Draft Council directive on the harmonization of laws and regulations governing pharmaceutical products

(Proposal submitted by the Commission to the Council on 5 November 1962)

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SECRETARIAT OF THE COMMISSION OF

THE EUROPEAN ECONOMIC COMMUNITY

Draft Council directive on the harmonization of laws and regulations governing pharmaceutical products

(Proposal submitted by the Commission to the Council on 5 November 1962)

The Council of the European Economic Community,

Having regard to the provisions of the Treaty and in particular Article 100 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

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

Whereas the main purpose of legislation on the production and distribution of branded pharmaceutical must be to safeguard public health;

Whereas, however, this object must be attained by means that do not hinder the development of the pharmaceutical industry and trade in its products within the Community;

Whereas certain national arrangements constitute obstacles to trade in pharmaceutical products within the Community and therefore directly affect the establishment and functioning of the Common Market;

Whereas these obstacles must be overcome by harmonization of legislation on pharmaceutical matters in general;

Whereas, however, such harmonization of legislation can only be brought about gradually, priority being given to those

disparities which may most affect the functioning of the Common Market,

Has adopted the present directive :

CHAPTER I

Definitions and field of application

Article 1

For the purposes of the present directive, the following definitions shall apply :

1. Branded pharmaceuticals

Any medical preparation sold under a special name and put up in a special way.

2. Medical preparation

Any substance or mixture which is claimed to cure or prevent disease in human beings (or animals).

The term includes any substance or mixture administered to human beings (or animals) for purposes of diagnosis or in order to restore, improve or influence organic functions.

For purposes of health control, medical preparations are deemed to include surgical sutures, sterile dressings and materials which, for the purposes referred to in the foregoing paragraph, are permanently or temporarily introduced into the human (or animal) organism.

3. Substance

Any matter, be it of :

human origin, such as human blood and blood derivatives;

animal origin, such as micro-organisms, whole animals, parts of organs, microbial or animal secretions, toxins, extracts, blood derivatives, etc.

vegetable origin, such as micro-organisms, plants, parts of plants, vegetable secretions, extracts, etc.

chemical origin, such as natural elements and chemicals and compounds produced by chemical processes.

Article 2

The provisions of Chapters III to V of the present directive shall apply only to branded pharmaceuticals for human use intended for sale in the Member States.

CHAPTER II

Licensing of branded pharmaceuticals

Article 3

No branded pharmaceutical may be offered for sale in the member countries except under licence issued by the competent authority in the said countries.

Article 4

The licence referred to in Article 3 shall be withheld if, on the basis of the particulars and supporting documents listed in Article 6, the branded pharmaceutical does not have the therapeutic potency claimed for it or if such potency is not adequately substantiated by the applicant, or if the nature and quantities of the ingredients are not stated. The licence shall also be withheld if the data and documents submitted in support of the application are not in conformity with the provisions of Article 6.

Article 5

The competent authorities of the Member States may refuse to license the sale of a branded pharmaceutical for use as a contraceptive if under their legislation the sale of pharmaceuticals intended essentially for such purposes is prohibited.

Article 6

The licence referred to in Article 3 shall be issued by the competent authority of the Member States on application by the manufacturer and, where appropriate, the distributor.

The application must be accompanied by the following particulars and supporting documents :

1. Name or registered trading name and address of the manufacturer, and, where appropriate, name or registered trading name and address of the distributor.

2. Trade name of the preparation (brand name, or usual description accompanied by brand name or by name of manufacturer, or scientific description accompanied by brand name or by name of manufacturer).

3. Nature and quantities of ingredients, as usually described, without empirical chemical formulae, and internationally recognized common name as recommended by the World Health Organization.

4. Short description of method of preparation.

5. Therapeutical indications, contra-indications and secondary effects.

6. Formulation, directions for use, dosage; indications as to stability.

7. Tests applied (qualitative and quantitative analysis of ingredients and finished product; special tests, e.g. for sterility, pyrogenic property, presence of heavy metals, stability; biological tests and tests for toxicity).

8. Results of physio-chemical, biological or micro-biological, pharmacological, toxicological and clinical tests.

9. One or more samples or dummies of the product as proposed to be offered for sale, together with accompanying prospectus if any.

10. For foreign products: licence issued for sale in the country of origin or another country.

11. Document attesting that the manufacturer holds a licence in his own country to produce pharmaceuticals.

Article 7

The Member States shall make arrangements for the licensing procedure to take place within the following time-limits:

1. 30 days from the date of submission for the decision as to whether, having regard to the terms of Article 6, the application can be entertained;

2. 90 days from the date of the decision provided for in paragraph 1 for the decision to grant or withhold the licence having regard to the terms of Article 4.

In exceptional cases, the time-limit prescribed in paragraph 2 may be extended for a further 90 days. The applicant shall be notified to this effect before the expiry of the initial time-limit.

Article 8

The Member States shall take steps to enable the applicant to furnish proof that the tests on the finished product described by him as required by Article 6 have been made.

Article 9

The licence granted under Article 3 shall not impair the liability under ordinary law of the manufacturer or where appropriate the distributor.

Article 10

The licence shall be valid for five years and shall be renewable for five-year periods at the request of the licensee submitted three months before the end of any such period.

CHAPTER III

Suspension or withdrawal of licence

Article 11

The competent authorities of the Member States shall suspend or withdraw the licence to sell a branded pharmaceutical if the latter appears to be harmful under normal conditions of use, if it does not have the therapeutic potency claimed for it or if the nature and quantities of its ingredients are not in conformity with the statement made in accordance with Article 6, paragraph 3.

The licence shall also be suspended or withdrawn if the particulars supplied in the supporting documents submitted pursuant to Article 6 are found to be incorrect or if the tests on the finished product stipulated in Article 8 have not been made.

Article 12

Any decision taken under Articles 4, 5 and 11 shall state the precise grounds therefor. The person concerned shall be notified thereof and at the same time be informed of the remedies open to him at law and of the time-limit within which an appeal may be lodged.

CHAPTER IV

Labelling

Article 13

The containers and outer packing of branded pharmaceuticals must bear the following particulars:

1. Name of the product, which may be either a brand name or the usual description accompanied by a brand name or by the name of the manufacturer, or a scientific description accompanied by a brand name or by the name of the manufacturer.

If the product bears a brand name and consists of a single active substance with a common international name recom-

mended by the World Health Organization, such name shall appear in bold lettering underneath the brand name.

2. Nature and quantities of the active principles and the quantity of each per unit or expressed in percentages according to the formulation.

If any of the active principles has a common international name recommended by the WHO, this name must also be used.

3. Reference number for identification (batch number).

4. Licence number.

5. Name and address of the manufacturer or, where appropriate, the distributor.

6. Method of administration.

7. Latest date for use in the case of products with a period of stability of less than three years.

8. Special storage precautions where appropriate.

The formulation and the contents must be stated on the outer packing.

Article 14

For products put up in ampoules, the particulars mentioned in the first paragraph of the foregoing article are to be given on the outer packing. On the containers, however, only the following particulars need be given :

i) name of the product;

ii) quantities of the active principles;

iii) method of administration;

iv) latest date for use.

Article 15

As regards small containers other than ampoules, holding only one dose and on which it is impossible to give the particulars referred to in Article 14, the provisions of Article 13 shall apply to the outer packing only.

Article 16

In the case of narcotics, the outer packing and the container must bear in addition to the particulars stipulated in Article 13 a special mark consisting of two parallel red lines.

Article 17

Where there is no outer packing, all the particulars which in pursuance of the foregoing articles should appear on that packing shall be given on the container.

Article 18

The particulars stipulated in paragraphs 6, 7 and 8 of Article 13 must be printed on the outer packing and on the container in the language or languages of the country in which the pharmaceutical products are offered for sale.

Article 19

Nothing in the chapter shall prevent the publication on the other packing of other particulars required by regulation and not explicitly referred to in this directive.

Article 20

If the provisions of the present chapter are not observed, and an order addressed to the person concerned has been ignored, the authorities of the Member States may suspend or withdraw the licence.

Any decision taken under the terms of the foregoing paragraph must state the grounds therefor. The person concerned shall be notified thereof and shall also be informed of remedies open to him at law and of the time-limit within which an appeal may be lodged.

CHAPTER V

Arrangements for application and transitional measures

Article 21

A licence may not be withheld, suspended or withdrawn except for the reasons set forth in this directive.

Article 22

The Member States shall put into effect any laws, regulations and administrative instructions needed to comply with the provisions of the present directive within twelve months of notification and shall inform the Commission forthwith of the action taken.

Article 23

Regulations made in pursuance of the present directive shall apply to products licensed for sale by virtue of the preceding provisions two years after the notification referred to in Article 22.

Article 24

The present directive is addressed to all Member States.