COMMON POSITION (EC) No 65/2003
adopted by the Council on 4 November 2003


(2003/C 305 E/03)

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 European 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 (4) requires that applications for 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 tests 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 within the meaning of Directive 2001/83/EC, he should not be required to provide the results of pre-clinical tests or the results of clinical trials.

(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 differing 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 provided 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 used only where no marketing authorisation can be obtained under Directive 2001/83/EC, in particular because of a lack of sufﬁcient scientiﬁc literature demonstrating a well-established medicinal use with recognised efﬁcacy and an acceptable level of safety. It should likewise not apply to homeopathic medicinal products eligible for marketing authorisation or for registration under Directive 2001/83/EC.

(5) The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, insofar as the efﬁcacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests do not seem necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in speciﬁed conditions of use. However, even a long tradition does not exclude the possibility that there may be concerns with regard to the product’s safety, and therefore 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 that no derogation should be made with regard to the necessary physico-chemical, biological and microbiological tests. Products should comply with quality standards in relevant European Pharmacopoeia monographs or those in the pharmacopoeia of a Member State.

(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.

(2) OJ C 61, 14.3.2003, p. 9.
(7) The simplified registration should be acceptable only where the herbal medicinal product may rely on a sufficiently long 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. Where there is limited evidence of use within the Community, it is necessary to assess carefully the validity and relevance of use outside the Community.

(8) With the objective of further facilitating the registration of certain traditional herbal medicinal products and of further enhancing harmonisation, there should be the possibility of establishing a Community list of herbal substances that fulfill certain criteria, such as having been in medicinal use for a sufficiently long time, and hence are considered not to be harmful under normal conditions of use.

(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 (1) (hereinafter: the Agency). The Committee should carry out tasks concerning the simplified registration and authorisation of medicinal products as provided for in this Directive. 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.

(10) It is important to ensure full consistency between the new committee and the Committee for Human Medicinal Products already existing within the Agency.

(11) In order to promote harmonisation, Member States should recognise registrations of traditional herbal medicinal products granted by another Member State based on Community herbal monographs or consisting of substances, preparations or combinations thereof contained in a list to be established. For other products, Member States should take due account of such registrations.

(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.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is hereby amended as follows:

1. In Article 1 the following points shall be added:

‘29. Traditional herbal medicinal product:

A herbal medicinal product that fulfils the conditions laid down in Article 16a(1).

30. Herbal medicinal product:

Any medicinal product, exclusively 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.

31. Herbal substances:

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed — usually 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 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 or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.’

2. The following Chapter shall be inserted in Title III:

‘CHAPTER 2a: Specific provisions applicable to traditional herbal medicinal products

Article 16a

1. A simplified registration procedure (hereinafter “traditional-use registration”) is hereby established for herbal medicinal products which fulfil all of the following criteria:

(a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

(b) they are exclusively for administration in accordance with a specified strength and posology;

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

(d) the period of traditional use as laid down in Article 16c(1)(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-standing use and experience.

2. Notwithstanding Article 1(30), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication(s).

3. However, in cases where the competent authorities judge that a traditional herbal medicinal product fulfils the criteria for authorisation in accordance with Article 6 or registration pursuant to Article 14, the provisions of this Chapter shall 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 particulars and documents:

(i) referred to in Article 8(3)(a) to (h), (j) and (k),

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

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

(iv) in case of combinations, as referred to in Article 1(30) or Article 16a(2), the information referred to in Article 16a(1)(e) relating to the combination as such; if the individual active ingredients are not sufficiently known, the data shall also 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 any such decision;

(c) bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least thirty years preceding the date of the application, including at least 15 years within the Community. At the request of the Member State where the application for traditional-use registration has been submitted, the Committee for Herbal Medicinal Products shall draw up an opinion on the adequacy of the evidence of the long-standing use of the product, or of the corresponding product. The Member State shall submit relevant documentation supporting the referral;

(d) a bibliographic review of safety data together with an expert report, and where required by the competent authority, upon additional 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 product, as referred to in paragraph 1(c), is characterised by having the same active ingredients, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology 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(c), is satisfied even where the marketing of 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. Where the product has been used in the Community for less than 15 years, but is otherwise eligible for simplified registration, the Member State where the application for traditional-use registration has been submitted shall refer the product to the Committee for Herbal Medicinal Products. The Member State shall submit relevant documentation supporting the referral.

The Committee shall consider whether the other criteria for a simplified registration as referred to in Article 16a are fully complied with. If the Committee considers it possible, it shall establish a Community herbal monograph as referred to in Article 16h(3) which shall be taken into account by the Member State when taking its final decision.

Article 16d

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

(a) a Community herbal monograph has been established in accordance with Article 16h(3), or

(b) the herbal medicinal product consists of herbal substances, preparations or combinations thereof contained in the list referred to in Article 16f.

2. For other herbal medicinal products as referred to in Article 16a, each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by another Member State in accordance with this Chapter.

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 indications do not comply with the conditions laid down in Article 16a,

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

(d) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience,

(e) the pharmaceutical quality is not satisfactorily demonstrated.

2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority that requests it, of any decision they take to refuse traditional-use registration and the reasons for the refusal.

Article 16f

1. A list of herbal substances, preparations and combinations thereof shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain with regard to each herbal substance the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance.

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

3. If a herbal substance, preparation or a combination thereof 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), 6(1), 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 subparagraph, 127 of this Directive as well as Commission Directive 91/356/EEC (*) shall apply, by analogy, to traditional-use registration granted under this Chapter.

2. In addition to the requirements of Articles 54 to 65 any labelling and user package leaflet shall contain a statement to the effect that:

(a) the product is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use; and

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

A Member State may require that the labelling and the user package leaflet shall also state the nature of the tradition in question.
3. In addition to the requirements of Articles 86 to 99 any advertisement for a medicinal product registered under this Chapter shall contain the following statement: “Traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use”.

Article 16h

1. A Committee for Herbal Medicinal Products is hereby established. That Committee shall be part of the Agency and shall have the following competence:

(a) As regards simplified registrations, to:

— perform the tasks arising from Article 16c(1) and (4),

— perform the tasks arising from Article 16d,

— prepare a draft list of herbal substances, preparations and combinations thereof, as referred to in Article 16f(1), and

— establish Community monographs for traditional herbal medicinal products, as referred to in paragraph 3 of this Article.

(b) As regards authorisations of herbal medicinal products, to establish Community herbal monographs for herbal medicinal products, as referred to in paragraph 3 of this Article.

(c) As regards referrals to the Agency under Chapter 4 of Title III, in relation to herbal medicinal products as referred to in Article 16a, to perform the tasks set out in Article 32.

(d) Where other medicinal products containing herbal substances are referred to the Agency under Chapter 4 of Title III, to give an opinion on the herbal substance where appropriate.

Finally, the Committee for Herbal Medicinal Products shall perform any other task conferred upon it by Community law.

The appropriate co-ordination with the Committee for Human Medicinal Products shall be ensured by a procedure to be determined by the Executive Director of the Agency in accordance with Article 57(2) of Regulation (EEC) No 2309/93.

2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Herbal Medicinal Products.

The alternates shall represent and vote for the members in their absence. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products and shall represent the competent national authorities.

The said Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the said Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.

The members of the said Committee may be accompanied by experts in specific scientific or technical fields.

3. The Committee for Herbal Medicinal Products shall establish Community herbal monographs for herbal medicinal products with regard to the application of Article 10(1)(a)(ii) as well as traditional herbal medicinal products. The said Committee shall fulfil further responsibilities conferred upon it by provisions of this Chapter and other Community law.

When Community herbal monographs within the meaning of this paragraph have been established they shall be taken into account by the Member States when examining an application. Where no such Community herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to.

When new Community herbal monographs are established, the registration holder shall consider whether it is necessary to modify the registration dossier accordingly. The registration holder shall notify any such modification to the competent authority of the Member State concerned.

The herbal monographs shall be published.

4. The general provisions of Regulation (EEC) No 2309/93 relating to the Committee for Human Medicinal Products shall apply by analogy to the Committee for Herbal Medicinal Products.
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.


Article 2
1. The Member States shall take the necessary measures to comply with this Directive by ...(**). They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. For the traditional herbal medicinal products as referred to in Article 1, 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 seven years after 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 Union.

Article 4
This Directive is addressed to the Member States.

Done at ...

For the European Parliament
The President

For the Council
The President

(*) Three years after the date of entry into force of this Directive.
(**) 18 months after the date of entry into force of this Directive.
STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION


The proposal is based on Article 95 of the Treaty.


3. The Economic and Social Committee adopted its Opinion on 18 September 2002 (4).

4. On 4 November 2003, the Council adopted its Common Position in accordance with Article 251 of the Treaty.

II. AIM

The aim of the proposal is, within the framework of Directive 2001/83/EC relating to medicinal products for human use, to set out specific rules and procedures on traditional herbal medicinal products in order to facilitate the achievement of the internal market for these products while guaranteeing a high level of health protection.

III. ANALYSIS OF THE COMMON POSITION

The Council has been examining the proposal since 2002. The Council's Common Position is consistent with the aims of the Commission's proposal.

However, the Council has agreed on a number of changes to the Commission's proposal, including editorial and linguistic changes. Apart from changes related to amendments by the European Parliament, the more substantial changes are:

— clarifying the definition of a herbal medicinal product (point 30 of Article 1);

— providing the Member States with the possibility to request the Committee for Herbal Medicinal Products for an opinion on the adequacy of the evidence of longstanding use in relation to Article 16c (1) (c);

— clarifying that medicinal use of corresponding products other than corresponding medicinal products shall be taken into account for the purposes of fulfilling the criteria of longstanding use in Article 16c (1) c if the corresponding product falls under the definition of Article 16c (2);

— clarifying the scope of the competent authorities' obligation to inform the applicant and the Commission of decisions on refusals of applications (Article 16e (2)).

(2) Not yet published in the Official Journal.
(3) Not yet published in the Official Journal.
A. European Parliament amendments accepted in full or in principle

1. Amendment 26 has been incorporated in full while amendments 2, 3, 5, 8, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24 have been accepted partly or in principle.

2. In relation to the Committee for Herbal Medicinal Products’ tasks and composition, the Council agrees with the aim of amendments 2, 20, 21 and 22 to set out a broad competence for the Committee in respect of herbal medicinal products, with due regard to the necessary coordination with the Committee for Human Medicinal Products, and to ensure the necessary expertise for evaluating herbal medicinal products.

   The Council has considered it useful to set out more precisely which tasks the Committee for Herbal Medicinal Products is to be entrusted with in relation to authorisations and registrations.

   Specifically as regards amendment 21, the Council believes that the aim of this amendment is achieved by applying the same provisions on the composition of the Committee for Herbal Medicinal Products as for the Committee for Human Medicinal Products in that they will provide for the possibility of appointing five additional members and for the members to be accompanied by experts.

   In relation to amendment 22 that proposes to allow for other references than monographs, the Council prefers as the Commission to restrict this possibility for cases where no monograph has yet been established. Where a monograph has been established, it should be taken into account when applying for registration as it constitutes a harmonised reference. In addition, the information referred to by the European Parliament can be used when establishing a monograph.

3. The Council can accept the principle of amendments 3 and 14 on having mutual recognition for registered traditional herbal medicines. However, given that products and traditions vary between Member States, the Council believes that it is advisable to make the mutual recognition dependent on the existence of a common reference that will facilitate mutual recognition. Therefore the Council has agreed to provide for mutual recognition when a Community herbal monograph has been established as well as when the product contains substances etc. figuring on the list established in accordance with Article 16f. For other products, there will be an obligation to take due account of registrations granted by other Member States in accordance with the new procedure.

4. The Council has incorporated the essence of amendment 5 and part of amendment 12 allowing for registration of herbal medicinal products that contain non herbal ingredients, however only as concerns vitamins and minerals and only if their action is ancillary regarding the specified claimed indication(s). The Council has chosen not to include other ‘non herbal ingredients’ as this term is too vague, and there is the risk that, in opening up the registration procedure to other unspecified combination products, the concept of a herbal medicinal product may be diluted. For similar reasons and for the sake of clarity, the Council believes that rather than opening up for such combination products via the definitions, it is more appropriate to do this via the criteria for registrations, cf. Article 16a (2).

5. The Council has incorporated amendment 8 and the part of amendment 15 that refer to ‘specified daily doses’, but believes that a reference to the strength should be maintained and that it would be appropriate to use the general term ‘posology’ which means dosage schedule, be it a daily schedule or other (Articles 16a (b) and 16f (1)).

6. The Council accepts the idea contained in amendment 12 that it could be justified to open up for registration of products that have been in use for less than 15 years in the Community but believes that for public health reasons the basic criteria should be kept but with the possibility to derogate from this criterion in cases where the Member State and the Committee for Herbal Medicinal Products consider that the product otherwise fulfils all criteria, in particular in relation to safety, efficacy and quality.
7. The essence of amendments 16, 17 and 19 concerning labelling and package leaflets have been incorporated as these provide for more neutral and concise labelling (Article 16g (2) (a) and (3)) and in case of amendment 17 for a useful additional statement (i.e. on reporting of adverse reactions, cf. Article 16g (2) (b)).

8. In relation to amendments 18, 23 and 24, the Council has accepted the principle of the amendments but as stated by the Commission in its amended proposal, the obligations proposed already follow from existing provisions in Directive 2001/83/EC read in conjunction with the present proposal and no rewording is thus necessary (1).

B. Amendments not accepted in total or partly

The Council has not been able to accept in total or partly amendments 1, 4, 6, 7, 9, 10, 11, 12, 13, 15, 25 and 27 for the same reasons as stated by the Commission in its amended proposal.

(1) Cf. Article 16g (1) referring to the application of provisions on good manufacturing practice and pharmacovigilance and Article 16g (2) referring to the application of in particular Article 59 (see paragraph 1, point c).