



COMMISSION OF THE EUROPEAN COMMUNITIES

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2002/0008 (COD)

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending the Directive 2001/83/EC as regards traditional herbal medicinal products

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

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(Text with EEA relevance)

1. BACKGROUND

Transmission of the proposal to the Council and to the European Parliament

- COM(2002) 1 final – 2002/0008 (COD) -

by virtue of article 175, paragraph 1 of the Treaty: 17 January 2002

Opinion of the European Economic and Social Committee: 18 September 2002

Opinion of the European Parliament – first reading: 21 November 2002

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The proposal aims to guarantee a high level of health protection for European patients by giving them access to medicines of their choice, provided all the necessary safeguards are met. It will also ensure a single market for herbal medicines by introducing harmonised rules and procedures and encourage cross-border trade in these products, which at the moment is very limited. The proposal provides for a simplified registration system for traditional herbal products. The quality requirements, which will have to be met, are the same as those for all medicinal products. But to avoid unnecessary testing and burdens on firms, the legislation foresees that new pre-clinical and clinical trials will not be necessary when sufficient knowledge already exists about a particular product.

3. OPINION OF THE COMMISSION ON THE AMENDMENTS ADOPTED BY THE PARLIAMENT

The European Parliament adopted 27 amendments in total, out of which the modified proposal incorporates one plus parts of a second amendment without any change and thirteen plus parts of three further amendments in principle, while ten plus parts of two further amendments are rejected.

3.1. Amendments accepted by the Commission: 3 (2nd sentence) and 26.

The Commission can accept the following amendments with the wording proposed by the European Parliament.

- The 2nd sentence of amendment 3, which deletes in the recital on the recognition of decisions taken by other Member States the possibility to refuse this recognition in case of major objections of public health.

“Recital 11, 2nd sentence:

In cases where the authorisation or registration refers to a herbal medicinal product for which a monograph has been established under this Directive, it should be recognised.”

- The amendment 26, which stipulates that the Commission shall present its report on the functioning of the new procedure within three years after the entry into force of the new directive:

“Article 16i, subparagraph 1:

Not later than three years after the date of entry into force of this Directive, the Commission shall present a report to the European Parliament and the Council concerning the application of the provisions of this chapter.”

3.2. Amendments accepted in principle by the Commission: 2, 3 (1st sentence), 5, 8, 12 (2nd and 3rd part), 14, 15 (reference to specified daily doses), 16, 17, 18, 19, 20, 21, 22, 23 and 24

- The Commission can accept in principle amendment 2 and the first part of amendment 20 aiming at extending the responsibilities of the new Committee for Herbal Medicinal Products. It is acceptable to extend the new committee’s responsibilities to issues regarding national authorisations and registrations of herbal medicinal products, including in particular the referral/arbitration procedure for such products. However, a rewording is needed since the new committee should not take over responsibilities for the centralised procedure, which is of little relevance for the herbal medicines and for which full coherence needs to be guaranteed by the existing committee. For medicinal products, which contain herbal ingredients without fulfilling the definition of a herbal medicinal product, the new Committee for Herbal Medicinal Product should be entitled to give an opinion on the herbal ingredients to be considered when deciding on the product in its entirety.

“Recital 9:

*Having regard to the particularities of herbal medicinal products, a Committee **for Herbal Medicinal Products** should be established within the European Agency for the Evaluation of Medicinal Products set up 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] 10 (hereinafter: the Agency). The Committee **should take over the tasks of the Committee for Human Medicinal Products (CPMP) with regard to authorisations or registrations of herbal medicinal products by the Member States; its tasks should relate in particular to establishing Community herbal monographs relevant for the registration as well as the authorisation of herbal medicinal products. It should be composed of experts in the field of herbal medicinal products.***

Article 16h, paragraph 1, subparagraphs 1 to 3:

A Committee for Herbal Medicinal Products is hereby established. That Committee shall be part of the Agency.

The Committee for Herbal Medicinal Products shall take over the tasks of the Committee for Human Medicinal Products with regard to authorisations or registrations by Member

States of herbal medicinal products.

Where other medicinal products containing herbal substances are referred to the Agency under Chapter 4 of Title III, the Committee for Herbal Medicinal Products shall, where appropriate, give an opinion on the herbal substance.”

- The Commission can accept in principle the 1st sentence of amendment 3 and amendment 14, that provide for an obligation of Member States to recognise decisions by other Member States instead of a mere obligation to take due account of such decisions. A rewording is necessary however since the obligation to recognise authorisations is already foreseen in the existing legislation and the obligation to recognise registrations should be limited to those granted on the basis of the new directive. In addition, to ensure the functioning of such recognition, the necessary procedural provisions need to apply. These provisions however can apply only “by analogy” inasmuch as the mutual recognition of simplified registrations is based on different dossiers than that of regular authorisations.

“Recital 11, 1st sentence:

*When deciding upon an application for registration of a traditional herbal medicinal product, the Member State concerned should be obliged to **recognise** registrations previously granted by another Member State for that product **on the basis of the provisions of this chapter.***

Article 16d:

Without prejudice to Article 16h(1), Chapter 4 of Title III shall apply by analogy to registrations granted in accordance with Article 16a.”

- The Commission can accept in principle amendment 5 and the 2nd part of amendment 12 that shall extend the simplified registration procedure to those medicinal products, which contain apart from herbal substance(s) in addition other non-herbal ingredients. However, a rewording of Article 1, paragraph 1 is needed to render more precisely that such combination product may contain in particular vitamins or minerals, but also other non-biological substances for which there is well document evidence for its safety. In addition, in all combination products the action of the non-herbal substances must be ancillary to that of the herbal ingredients. Substances of a biological origin pose specific risks so that the regular procedure with the full scientific data has to be maintained to safeguard public health. In addition, the inclusion requires a change of Art. 1, paragraph 1 point 30 which contains the definition of a herbal medicinal product and not of Art. 1, paragraph 1, point 29. Article 16c, paragraph 4 to the contrary does not need to be changed; the extension of the simplified procedure to certain combination products flows already from the amended Article 1, paragraph 1 point 30, read together with the concept of a “corresponding medicinal product” as referred to in Article 16c, paragraph 2.

“Article 1, paragraph 1, point 29:

Traditional herbal medicinal product:

a herbal medicinal product that fulfils the conditions laid down in Article 16a;

Article 1, paragraph 1, point 30:

Herbal medicinal product

*any medicinal product, containing as active ingredients, one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations; **in addition, the product may contain vitamins or minerals or other non-biological substances for which there is well documented evidence for its safety; the action of the non-herbal substances must be ancillary to that of the herbal active ingredients.***

- The Commission can accept in principle amendment 8 and part of amendment 15 (reference to specified daily doses) that introduces the dosage schedule. However, the current term “specified strength” relates to the dose and hence needs to be maintained in parallel to the dosage schedule. In addition, “specified daily doses” should be replaced by the general term “posology”, which means the dosage schedule, be it a daily schedule or other.

“Article 16a, point b:

*they are exclusively for administration in accordance with a specified strength **and posology**;*

Article 16f, paragraph 1:

*The Committee referred to in Article 16h shall set up a list of herbal substances. The list shall contain with regard to each herbal substance the therapeutic indication, the specified strength **and the posology**, the route of administration and any other information necessary for the safe use of the herbal substance.”*

- The Commission can accept in principle the 3rd part of amendment 12 (reference to the minimum time of use) that reduces the minimum time of use within the Community from 15 to 10 years. However, with regard to the directive’s key objectives to safeguard public health while promoting the free movement of herbal medicines, it is preferable to maintain as a rule the requirement of 30 years in total and at least 15 years in the Community. In order to assess whether for a particular product an exception from this rule can be accepted, the product should be referred to the new committee for herbal medicines at the EMEA. The committee could be empowered to analyse whether the available information on at least 30 years of use is sufficient, even if the minimum time of use is less than 15 or even 10 years. For reasons of clarity, the rule of 30/15 years should be moved to Article 16c, paragraph 1, point (c). This requires the following rewording and alignment:

“Article 16c, paragraph 1, point (c):

*bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding medicinal product has been in medicinal use throughout a period of at least thirty years, **including at least 15 years within the Community**;*

Article 16c, paragraph 4:

If the product has been available within the Community for less than 15 years, the Member State where the application for traditional use registration has been lodged shall refer the product to the Committee for Herbal Medicinal Products. The Committee shall analyse whether the other criteria for a simplified registration as referred to in Article 16a are

fulfilled. On this basis, the Committee shall establish a Community herbal monograph as referred to in Article 16h(3) on whose basis the Member State shall grant or refuse the registration.”

- The Commission can accept in principle the amendment 16 regarding particularities of the labelling and user package leaflets of traditional herbal medicines. A rewording is necessary though to ensure that it is clear from the labelling and the leaflet that safety and efficacy are based on information on the traditional use without the regular scientific data. In addition, a clarification is needed that the product could be registered for more than one specified indication.

“Article 16g, paragraph 2, point a:

*the product is a herbal medicinal product for traditional use in a specified indication/**specified indications** and that the **safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience**; and”.*

- The Commission can accept in principle the amendment 17, which extends the warning to consult a doctor or a qualified practitioner to situations where adverse reactions occur. However, it should be reworded inasmuch the wording needs to take into account that the patient often will not be able to decide whether an adverse reaction is “serious” or not. To the contrary, the patient will be able to decide whether or not the adverse reaction is mentioned in the package leaflet:

“Article 16g, paragraph 2, point b:

*the user should consult a doctor or a qualified practitioner if the symptoms persist during the use of the medicinal product **or should adverse effects not mentioned in the package leaflet occur.**”*

- The Commission can accept in principle the amendment 18 according to which the labelling and user package leaflets of traditional herbal medicines shall point to possible dangerous interactions with food and/or medicinal products. However, such obligation follows already from Article 16g, paragraph 2 read together with Article 59, paragraph 1, point c. The additional reference in Article 16g is redundant therefore.
- The Commission can accept in principle the amendment 19 regarding advertising for traditional herbal medicines. A rewording is necessary though to align this provision with Article 16g, paragraph 2, point a as changed in response to amendment 16.

“Article 16g, paragraph 3:

*In addition to the provisions laid down in Articles 86 to 99 any advertisement for a medicinal product registered under this chapter shall contain the following statement: **‘the safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience’**”.*

- The Commission can in principle accept the 2nd part of amendment 20, which provides for an obligation of the Executive Director of the European Medicines Evaluation Agency to ensure the co-ordination between the new Committee for Herbal Medicinal Products and the existing Committee for Human Medicinal Products. However, a rewording is necessary to refer to the legal tools available to the Executive Directives. In fact, the provision of Article 16h, paragraph 3, second sentence can be used for this purpose, which provide

already for some co-ordination by the Executive Director, even in a more restricted context. Article 16h, paragraph 3 hence needs to be aligned to avoid unnecessary repetition:

“Article 16h, paragraph 1, subparagraph 4:

The appropriate co-ordination with the Committee for Human Medicinal Products shall be ensured by a procedure to set up by the Executive Director of the Agency according to Article 55(2) of Regulation 2309/93.”

Article 16h, paragraph 3, subparagraph 1:

The Committee shall establish Community herbal monographs for herbal medicinal products with regard to the application of Article [10a] [10(1)(a)(ii)] as well as traditional herbal medicinal products. The Committee shall fulfil further responsibilities conferred upon it by provisions of this chapter and other Community law.”

- The Commission can accept in principle the amendment 21 aiming to ensure that the experts of the various backgrounds are represented in the Committee for Herbal Medicinal Products. However, a rewording is necessary to align the composition of this Committee and the procedure to nominate its members with that proposed for the other scientific committees at the EMEA.

“Article 16h, paragraph 2:

With a view to the appointment of the members of the Committee for Herbal Medicinal Products, each Member State shall propose at least five persons selected on the basis of their role and their experience in the evaluation of herbal medicinal products.

On the basis of those proposals the Executive Director shall appoint one member per Member State, taking into account the need for the committee to be multidisciplinary in nature. Those members shall maintain relevant contacts with the competent national authorities.

The members appointed on a proposal from the Member States may propose to the Executive Director (with a view to securing their appointment) up to five additional members for the committee, chosen on the basis of their specific scientific competence.

The members of the committee shall be appointed for a three-year period which shall be renewable.

Wherever possible, the committee shall seek to establish contacts, on an advisory basis, with associations of people affected, patients and people working in the sector.”

- The Commission can accept in principle the amendment 22 that shall allow the use of monographs, publications or data in the simplified procedure, even if not established by the Committee for Herbal Medicinal Products. A rewording is necessary to clarify that such information shall be used only where the Committee for Herbal Medicinal Products has not yet established specific monographs.

“Article 16h, paragraph 3, subparagraph 2:

When Community herbal monographs in the sense of this paragraph have been established they shall be used as the basis for any application. Where no such Community herbal monograph has yet been established, other appropriate monographs, publications or data

may be referred to.”

- The Commission can accept in principle the amendment 23 according to which the provisions on pharmacovigilance of Directive 2001/83/EC shall apply to traditional herbal medicines. However, such obligation follows already from Article 16g, paragraph 2 read together with Article 101. The additional reference in Article 16h is redundant therefore.
- The Commission can accept in principle the amendment 24 according to which the provisions on good manufacturing practice of Directive 2001/83/EC shall apply to traditional herbal medicines. However, such obligation follows already from Article 16g, paragraph 2 read together with Articles 40 ff. The additional reference in Article 16h is redundant therefore.

3.3. Amendments not accepted by the Commission: 1, 4, 6, 7, 9, 10, 11, 12 (1st part), 13, 15 (apart from reference to specified daily doses), 25 and 27.

- The Commission cannot accept amendment 1 that would allow Member States having a tradition of use of herbal medicinal products from outside the Community to register such products regardless of the time of use within the Community where valid evidence from outside the Community exists. Generally, the minimum time of use within the Community is therefore indispensable to exempt the products from the regular requirement to submit scientific data on safety and efficacy. An exception is acceptable only on the basis of an assessment by new Committee for Herbal Medicinal Products has assessed on a European level as explained in the response to the 3rd part of amendment 12.
- The Commission cannot accept amendment 4 obliging the Commission to present a legislative proposal on traditional herbal medicines for veterinary use by 2006. This commitment would undermine the Commission’s right of initiative. In addition, the experience with the simplified procedure has to be evaluated before it can be evaluated whether such an extension is appropriate.
- The Commission cannot accept amendment 6 on the definition of a herbal medicinal product. The definition contained in the Commission’s proposal is identical with the scientific definition of herbal medicinal products agreed within the Council of Europe (European Pharmacopoeia). There is no reason to deviate from this agreed scientific definition, which in addition is already used in some national legal systems. Regarding the reference to «pharmacologically active levels», the distinction between a medicinal product and other categories of products (like food supplements) is laid down in Art. 1 point 1 (in the version proposed by Commission proposal COM(2001) 404 final – the «Review 2001»). The reference to pharmacological activity is part of that general definition of a medicinal product and should not be repeated in the separate proposal on traditional herbal medicinal products.
- The Commission cannot accept amendment 7 regarding the therapeutic indications, for which a product could be registered under the new simplified procedure by referring to its classification as “non-prescription” medicine. The classification of a medicine is the outcome of the assessment procedure and cannot serve as a criterion for validating the application. In addition, the current wording goes beyond the proposed amendment since the indication must be « adapted to a traditional herbal medicinal product » and « by virtue of its composition and purpose » it shall be « intended and designed for use without intervention of a medical practitioner » for certain purposes.

- The Commission cannot accept amendment 9, amendment 11, the 1st part of amendment 12 introducing a reference to the pharmacological activity of the herbal ingredients contained in the traditional herbal medicinal product. The reasoning is the same like for amendment 6. The proposed reference to herbal substances, herbal preparations or active ingredients is covered by the concept of a corresponding medicinal product contained already in the proposal and therefore redundant. For the same reason, amendment 13 is not acceptable that refers to such herbal products containing herbal ingredients below pharmacological level.
- The Commission cannot accept amendment 10 regarding the data to be submitted by the applicant. Article 16c, paragraph 1, point d is dealing only with the product's safety so that a reference to the therapeutic utility is not appropriate.
- The Commission cannot accept amendment 15 (apart from the reference to specified daily doses) according to which the Committee for Herbal Medicinal Products should draw up a classification of herbal medicinal products. Such a provision is redundant since the Committee will have to determine whether a particular product fulfils the criteria for an authorisation based on well-established medicinal use or for a simplified registration based on traditional use anyway when establishing the lists and monographs foreseen by the new Directive. Further categories of herbal medicinal products are not foreseen by the current law.
- The Commission cannot accept amendment 25 that excludes certain categories of products from the scope of the new Directive. As far as these products do not fulfil the definition of a medicinal product as contained in Article 1, paragraph 1 of Directive 2001/83/EC, they are automatically excluded from the new Directive anyway. Amendment 25 is therefore redundant.
- The Commission cannot accept amendment 27 allowing Member States to introduce or retain specific national laws for traditional medicines other than those of a herbal origin. National break-out clauses that allow Member States to disregard the harmonisation as embodied in the directive are not acceptable against the intention to contribute to completing the single market. Such clauses are also conflicting with the objective underlying several amendments to reinforce mutual recognition of simplified registrations.

4. MODIFIED PROPOSAL

In keeping with Article 250, paragraph 2, of the EC treaty, the Commission has modified its proposal along the lines indicated.