COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 28 May 1980

Proposal for a

COUNCIL DIRECTIVE

amending Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

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(presented by the Commission to the Council)

EXPLANATORY MEMORANDUM

1. The national provisions relating to the import and marketing of proprietary medicinal products have been the subject of a series of Council Directives (65/65/EEC of 26 January 1965, 75/318/EEC and 75/319/EEC of 20 May 1975).

2. In a judgment of 26 May 1976 (Case 104/75 (De Peijper) [1976] ECR 613), the Court of Justice was called upon to decide on the compatibility with the Treaty, and in particular with Articles 30 et seq., of certain national practices which lead to channelling imports in such a way that only certain economic operators can undertake them, others being excluded from doing so.

   In accordance with the Court's judgment, steps must be taken to prevent the regulations and practices allowing "the manufacturer of the pharmaceutical product in question and his duly appointed representatives, 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." It must also be ensured that the health and life of persons can be protected effectively by measures which are less restrictive to intra-Community trade without it "obviously being beyond the means which can reasonably be expected of an administration operating in a normal manner".

3. It appears that the Member States have not all drawn the same conclusions from this judgment of the Court of Justice. Some have amended their laws; others, without amending them, have been tacitly in favour of removing the monopoly position in respect of the import and marketing of proprietary medicinal products of the manufacturer and his approved representatives.

   Under these conditions, even if, as the Court has pointed out, the Member States cannot invoke directives in order to avoid the obligations laid down in the Treaty, it seems advisable to supplement the Community Directives in order to remove the barriers.

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4. To attain these ends, the provisions of Directive 65/65/EEC must be supplemented by a system of registration of parallel importers: the parallel importers are registered as the persons responsible for marketing when the product imported and the product authorized are identical (first subparagraph of Article 1(4)). Thus, one can draw a clear distinction between the product which receives a marketing authorization and the persons responsible for its marketing, who are registered.

   The applicant for registration supplies the information he has readily available (second subparagraph of Article 1(4)).

   The competent authority will be able to examine without delay the conformity of the product imported in parallel with the authorized product: it will be obligatory for the applicant for the marketing authorization to show in his file any changes made to the product in the various Member States and to supply the particulars and documents concerning such changes and to keep his file up to date (Article 1(1)).

5. In order to avoid purely formal changes in products, which would make the supervision of the market that devolves on the competent authorities in accordance with the provisions of Chapter V of Directive 75/319/EEC more difficult, new cases for refusal of authorization to market are proposed in Article 1(2) and (3): changes in composition must be justified therapeutically, changes of name must be for legitimate reasons and must not cause any risk of confusion or lead to mistakes as to the qualities or properties of the product.

6. After the person responsible for marketing has been registered, the authorities must still be able to check at any time and ascertain whether the imported medicine is in conformity with the particulars shown in the file. In the case of products imported by the manufacturer or the approved importer, this conformity is proved by the control reports signed by the qualified person, which accompany the product. In the case of products imported in parallel, other methods of proof are provided for in Article 1(2) at the discretion of the person responsible for marketing.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Article 4 of Council Directive 65/65/EEC[1] as amended by Directive 75/319/EEC[2] provides that in order to obtain marketing authorization the person responsible for marketing shall make an application to the competent authority of the Member State concerned; whereas Article 22 of Directive 75/319/EEC as amended by Directive 78/420/EEC[3] makes exemption from controls subject to the presentation of control reports signed by the qualified person;

Whereas it is advisable to prevent the manufacturer from being able to monopolize the importation and marketing of proprietary medicinal products by merely refusing to produce the documents relating to the proprietary product in general or to a specific batch of that proprietary product;

Whereas it is consequently necessary to supplement the provisions of Directive 65/65/EEC to allow the registration of parallel importers as persons responsible for marketing, which is necessary for the proper supervision of the market by the competent authorities; whereas, in order to avoid purely formal changes in proprietary medicinal products, it is also advisable to provide for new cases of refusal of marketing authorization;

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[1] OJ N° 22, 9 February 1965, p.369/65
[2] OJ N° L 147, 9 June 1975, p.13
[3] OJ N° L 123, 11 May 1978, p.26

Whereas it is necessary to amend the provisions of Directive 75/319/EEC to facilitate proof of the conformity of the imported proprietary product with the particulars shown in the file,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 65/65/EEC shall be amended as follows:

1. Point 11 of the second paragraph of Article 4 shall be replaced by the following:

   "11. An authorization obtained in another Member State or in a non-member country to place the relevant proprietary medicinal product on the market, provided that such authorization exists, with specification of the changes made to this proprietary product in the various Member States and the particulars and documents concerning such changes."

2. The following two paragraphs shall be added to Article 4:

   "The holder of the marketing authorization shall forthwith communicate to the competent authorities any new factor which involves a change in the particulars and documents listed in the second paragraph on any additional instruction, and in particular any prohibition or restriction laid down by the competent authorities of the States where the medicine is marketed.

   The holder of the marketing authorization shall forthwith communicate to the competent authorities any amendment which he proposes to make to the particulars and documents listed in the second paragraph."

3. The first paragraph of Article 5 shall be replaced by the following:

   "The authorization provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the proprietary medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative or quantitative composition is not as declared, or that the qualitative or quantitative composition of the proprietary product has been changed, without therapeutic justification, compared with that authorized in another Member State."

4. The following third paragraph shall be added to Article 5:

"Lastly, marketing authorization shall be refused if the name of the proprietary product risks causing confusion with a proprietary product which has already been registered and which has a different qualitative composition as far as the active principles are concerned, or if the name of the proprietary product is liable to induce misunderstandings as to its qualities on properties, or if the name requested is different from that used in the other Member States for the same proprietary product, unless legitimate reasons justify the use of such different name."

5. The following Articles 10a and 10b shall be inserted after Article 10:

"Article 10a

The competent authorities shall register the other persons responsible for marketing who so request, within 45 days of such request, except where the proprietary product they wish to place on the market is not authorized in the Member State from which it comes or if it has not been manufactured by the same manufacturer or the same group of manufacturers or if, in comparison with the authorized proprietary product, it presents differences which affect its therapeutic effect or harmfulness.

The following particulars shall be appended to this request:

1. Name or business name and address of the person responsible for placing the product on the market,
2. Member State from which the proprietary product to be imported comes,
3. Name of the proprietary product in the Member State from which it comes and number of the marketing authorization,
4. Name of the proprietary product in the Member State to which the application for registration is addressed and number of the marketing authorization,
5. Pharmaceutical form.

.../...

Article 10 b

The competent authorities shall cancel the registration provided for in Article 10 a where it appears that the proprietary medicinal product in question no longer satisfies the conditions referred to in that Article."

6. The first sentnece of the first paragraph of Article 12 shall be replaced by the following:

"All decisions taken pursuant to Articles 5, 6, 10a, 10b and 11 shall state in detail the reasons on which they are based."

Article 2

The following Article 22a shall be inserted after Article 22 of Directive 75/319/EEC:

"Article 22 a

1. Where the person responsible for marketing pursuant to Article 10a does not have the control reports referred to in the second sub-paragraph of Article 22(1), he may require from the competent authorities:

(a) that the control reports be supplied to him;

(b) that the controls determined by the competent authorities in accordance with the provisions of this Chapter be carried out;

(c) that the controls be carried out by a laboratory designated for this purpose by the competent authorities.

2. Member States shall adopt all appropriate provisions to ensure that the manufacturer supplies them forthwith, upon request, with the control reports referred to in paragraph 1 for any batch or part of a batch of proprietary products.

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3. Upon request, the competent authorities concerned shall forthwith communicate to each other the control reports referred to in paragraph 1."

Article 3

Member States shall bring into force the provisions necessary in order to comply with this Directive within six months of its notification and shall forthwith inform the Commission thereof.

Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive is addressed to the Member States.