporate name and permanent address of the parallel importer;

d) numbers of the marketing authorizations in the Member State into which the product is imported and in the Member State from which it comes;

e) any other general information useful for the marketing of the proprietary medicinal product in the Member State into which it is imported, i.e.

   — qualitative and quantitative composition in terms of active principles, by dosage unit or in percentage, using the international non-proprietary names recommended by the World Health Organization where such names exist,

   — pharmaceutical form and route of administration,

   — therapeutic indications and normal dosage,

   — contra-indications and main side-effects,

   — storage precautions, if any;

f) one or more specimens or mock-ups of the proprietary product in the form in which it will be marketed in the Member State into which it is imported, including the package leaflet, if any.

To enable the authorities to be effectively informed of the marketing of each batch of the product imported, the parallel importer should, in the Commission's view, register the origin, quantity and batch numbers of the imported medicinal products whenever he imports them, and hold this information at the disposal of the competent authorities.

The Commission points out that pursuant to Chapter IV of Directive 75/319/EEC each batch of proprietary medicinal products manufactured in a Member State is checked by the manufacturer who makes out a certificate and registers the operations carried out in documents that remain at the disposal of the agents of the competent authority for at least five years. Because these control reports are sent to him by the manufacturer, the duly appointed importer is exempt from repeating the controls in the Member State into which the product is imported.

Since the parallel importer does not have access to these control reports, the national authorities have to adopt a more active policy when they wish to verify the controls carried out by the manufacturer on a given batch. They can choose for this purpose one of the four approaches given in the De Peijper judgment, i.e.:

— they can obtain the manufacturing control reports by taking legislative or administrative measures compelling the manufacturer himself, or his duly appointed representative, to supply them;

— they can obtain these reports through the authorities in the country of manufacture;

— they can, whenever possible, lay down a presumption of conformity with the specifications of the medicament and it would be up to them, in appropriate cases, to rebut this presumption after verification of the conformity;

— as far as this presumption is fully impracticable, they can allow the parallel importer to provide proof of conformity by any means other than by documents to which he has no access.

The parallel importer is liable, in the same way as the person responsible for marketing, to the measures taken by the Member States to withdraw the product, to suspend or revoke the authorization or to prohibit supply of the product, pursuant to Article 28 of Directive 75/319/EEC.

By appropriate cooperation between the Member State authorities, it would be possible to supplement, if necessary, the monitoring measures compatible with Article 36 of the Treaty, designed to check the conformity of medicinal products imported in parallel.

In the De Peijper judgment, the Court held that simple cooperation between the authorities of the Member States would enable them to obtain on a reciprocal basis the documents necessary for checking certain largely standardized and widely distributed products.

In addition to the obligations resulting from Article 5 of the EEC Treaty, the obligation for the competent authorities to communicate to each other such information as is appropriate to guarantee that the requirements for the marketing or manufacturing authorizations are fulfilled is specifically spelled out in Article 30 of Directive 75/319/EEC.

The Commission for its part is prepared to do everything it can to assist the Member States in exchanging the information they consider necessary to check the conformity of parallel imports of proprietary medicinal products.

The Commission considers that the Committee for Proprietary Medicinal Products, set up by Directive 75/319/EEC, provides a suitable forum for any exchanges of information between the representatives of the Member States responsible for marketing authorizations for proprietary medicinal products. The Commission also holds at the disposal of Member States a continuously updated list of the persons appointed by the competent authorities to supply at short notice any necessary information on marketing or manufacturing authorizations in application of Articles 30 and 33 of Directive 75/319/EEC.