



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market, regulatory environment, industries under vertical legislation
Pharmaceuticals and cosmetics

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PROVISIONS OF A DIRECTIVE ON TRADITIONAL MEDICINAL PRODUCTS

CHAPTER I

Definitions and scope

Article 1

1. This Directive applies to herbal medicinal products for human use, to the exclusion of herbal medicinal products prepared in accordance with a magistral or an officinal formula as defined in Article 1 (4) and (5) of Directive 65/65/EEC.
2. **[To be discussed: the Member States may also apply this Directive to other classes of medicinal product for human use listed in annex]**
3. The medicinal products referred to in paragraph 1 [2] shall be identified by a reference on their labels, in clear and legible form, to their traditional use registration.

Article 2

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

1. Herbal medicinal product : any medicinal product which consists exclusively of a herbal drug or a herbal drug preparation, or both, together with any excipient.
2. Herbal drug : **[to be defined Herbal Medicinal Products WP].**
3. Herbal drug preparation : **[to be defined Herbal Medicinal Products WP].**

CHAPTER II

Placing on the market

Article 3

[1. The Member States may provide that medicinal products for human use to which this Directive applies may, as an alternative to being authorised in accordance with Articles 4 to 21 of Directive 65/65/EEC or Regulation 2309/93, be registered in accordance with this Directive referred to below as “traditional use registration”. If a medicinal product falls under the scope of the above mentioned Directive or Regulation it can not be registered as "traditional use registration".]

2. When granting registration in accordance with this Directive, each Member State shall take due account of registrations previously granted by another Member State as well as any relevant expert scientific opinion issued by any body established by the European Medicines Evaluation Agency.

3. If a Member State chooses not to establish a procedure for traditional use registration, it shall inform the Commission accordingly. The Member State concerned shall by.....at latest, allow the use in its territory of herbal medicinal products registered by other Member States.

Article 4

1. In order to obtain traditional use registration, the person responsible for placing the medicinal product on the market shall make application for registration to the competent authority of the Member State concerned.

2. The person responsible for placing the medicinal product on the market shall be established in the Community.

3. Subject to paragraphs 4 to 7 and Article 5, 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;
- b) details of any authorisation or registration obtained in another Member State, or in a third country, to place the 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 or expert evidence to the effect that the product in question, or a product or products with:
 - i) the same ingredients;
 - ii) a similar intended purpose;
 - iii) an equivalent dosage; and
 - iv) the same route of administration

as the product in question (“corresponding products”), has been in use in one or more of the Member States throughout a period of at least thirty years immediately preceding the date of the application;

- d) a bibliographic review of safety data and an expert report on that data.

[4. A Member State may provide that, as an alternative to supplying evidence of use throughout a period of thirty years as referred to in sub-paragraph c) of paragraph 3, the period may be reduced below 30 years when the applicant may supply evidence of use in either:

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

throughout a period of thirty years immediately preceding the date of the application]

5. An applicant need not provide the evidence specified in paragraphs 3 b) to d) and 4, where the product is of a class specified in a list as referred to in Article 5 which is issued by the Member State concerned by the application.

6. The summary of product characteristics provided pursuant to paragraph 3 a) need not contain the data specified in paragraph 4 of Article 4a of Directive 65/65/EEC

7. In sub-paragraph c) of paragraph 3:

- a) in paragraph i), “ingredients” do not include excipients;
- b) the condition in paragraph ii) is satisfied even if the products referred to have also been marketed for some or all of the period referred to in that sub-paragraph for a purpose other than a similar purpose;
- c) paragraph iv) is satisfied even if the products referred to have also been used for some or all of the period referred to in that sub-paragraph in respect of other routes of administration;
- d) the requirement to show use throughout a period of thirty years is satisfied even if some or all of the use was not licensed by the Member State in question.

Article 5

1. The list referred to in Article 4 paragraph 5 is a list of classes of medicinal product which are defined by reference to the criteria specified in paragraph 2 (whether or not they are also defined by reference to any other criteria) and which the Member State in question concludes, on the basis of expert advice, are not harmful in normal conditions of use.
2. The criteria referred to are that the products :
 - a) consist of specified ingredients;
 - b) are indicated exclusively for specified purposes [**minor indications**];
 - c) are for administration in accordance with a specified dosage;
 - d) are for administration exclusively by a specified route; and
 - e) have been used throughout a period of thirty years as referred to in Article 4 paragraph 3 c) or, where the Member State in question has made provision as referred to in Article 4 paragraph 4, throughout a period of thirty years as referred to in Article 4 paragraph 4 (in either case with the references in those provisions to the date of the application being read as a reference to the date of the advice).
3. The criteria referred to in paragraph 2 must be consistent with the criteria for refusal of registration of a medicinal product in Article 8 paragraph 1 e) to h).

Article 6

1. Subject to paragraphs 2 and 3 below, the Annex to Directive 75/318/EEC shall apply by analogy to the particulars and documents specified in Article 4 paragraph 3 a).
2. In addition to the requirements of the Annex referred to in paragraph 1:
 - a) the product shall comply with any relevant monographs in the *European Pharmacopoeia*;
 - b) the particulars and documents must be provided in accordance with any relevant CPMP notes for guidance on the quality of medicinal products; and
 - c) any product which contains a plant extract shall be prepared by extraction methods in accordance with the *European Pharmacopoeia*, unless the competent authority of the Member State in question concludes that this is not necessary in order to demonstrate the quality and safety of the medicinal product.
3. A Member State may provide that, in respect of a specified class of medicinal product having a **simple presentation [a more precise expression than “simple presentation”**

should be found in order to cover simple products such as herbal teas], a simplified dossier may be provided in place of the particulars and documents specified in Part 2 of the Annex referred to in paragraph 1. In the event that it makes use of this option, it shall inform the Commission accordingly.

Article 7

When traditional use registration is granted, the person responsible for placing that product on the market shall be informed, by the competent authority of the Member State concerned, of the summary of the product characteristics as approved by it. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the registration is granted or subsequently.

Article 8

1. Subject to paragraph 2, traditional use registration shall be refused for a medicinal product if, after verification of the particulars and documents specified in Article 4, and any other information obtained by the competent authority concerned relating to the harmfulness of the product in normal conditions of use, it proves that:

- a) the qualitative and quantitative composition is not as declared;
- b) the particulars and documents submitted in support of the application do not comply with Article 4;
- c) the product is harmful in the normal conditions of use;
- d) the product has not been used throughout a period of thirty years as referred to in Article 4 paragraph 3 c) **[or, where appropriate, Article 4 paragraph 4];**
- e) the product would be classed as a medicinal product subject to medical prescription as referred to in Directive 92/26/EEC;
- [f) a marketing authorisation has been issued under Directive 65/65/EEC or under Regulation 2309/93/EEC in respect of a product which is essentially similar to the product the subject of the application;]**
- g) the product is for administration otherwise than by oral administration, external administration or inhalation; or
- h) the product contains a substance referred to in Article 9 or the application specifies an indication as referred to in Article 10.

2. Where the product falls within a class of product specified in a list as referred to in Article 4 paragraph 5, which has been issued by the Member State in question, paragraph 1 c) to e), g) and h) shall not apply.

3. Where a class of medicinal product ceases to be included in a list as referred to in Article 4 paragraph 5, and traditional use registration for a medicinal product of that class has been granted under this Directive, the registration may be suspended or revoked by the competent authority of the Member State in question on the ground that any of the conditions in paragraphs c) to e) of Article 8 are not satisfied, subject to giving the holder of the registration a reasonable opportunity to provide the particulars and documents necessary to demonstrate that the condition or conditions in question are satisfied.

Article 9

1. The Commission may adopt a Directive in accordance with the procedure set out in Article 5 of Council Decision 1999/468/EC, specifying substances which may not be included in medicinal products the subject of traditional use registration under this Directive.

2. A Member State may specify substances, in addition to any specified in a Directive under paragraph 1, which may not be included in medicinal products the subject of traditional use registration under this Directive.

Article 10

1. The Commission may adopt a Directive in accordance with the procedure set out in Article 5 of Council Decision 1999/468/EC, specifying indications which may not be included in a statement of product characteristics in connection with an application for traditional use registration under this Directive.

2. A Member State may specify indications, in addition to any specified in a Directive under paragraph 1, which may not be included in a statement of product characteristics in connection with an application for traditional use registration under this Directive.

CHAPTER III

Application of other Directives

Articles 11

Subject to paragraph 2, Articles 6, 7 paragraph 1, 8, 9, 9a and 10 paragraph 1, 11 and 12 of Directive 65/65/EEC shall apply, by analogy, to traditional use registration granted under this Directive.

Article 12

1. Subject to paragraphs 2 and 3 below, Directives 75/319/EEC, 92/25/EEC, 92/26/EEC, 92/27/EEC and 92/28/EEC shall apply by analogy to medicinal products subject to traditional use registration under this Directive.
2. Chapter III of Directive 75/319/EEC shall not apply.
3. The labelling and 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 medicine for use in a specified indication and that the efficacy of the product has not been clinically proven; and
 - b) the user should consult a doctor if the symptoms persist during the use of the medicinal product.
4. A Member State may provide that the labelling and user package leaflet referred to in paragraph 3 shall also state the nature of the tradition in question.
5. Any advertisement for a traditionally used medicinal product the subject of registration under this Directive shall contain the statements referred to in paragraphs 3 and 4.

CHAPTER IV

Information sharing and final provisions

Article 13

The competent authorities of the Member States shall, on their own initiative, or at the request of a competent authority of another Member State, provide to the Commission and to any competent authority which makes such a request, any decision it makes to refuse traditional use registration on safety grounds, and the reasons for this.

Article 14

1. The Member States shall take the measures necessary to comply with this Directive by *[date]*. They shall forthwith inform the Commission thereof. When Member States adopt the said measures, they shall contain a reference to this Directive or be accompanied by such reference when they are officially published. The procedure for making such reference shall be adopted by the Member States.
2. Not later than *[date]*, the Commission shall present a report to the European Parliament and the Council concerning the application of this Directive and the Report shall include an assessment of the scope for moving towards a more harmonised regulatory approach towards any traditionally used medicinal products which have a common pattern of usage across the European Union.

[Specific provision for transitional arrangements in Member States in view of the possibly large volume of products requiring assessment in some Member States.]