P5_TA(2002)0561

Traditional herbal medicinal products ***I

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC as regards traditional herbal medicinal products (COM(2002) 1 – C5-0026/2002 – 2002/0008(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 1[1]),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0026/2002),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0365/2002),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

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1 OJ C 126 E, 28.5.2002, p.263.

P5_TC1-COD(2002)0008

Position of the European Parliament adopted at first reading on 21 November 2002 with a view to the adoption of European Parliament and Council Directive *2002/…/EC* amending Directive 2001/83/EC as regards traditional herbal medicinal products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [4] requires that applications for the authorisation to place a medicinal product on the market have to be accompanied by a dossier containing particulars and documents relating in particular to the results of physico-chemical, biological or microbiological as well as pharmacological and toxicological tests and clinical trials carried out on the product and thus proving its quality, safety and efficacy.

(2) Where the applicant can demonstrate by detailed references to published scientific literature that the constituent or the constituents of the medicinal product have a well established medicinal use with recognised efficacy and an acceptable level of safety in the sense of Directive 2001/83/EC, he should not be required to provide the results of pre-clinical tests or the results of clinical trials.

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1 *OJ C 126 E, 28.5.2002, p. 263.*

2 OJ ...

3 *Position of the European Parliament of 21 November 2002.*

4 OJ L 311, 28.11.2001, p. 67.

(3) A significant number of medicinal products, despite their long tradition, do not fulfil the requirements of a well established medicinal use with recognised efficacy and an acceptable level of safety and are not eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted different procedures and provisions. *The* differences *that* currently *exist* between the provisions laid down in the Member States may hinder trade in traditional medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products. They may also have *an* impact on the protection of public health since the necessary guarantees of quality, safety and efficacy are not always given at present.

(4) Having regard to the particular characteristics of these medicinal products, especially their long tradition, it is desirable to provide a special, simplified registration procedure for certain traditional medicinal products. However, this simplified procedure should be eligible only where no marketing authorisation under Directive 2001/83/EC, in particular due to lack of sufficient scientific literature demonstrating a well established medicinal use with recognised efficacy and an acceptable level of safety, can be obtained. It should likewise not apply to homeopathic medicinal *products* eligible for a marketing authorisation or for a registration under Directive 2001/83/EC.

(5) The long tradition of the medicinal product *allows clinical* trials *to be dispensed with where* the efficacy of the medicinal product is plausible on the basis of long-term use and experience. Pre-clinical tests do not seem *necessary where,* on the basis of the information on its traditional use, *the medicinal product* proves not to be harmful in specified conditions of use. However, even the long tradition does not exclude *the fact* that there may be concerns with regard to the product's safety, *so the* competent authorities should be entitled to ask for all data necessary for assessing the safety. The quality aspect of the medicinal product is independent of its traditional use, *so no* derogation should be made with regard to the necessary physico-chemical, biological and microbiological tests.

(6) The vast majority of medicinal products with a sufficiently long and coherent tradition are based on herbal substances. It therefore seems appropriate to limit the scope of the simplified registration in a first step to traditional herbal medicinal products.

(7) The *simplified* registration should be acceptable only where the herbal medicinal product may rely on a sufficiently *long-term* medicinal use in the Community. Medicinal use outside the Community should be taken into account *only if* the medicinal product has been used within the Community for a certain time. ***Nevertheless, those Member States which have a tradition of using herbal medicinal products from outside the Community should be able to register such products regardless of the time of use within the Community, where valid evidence from outside the Community exists.***

(8) With the objective *of* further *facilitating* the registration of certain traditional herbal medicinal products and to further enhance harmonisation, there should be *a* possibility to establish a Community list *of* herbal substances that fulfil certain criteria, such as being in medicinal use for a sufficiently long time, and hence do not seem harmful in the normal conditions of use.

(9) Having regard to the particularities of herbal medicinal products, ***a committee on herbal medicinal products*** should be established within the European Agency for the Evaluation of Medicinal Products set up by *European Parliament and Council* Regulation *(EC) No .../2002 of ... [laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency]*[1] (hereinafter "the Agency"). The committee should be composed of experts in the field of herbal medicinal products. Its tasks should relate in particular to establishing Community herbal monographs relevant for the registration as well as the authorisation of herbal medicinal products. ***In addition, the committee should take over the tasks of the Committee for Human Medicinal Products with regard to the evaluation of herbal medicinal products.***

(10) It is important to ensure full consistency between the new committee and the Committee for Human Medicinal Products already existing at the Agency. In particular, *for* a procedure regarding an *application which* concerns a herbal medicinal product and *which is based* on Directive 2001/83/EC, appropriate *coordination* between the two committees should be ensured, *under* the provisions of Article *67(2)* of Regulation *(EC) No .../2002 [laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency]*.

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[1] *OJ L*

(11) When deciding upon an application for registration of a traditional herbal medicinal product, the Member State concerned should be obliged to ***recognise*** authorisations or registrations previously granted by another Member State for that product. 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.***

(12) The Commission should present a report on the application of the chapter on traditional herbal medicinal products to the European Parliament and to the Council including an assessment on the possible extension of traditional use registration to other categories of medicinal products.

(13) It is therefore appropriate to amend Directive 2001/83/CE accordingly.

(14) By 31 December 2006 the Commission should propose analogous amendments to European Parliament and Council Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products[1], in which connection the behaviour of residues in animals for food production requires particular attention and examination,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is amended as follows:

(1) In Article 1 the following points 29 to 32 are added:

"29. Traditional herbal medicinal product:

a herbal medicinal product ***in different preparations, alone or in combination with other non-herbal ingredients,*** that fulfils the conditions laid down in Article 16a;

30. Herbal medicinal product:

any medicinal product ***in different preparations,*** containing ***one or more active ingredients, at pharmacologically active levels, originating from herbal, plant or other vegetable substances, for the efficacy and safety of which there is well-documented experimental and clinical evidence;***

[1] ***OJ L 311, 28.11.2001, p. 1.***

31. Herbal substances:

all mainly whole, fragmented or cut plants, plant parts, algae, fungi *and* lichen in an unprocessed, *usually dried* form but sometimes *also* 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 plant part used and the botanical name according to the binomial system (genus, species, variety and author);

32. Herbal preparations:

preparations 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."

(2) The following new chapter 2a is inserted in title III:

"Chapter 2a: Specific provisions applicable to traditional herbal medicinal products

Article 16a

A simplified registration procedure (hereinafter "traditional use registration") is hereby *introduced* for herbal medicinal products which fulfil the following criteria:

(a) they are ***classified as available without medical prescription***;

(b) they are exclusively for administration in accordance ***with specified daily doses***;

(c) they are an oral, external and/or inhalation preparation;

(d) the period of traditional use as stipulated in Article 16c(1), *point* (c) has elapsed;

(e) the data on the traditional use of the medicinal product *are* sufficient, in particular, the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-term use and experience.

However, in cases where the competent authorities judge that a traditional herbal medicinal product fulfils the criteria for an authorisation in accordance with Article 6 or a registration pursuant to Article 14, the provisions of this chapter do not apply.

Article 16b

1. The applicant and registration holder shall be established in the Community.

2. In order to obtain traditional use registration, the applicant shall submit an application to the competent authority of the Member State concerned.

Article 16c

1. The application shall be accompanied by:

(a) the *following information:*

(i) *the particulars and documents* referred to in Article 8(3) *points* (a) to (h), (j) and (k),

(ii) the results of pharmaceutical tests referred to in the first indent of Article 8(3) *point* (i),

(iii) the summary of product characteristics without the data specified in Article 11(4),

(iv) in case of a *combination as* referred to in Article 1 *point* 30, *the information* referred to in Article 16a *point* (e) relating to the combination as such; if the individual active ingredients are not sufficiently known, the data *also need to* relate to the individual active ingredients;

(b) any authorisation or registration obtained by the applicant 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 or expert evidence to the effect that ***the herbal substances, herbal preparations or their active ingredients at a pharmacological level in*** the medicinal product in question, or a corresponding medicinal product***, have*** been in medicinal use in the Community *over* a period of at least thirty years preceding the date of application;

(d) a bibliographic review of safety data together with an expert report ***on the pharmacological and toxicological properties as well as on the possible therapeutic utility***, and, where required by the competent authority, upon justified request, data necessary for assessing the safety of the medicinal product.

Annex I shall apply by analogy to the particulars and documents specified in point (a).

2. A corresponding medicinal product, as referred to in paragraph 1, *point* (c), is characterised by having the same active ingredients, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and the same or similar route of administration as the medicinal product applied for.

3. The requirement to show medicinal use throughout the period of thirty years referred to in paragraph 1, *point* (c), is satisfied even where the marketing of ***the herbal substances, herbal preparations or their active ingredients at a pharmacological level in*** the product has not been based on a specific authorisation. It is likewise satisfied if the number or quantity of ingredients of the medicinal product has been reduced during that period.

4. If ***the herbal substances, herbal preparations or their active ingredients at a pharmacological level in*** the product***, also when in association with vitamins, oligoelements and other natural ingredients with the exception of biological material,*** have been ***in medicinal use*** within ***a specified territory or territories outside*** the Community for ***a continuous period of time, which, together with a minimum of 10 years within the Community,*** *constitutes* the period of 30 years***, evidence to that effect may be supplied by the applicant.***

5. Traditional herbal products containing a dose of herbal substances or herbal preparations which is below pharmacological level, which accordingly fall under food legislation, shall continue to be regulated under the same conditions in the Community.

Article 16d

When evaluating an application for traditional use registration, each Member State shall ***recognise*** registrations or authorisations granted by another Member State.

Article 16e

1. Traditional use registration shall be refused if the application does not comply with Articles 16a, 16b or 16c or if at least one of the following conditions is fulfilled:

(a) the qualitative and/or quantitative composition is not as declared,

(b) the therapeutic indications do not comply with the conditions laid down in Article 16a,

(c) the product could be harmful in the normal conditions of use,

(d) data 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 pharmaceutical quality is not satisfactorily demonstrated.

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

Article 16f

1. The Committee referred to in Article 16h shall set up a ***classification of herbal medicinal products, taking into account their composition and their pharmacological and toxicological effects. Within this classification, the Committee shall indicate for each herbal medicinal product therapeutic indications, route(s) of administration, daily doses, possible adverse reactions and any risk of interactions with drugs, alcohol and foods; it shall also provide any other information required for their safe use, especially by children, pregnant women and elderly people.***

2. If an application for traditional use registration relates to a herbal substance contained in the *list referred* to in paragraph 1, the data specified in Article 16c(1), *points* (b), (c) and (d) does not need to be provided. Article 16e(1), *points* (c) and (d) shall not apply.

3. If a herbal substance ceases to be included in the *list referred* to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and *documents referred* to in Article 16c(1) are submitted within three months.

Article 16g

1. Articles 3(1) and (2), 4(4), 12, 17(1), 19, 20, 23, 24, 25, 40 to 52, 70 to 85, 101 to 108, 111(1) and (3), 112, 116 to 118, 122, 123, 125, 126 second indent, 127 of this Directive, as well *as Directive* 91/356/EEC* shall apply, by analogy, to traditional use registration granted under this chapter.

2. In addition to the provisions laid down in Articles 54 to 65, any labelling and user package leaflet shall contain a statement to the effect that:

(a) the product is a herbal medicinal product for traditional use in a specified indication and that the efficacy of the ***product relies*** exclusively on long-term use and *experience*;

(b) *the* user should consult a doctor or a qualified practitioner if the symptoms persist during the use of the medicinal product ***or if adverse reactions occur;*** *and*

(c) the product may have side effects, or toxic effects, and that there is a risk of dangerous interaction with foods and/or drugs taken concomitantly.

A Member State may provide that the labelling and the user package leaflet shall also state the nature of the tradition in question.

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 ***a statement to the effect that the product is traditionally used and that its efficacy relies on long-term use and experience.***

Article 16h

1. 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 the evaluation of herbal medicinal products.***

In cases where issues involve both committees, the Executive Director shall ensure appropriate coordination with a view to achieving a common position.

2. The Committee for Herbal Medicinal Products 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 ***(pharmacognosy, pharmacology, toxicology, extensive practical expertise of herbal medicine)*** in the evaluation of herbal medicinal products***.*** ***They*** shall represent their competent authorities.

3. The Committee shall establish Community herbal monographs for herbal medicinal products with regard to the application of Article [10a] [10(1), *point* (a), *point* (ii)] as well as traditional herbal medicinal products. The appropriate *coordination* with the committee for Human Medicinal Products shall be ensured by the Executive Directive of the Agency according to Article *67(2)* of Regulation *(EC) No .../2002 [laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency]*. The Committee shall fulfil further responsibilities conferred upon it by provisions of this chapter and other Community *laws*.

When Community herbal monographs in the sense of this paragraph have been established they shall be used as the basis for any application. ***Other appropriate monographs, publications or data may be referred to by the applicant or by the competent authorities of Member States.***

When new Community herbal monographs are established, the registration holder shall within one year *of* the date of establishment of such *a* monograph, introduce a modification to the registration dossier in order to comply with that monograph. The registration holder shall notify that modification to the competent authority of the Member State concerned.

4. The Committee shall adopt its own rules of procedure.

5. The provisions concerning pharmaco-vigilance shall be applied also to herbal medicinal products.

6. Herbal medicinal products produced in Member States or imported from third countries shall fulfil the requirements of good manufacturing practice and quality control pursuant to this Directive.

7. This Directive shall not apply to:

(a) food as defined in Regulation (EC) No 178/2002**,

(b) food supplements as defined in Directive 2002/46/EC,***

(c) cosmetic products as defined in Directive 76/768/EEC*.***

Article 16i

Before ... *****, the Commission shall present a report to the European Parliament and the Council concerning the application of the provisions of this chapter.

The report shall include an assessment on the possible extension of traditional use registration to other categories of medicinal products. ***In the absence of such an extension, a Member State may introduce or retain on its territory specific regulations for traditionally used non-conventional medicinal products other than those referred to in Article 16a. The regulations on quality, safety and efficacy shall comply with the respective principles and characteristics of the non-conventional therapeutic approaches.***

In this case, the Member State concerned shall notify the Commission of the specific rules in force.

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* *Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 193, 17.7.1991, p.30).*

** ***European Parliament and Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).***

*** ***European Parliament and Council Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).***

**** ***Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169). Directive as last modified by Commission Directive 2002/34/EC (OJ L 102, 18.4.2002, p. 19).***

***** ***Three years after the date of entry into force of this Directive."***

Article 2

1. The Member States shall take the measures necessary to comply with this Directive by 31 December 2004. 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 traditional herbal medicinal products as referred to in Article 1 of this Directive, which are already on the market on the entry into force of this Directive, the competent authorities shall apply the provisions of *this* Directive within five years *of* its entry into force.

Article 3

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at ,

For the European Parliament — For the Council

The President — The President