

DIRECTIVE ON TRADITIONAL MEDICINAL PRODUCTS

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Chapter I

Scope and definitions

Article 1 – Scope of application

1. This Directive applies to herbal medicinal products for human use other than those referred to in paragraph 2. It applies also to those classes of medicinal products for human use listed in the annex to the Directive.
2. The Directive does not apply to medicinal products, which can be authorised in accordance with Article 3 of Directive 65/65/EEC or can be registered pursuant to Article 7 of Directive 92/73/EEC.
3. The provisions of this Directive do not apply to magistral or officinal formula as defined in Article 1 of Directive 65/65/EEC.

Article 2 - Definitions

For the purpose of this Directive, the following definitions shall apply:

1. Herbal medicinal product is any medicinal product, which consists exclusively of one or more herbal substance or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.
2. Herbal substances are all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the botanical name according to the binomial system (genus, species, variety and author).
3. Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration and fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Chapter II

Registration

Article 3 – Application

1. In order to obtain traditional use registration, an application shall be addressed to the competent authority of the Member State concerned.
2. The applicant and registration holder shall be established in the Community.
3. The application shall be accompanied by:
 - a) the particulars and documents referred to in Article 4, paragraphs 1 to 10, of Directive 65/65/EEC, with the exception of the results of pharmacological and toxicological tests and the results of clinical trials as referred to in paragraph 8 of that Article. The summary of product characteristics need not contain the data specified in paragraph 4 of Article 4a of Directive 65/65/EEC;
 - b) details of any authorisation or registration obtained in another Member State, or in a third country, to place the medicinal product on the market, and details of any decision to refuse to grant an authorisation or registration, whether in the Community or a third country, and the reasons for such a decision;
 - c) bibliographical and expert evidence to the effect that the medicinal product in question, or a corresponding medicinal product has been in use in the Community throughout a period of at least thirty years preceding the date of application. The requirement to show use throughout a period of thirty years is satisfied even if some or all of the use was not licensed in this Member State. It is likewise satisfied if the number or quantity of ingredients of the medicinal product has been reduced during the period as mentioned in this article.

A corresponding medicinal product is characterised by

- i) the same ingredients, irrespective of the excipients used;
 - ii) a similar intended purpose;
 - iii) an equivalent strength;
 - iv) the same route of administration
- as the medicinal product applied for.
- d) a bibliographic review of safety data together with an expert report. Where a competent authority considers it necessary for assessing the safety of a particular medicinal product, it may require the applicant to present data.
4. As an alternative to supplying evidence of use throughout a period of thirty years within the Community as referred to in *litera c)* of paragraph 3 of this Article, the applicant may supply evidence of use throughout a period of thirty years in either:

- a) a specified territory or territories outside the Community, or
- b) partly in one or more of the Member States, and partly in such a specified territory or territories,

if during this period of time the product has been on the market within the Community for at least 15 years.

5. When Community scientific monographs in the sense of Article 14 paragraph 3 of the present Directive have been adopted, they shall be used as the basis for any application.

Article 4 – Dossier on testing

1. Subject to paragraphs 2 and 3 of the present Article, the Annex to Directive 75/318/EEC shall apply by analogy to the particulars and documents specified in Article 3 paragraph 3 a).
2. In addition to the requirements referred to in paragraph 1:
 - a) the medicinal product shall comply with any relevant monographs in the European Pharmacopeia;
 - b) any medicinal product which contains a plant extract shall be prepared by extraction methods in accordance with the European Pharmacopeia, unless the competent authority of the Member State in question concludes that this is not necessary for demonstrating the quality and safety of the medicinal product.
3. In the case of herbal medicinal products consisting of comminuted herbal substances or their mixtures used for tea infusions or of a tincture without any other excipients, a simplified dossier may be provided instead of the particulars and documents specified in Part 2 of the Annex to the Directive 75/318/EEC. This applies, if the ingredient(s) of the medicinal product is (are) covered by a monograph of the European Pharmacopeia. The Committee referred to in Article 16 shall adopt detailed guidance on the precise contents of the simplified dossier.

Article 5 – Allowed substances/indications

The Commission may adopt a Directive in accordance with the regulatory procedure set out in Article 5 of Council Decision 1999/468/EC, specifying substances and/or indications which may be included in medicinal products eligible for a traditional use registration under this Directive. The period as mentioned in Article 5 paragraph 6 of Decision 1999/468/EC shall be three months.

Article 6 – Registration by other Member States

When granting traditional use registration, each Member State shall take due account of registrations previously granted by another Member State.

Article 7 – Refusal of registration

Traditional use registration shall be refused if, after verification of the particulars and documents specified in Article 3 and any other information by the competent authority relating to the harmfulness of the product in normal conditions of use:

- a) the qualitative and/or quantitative composition is not as declared,
- b) the particulars and documents submitted in support of the application do not comply with Article 3,
- c) the product could be harmful in the normal conditions of use,
- d) information on traditional use is insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-term use and experience,
- e) the product would be classed as a medicinal product subject to medical prescription as referred to in Directive 92/26/EEC,
- f) the medicinal product is other than an oral preparation, a cutaneous preparation or an inhalation preparation,
- g) the application contradicts provisions of a Directive mentioned in Article 5, or
- h) the pharmaceutical quality are not fully demonstrated.

Article 8 – List with specific traditional medicinal products

1. The Committee as referred to in Article 14 sets up a list of medicinal products, which are not harmful in the normal conditions of use.
2. To be included in such a list, the medicinal product must:
 - a) consist of specified ingredients;
 - b) be indicated exclusively for indications adapted to medicinal products mentioned in Article 1 paragraph 1 of the present Directive which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
 - c) be exclusively for administration in accordance with a specified strength;
 - d) be exclusively for administration by a specified route of administration;
 - e) have been used throughout a period of thirty years as referred to in Article 3.
3. If an application for registration under this Directive relates to a medicinal product contained in such a list, the evidence specified in Article 3 paragraphs 3 b) to d) does not need to be provided. Furthermore, litera c) to e) and g) of Article 7 shall not apply either.
4. If a class of medicinal products ceases to be included in the list, registrations for such products that have been based on paragraph 3 of the present article shall be revoked unless

the particulars and documents for a normal traditional use registration are submitted within reasonable time.

Article 9 - Adaptation to new monographs

When new Community scientific monographs in the sense of Article 14 paragraph 3 are adopted, the registration holder shall within one year after the date of adoption of such monograph, introduce a variation to the registration dossier in order to comply with this monograph.

Chapter III

Application of other Directives

Article 10 – General reference

Articles 6, 7 paragraph 1, articles 8, 9, 9a and 10 paragraph 1 as well as articles 11 and 12 of Directive 65/65/EEC shall apply, by analogy, to traditional use registration granted under this Directive. Subject to provisions of Articles 11 and 12 of the present Directive, also Directive 75/319/EEC apart from its Chapter III as well as Directives 92/25/EEC, 92/26/EEC, 92/27/EEC and 92/28/EEC shall apply by analogy to medicinal products to be registered under this Directive.

Article 11 – Labelling and package leaflet

1. The labelling and the user package leaflet referred to in Directive 92/27/EEC shall, in addition to the particulars referred to in that Directive, contain a statement to the effect that:
 - a) the product is a traditional use medicinal product for use in a specified indication and that the efficacy of the product has not been clinically proven but relies exclusively on long-term use and experience; and
 - b) the user should consult a doctor if the symptoms persist during the use of the medicinal product.
2. A Member State may provide that the labelling and the user package leaflet referred to in this Article shall also state the nature of the tradition in question.

Article 12 - Advertising

Any advertisement for a medicinal product registered under this Directive shall contain the statements referred to in Article 11.

Chapter IV

Final provisions

Article 13 – Information about refusal of registration

The competent authorities of the Member States shall provide the Commission and any competent authority requesting this, any decision it makes to refuse traditional use registration on safety grounds, and the reasons for this.

Article 14 - Committee

1. A Committee is hereby set up, which shall be part of the European Agency for the Evaluation of Medicinal Products established by Council Regulation (EEC) No. 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.
2. The Committee shall consist of one member nominated by each Member State for a term of 3 years which shall be renewable. They shall, as appropriate, be chosen by reason of their role and experience in the evaluation of medicinal products referred to in Article 1 paragraph 1 and shall represent their competent authorities.
3. The Committee shall establish Community scientific monographs for traditional medicinal products and fulfil further responsibilities conferred upon it by this Directive and other Community law, in particular with regard to the implementation of Commission Directive 1999/83/EC as far as herbal medicinal products are concerned.
4. It shall adopt its own rules of procedure.

Article 15 – Implementation

1. The Member States shall take the measures necessary to comply with this Directive by _____. They shall forthwith inform the Commission thereof. When Member States adopt the said measures, these shall contain a reference to this Directive or be accompanied by such a reference when officially published.
2. For the medicinal products as referred to in Article 1 paragraph 1 of the present Directive which are already on the market on the entry into force of this Directive, the competent authorities apply the provisions of the present Directive within five years after its entry into force.
3. Five years after the entry into force of this Directive, the Commission shall present a report to the European Parliament and the Council concerning the application of this Directive. The report shall include an assessment of the scope for moving towards a more harmonised regulatory approach including any traditionally used medicinal products, which have a common pattern of usage across the European Union.

Annex

Other classes of medicinal products for human use in the sense of Article 1 paragraph 1

[To be included: traditional medicinal products other than herbal medicinal products]