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INFORMATION MEMO

TOWARDS EUROPEAN LEGISLATION ON PHARMACEUTICAL PRODUCTS
(First Directive)

Despite the dynamic character of the pharmaceutical industry and the increasing consumption of its products, intra-Community trade in this sector has remained at a relatively low level during the first years of the Common Market.

In order to protect public health, the authorities in all the Member States have issued numerous regulations on pharmaceutical products. They differ on many points from country to country, and this has tended to isolate markets and limit the free movement of such products. Disparities between laws in the various countries, owing to the influence they exercise on production and distribution costs, cause distortion of competition between manufacturers in the Community.

Hence the importance of the directive on branded pharmaceuticals now adopted by the Council of Ministers. It is a first step in the progressive alignment of laws on pharmaceuticals in the six member countries. The object is to stimulate this branch of trade, placing producers on equal terms as regards competition while protecting public health.

This directive requires the Member States to incorporate in their legislation, within eighteen months from notification of the directive, a number of rules which can be summarized as follows:

1. No branded pharmaceutical can be offered for sale without a licence;

2. The issue of licences will be subject to a number of formalities and conditions;

   (i) Formalities: an application accompanied by certain particulars and documents must be submitted;

   (ii) Conditions: the authorities must refuse to issue a licence

      (a) if the pharmaceutical appears to be harmful under normal conditions of use;

      (b) if it does not have the therapeutic potency claimed for it or if such potency is not adequately substantiated by the applicant;

.../...

(c) if the nature and quantity of its ingredients are not in conformity with those stated.

The licensing procedure may not exceed 120 days from the date of application, save in exceptional cases

3. The licence can be suspended or withdrawn if, subsequently, it is found that the branded pharmaceutical is harmful, that it does not have the therapeutic potency claimed for it or that the nature and quantity of its ingredients are not in conformity with those stated.

It is of particular interest to note that the Council of Ministers has been able to reach agreement on the question of therapeutic potency, which had caused difficulties and given rise to lengthy discussions among the experts.

4. The directive also contains detailed rules on labelling. This is to ensure that branded pharmaceuticals offered for sale in any EEC country bear the same particulars considered essential from the point of view of public health.

Alighnment in this matter is undoubtedly of considerable interest to both producers and consumers.

5. This directive will be followed by other measures; indeed a proposal for a second directive, which to a certain extent supplements the first one, has already been submitted to the Council of Ministers.

It deals with the supporting documents, concerning tests, which must accompany the application for a licence, the manufacturers' obligations in respect of testing their products, and the inspections of conditions of production and sale to be carried out by the national authorities.

Further proposals are in preparation. One on the use of colouring matters in drugs and another concerning advertising have reached an advanced stage.

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