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# COUNCIL DIRECTIVE

## of 26 January 1965

## on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

(65/65/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

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[1];

Having regard to the Opinion of the Economic and Social Committee[2];

Whereas the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health;

Whereas, however, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community;

Whereas trade in proprietary medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations); and whereas such disparities directly affect the establishment and functioning of the common market;

Whereas such hindrances must accordingly be removed; and whereas this entails approximation of the relevant provisions;

Whereas, however, such approximation can only be achieved progressively; and whereas priority must be given to eliminating the disparities liable to have the greatest effect on the functioning of the common market;

HAS ADOPTED THIS DIRECTIVE:

### CHAPTER I

### Definitions and scope

#### *Article 1*

For the purposes of this Directive, the following shall have the meanings hereby assigned to them;

1. *Proprietary medicinal product:*

Any ready-prepared medicinal product placed on the market under a special name and in a special pack.

2. *Medicinal product:*

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

[1] OJ No 84, 4.6.1963, p. 1571/63.
[2] OJ No 158, 16.10.1964, p. 2508/64.

3. *Substance:*

Any matter irrespective of origin which may be:

— human, e.g.

human blood and human blood products;

— animal, e.g.

micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, etc;

— vegetable, e.g.

micro-organisms, plants, parts of plants, vegetable secretions, extracts, etc;

— chemical, e.g.

elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

*Article 2*

The provisions of Chapters II to V shall apply only to proprietary medicinal products for human use intended to be placed on the market in Member States.

CHAPTER II

**Authorisation to place proprietary medicinal products on the market**

*Article 3*

No proprietary medicinal product may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State.

*Article 4*

In order to obtain an authorisation to place a proprietary medicinal product on the market as provided for in Article 3, the person responsible for placing that product on the market shall make application to the competent authority of the Member State concerned.

The application shall be accompanied by the following particulars and documents:

1. Name or corporate name and permanent address of the person responsible for placing the proprietary product on the market and, where applicable, of the manufacturer.

2. Name of the proprietary product (brand name, or common name together with a trade mark or name of the manufacturer, or scientific name together with a trade mark or name of the manufacturer).

3. Qualitative and quantitative particulars of all the constituents of the proprietary product in usual terminology, but excluding empirical chemical formulae, with mention of the international non-proprietary name recommended by the World Health Organisation where such name exists.

4. Brief description of the method of preparation.

5. Therapeutic indications, contra-indications and side-effects.

6. Posology, pharmaceutical form, method and route of administration and expected shelf life if less than three years.

7. Control methods employed by the manufacturer (analysis and assay of the constituents and of the finished product, special tests, e.g. sterility tests, tests for the presence of pyrogenic substances, the presence of heavy metals, stability tests, biological and toxicity tests).

8. Results of:

— physico-chemical, biological or microbiological tests;

— pharmacological and toxicological tests;

— clinical trials.

However:

(a) a List of published references relating to the pharmacological tests, toxicological tests and clinical trials may be substituted for the relevant test results in the case of:

(i) a proprietary product with an established use, which has been adequately tested on human beings so that its effects, including side-effects, are already known and are included in the published references;

(ii) a new proprietary product, in which the combination of active constituents is