

傳統草藥部分修訂指令草案
Traditional Herbal Medicinal Products
(Amending)

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欧洲议会和理事会关于修订 2001/83/EC 指令中传统草药品部分的指令草案

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending the 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 6 ,
Having regard to the opinion of the Economic and Social Committee 7 ,
Acting in accordance with the procedure laid down in Article 251 of the Treaty 8 ,
欧共体欧洲议会和理事会
遵照欧共体条约，特别是其中的第 95 条，
遵照委员会的提议 6
遵照经济和社会委员会的意见 7
依照条约第 251 条项下规定的程序 8

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 9 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.

鉴于:

(1) 2001 年 11 月 6 日，欧洲议会和理事会就共同体法典中人用药品的 2001/83/EC 指令要求，欲获得药品市场准入的申请者，应提供技术细节和文件，它们应包括产品的理化，生物或微生物、药理、毒理和临床试验结果，从而得出其质量，安全性和有效性的证据。

(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.

(2) 若申请者引用发表的详细的科学文献，来阐述药品的单一成分或多个成分具有确切的临床应用，并根据 2001/83/EC 指令的要求，说明它具有确认的疗效和可接受的安全性水平，这样，他可以不必提供临床前或临床研究结果。

(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. These differences currently existing 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 impact on the protection of public health since the necessary guarantees of quality, safety and efficacy are not always given at present.

- (3) 大量的药品，尽管它们很长的历史，如果不能满足具有确切的医疗用途、确认的疗效和可接受的安全性水平的要求，是得不到市场授权的。为了维持市场上的这些产品，成员国已经颁布了不同的程序和规定。各成员国当前已有的各种规定上的差别，可能会阻碍共同体内传统药品的贸易，并导致这些产品生产者间竞争的歧视和扭曲。由于现有产品并不是都具有必要的质量、安全、疗效等的必要保证，它们也许会对公众健康的保护产生影响。
- (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 product eligible for a marketing authorisation or for a registration under Directive 2001/83/EC.
- (4) 考虑到这些药品的特殊性质，特别是具有悠久的历史，对某些传统药品提供一个专门的、简化注册程序是值得的。然而，这种简化程序仅仅适合于在 2001/83/EC 指令中不能获得市场许可的药品，特别是那些由于缺少足够的科学文献来证实其疗效的确切性和其安全性达到可接受水平者。它同样不适合可以获得市场准入或根据 2001/83/EC 指令可以注册的顺势疗法药品。
- (5) The long tradition of the medicinal product enables to renounce clinical trials, insofar as 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 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 the long tradition does not exclude that there may be concerns with regard to the product's safety, so that 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.
- (5) 药品的悠久传统可以放弃临床试验，因此在长期应用和实践的基础上得出药品的有效性似乎是有道理的。依据药品的传统应用信息，在特定情况下使用证明不是有害的，其临床前研究似乎不是必须的。然而，即便是悠久的传统也不能排除对产品安全性的担心，因此主管当局有权要求提供所有必要的资料以评价其安全性。药品质量方面是独立于传统应用的部分，关于其必要的理化的、生物的和微生物的试验是不能缺少的。
- (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.
- (6) 由于有悠久历史和长期应用的大量传统药品是以草药物质为基础的。所以，第一步简化注册的范围限于传统草药看来是合适的。
- (7) The facilitated 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.
- (7) 便利的注册应只接受那些在共同体内有长期临床应用的草药品。共同体以外的医疗应用仅考虑那些曾经在共同体内应用过的药品。

- (8) With the objective to further facilitate the registration of certain traditional herbal medicinal products and to further enhance harmonisation, there should be the possibility to establish a Community list with 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.
- (8) 为了达到进一步便于某些传统草药注册的目的并进一步加强协调,有可能建立一个草药物质的共同体目录,该目录中的草物质要达到一定的标准,例如,具有足够长的药用历史,从而在正常使用下无害。
- (9) Having regard to the particularities of herbal medicinal products, a specific committee 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 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.
- (9) 考虑到草药的特性,应在理事会设立的欧盟药品审评中心内部成立一个专门的委员会 [1993年7月22日,(EEC) No 2309/93 设立了人用和兽用药品批准和监督的共同体程序并设立了欧洲药品审评中心] 10 (下文:简称中心)。委员会应由草药领域的专家组成。其任务主要是建立适用于草药注册和授权的共同体草药专论。
- (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 in case of a procedure regarding an application, which concerns a herbal medicinal product and relies on Directive 2001/83/EC, appropriate co-ordination between the two committees should be ensured, relying on the provisions of Article 55(2) of Regulation 2309/93.
- (10) 保证新委员会和中心目前的人用药品委员会的完全一致是非常重要的,特别涉及到草药的申请程序并依据 2001/83/EC 指令进行处理时,两个委员会应依据 2309/93 条例中第 55 条第二节的规定,进行适当的合作。
- (11) When deciding upon an application for registration of a traditional herbal medicinal product, the Member State concerned should be obliged to take due account of authorisations or registrations previously granted by another Member State for that product. In case 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, unless there are major objections of public health.
- (11) 在决定一个传统草药的注册申请时,有关的成员国有责任适当考虑以前另一个成员国对该产品的授权和注册。对于依照本指令下已建立的专论进行授权和注册的草药,应当认可,除非招到公众健康的极力反对。
- (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.
- (12) 欧盟委员会应给欧洲议会和理事会提交一个有关传统草药章节申请的报告,包括传统应用注册

可能扩展到其他类药品的一个评价。

- (13) It is therefore appropriate to amend Directive 2001/83/CE accordingly,
(13) 因此，应适当的修订 2001/83/CE 指令。

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 that fulfils the conditions laid down in Article 16a;

- (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.

- (31) Herbal substances:

all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances.

Herbal substances are precisely defined by the 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.»

已经采纳该指令：

第 1 条

2001/83/EC 指令修订如下：

- (1) 在第 1 条中加入以下几点：(29) - (32)：

«(29)传统草药品

达到了第 16a 条规定的条件的一个草药产品；

- (30) 草药药品

包含一个或多个草药物质或一个或多个草药制剂，或一个或多个草药物质与一个或多个草药制剂的复方作为活性成份的任何一种药品；而且，产品可以含有由文献证明其安全性的维生素或矿物质或其他非生物成分；这些非草药成分的功效必须对草药活性成分的功效是辅助性的。

- (31) 草药物质

所有基本完整的全株，碎片或切制的植物，植物部位，藻类，真菌类，未经炮制的苔藓类，

通常是干燥形态，但有时也是新鲜的。不经特殊处理的某些分泌物也作为草药物质。

草药物质由使用的植物部位来定义，植物名依照双名系统（属，种，变种和命名人）。

(32) 草药制剂

由草药物质制备而得到，处理方法如萃取，蒸馏，压榨，分馏，纯化，浓缩和发酵。它包括粉碎或粉状的草药物质，酊剂，提取物，挥发油，压榨汁和加工分泌物。“

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

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

(2) 下述新加的 Chapter 2a 插入第 III 篇中

Chapter 2a: 适用于传统草药药品的具体条款

Article 16a

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

- (a) they are indicated exclusively for indications adapted to a traditional herbal medicinal product, which, by virtue of its composition and purpose, is intended and designed for use without the intervention 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;
- (c) they are an oral, external and/or inhalation preparation;
- (d) the period of traditional use as stipulated in Article 16c (1) (c) has elapsed;
- (e) the data on the traditional use of the medicinal product is 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.

第 16a 条

草药品满足如下标准者，可进入简化注册程序（之后称“传统应用注册”）。

- (a) 他们有适合于传统草药品的独特适应症。这些传统草药品以其组成和效果的优势，在没有医生诊断或开方或监督治疗的干涉下就能使用。
- (b) 它们可以根据指定作用强度和剂量进行专门管理。
- (c) 它们是口服，外用和/或吸入制剂。
- (d) 已过第 16c (1) (c)条规定的传统应用期。
- (e) 药品的传统应用资料是充分的，特别是产品被证明在指定的条件下使用是无害的，在长期使用和经验的基础上，其药理作用或药效是有道理的。

然而，主管当局判定某传统草药品达到与第 6 条授权一致的许可标准，或依照第 14 条的注册，则不适用本章的条款。

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.

第 16b 条

- 1、申请者和注册持有者应确定在共同体范围内。
- 2、为了获得传统应用注册，申请者应向有关成员国主管当局提交申请。

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 pharmaceutical tests referred to in the first indent of Article 8(3) (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 (30), the information data referred to in Article 16a (e) relating to the combination as such; if the individual active ingredients are not sufficiently known, the data need 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 such a decision;
- (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;
- (d) a bibliographic review of safety data together with an expert report, 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).

第 16c 条

- 1、申请应附有下列资料：

(a) 细节和文件

- (i) 遵照第 8 条(3)(a)到(h),(j)和(k)
 - (ii) 依照第 8 条(3) (i) 第一段的药理学试验结果
 - (iii) 产品特性概要，不含第 11(4)条中规定的详细数据。
 - (iv) 如第 1 (30)条指出的那样，对于草药复方，与复方有关（第 16a (e)条）的资料数据的引用，尽管个别的活性成分尚不完全清楚，所需数据也要与各自活性成分相关。
- (b) 申请者在其它成员国或第三国得到的任何药品市场准入授权或注册，无论在共同体内或第三国，任何否决其准予授权或注册的细节以及做出该决定的原因。
- (c) 关于那些在申请日前已应用至少 30 年，包括在共同体内使用期至少 15 年的该药品或仿制药品的功效的文献证据或专家证据。
- (d) 安全性数据的文献综述和专家报告，如果主管当局正当要求，需提供必要的资料来评价药品的安全性。类似的方式，附录 I 也适用于 (a) 项中所规定的细节和文件。

2. A corresponding medicinal product, as referred to in paragraph 1 (c), is characterized 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.
- 2、仿制藥品，如第 1 段（c）中所指的，是指利用相同的活性成分（不考慮所使用的賦形劑），相同或相似的治疗目的，相同效价，作为药品使用时相同或相似的给药途径。
 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.
 - 3、即使是产品上市没有得到特殊的授权，在第 1 段（c）中提及的通过 30 年的使用历史来表明其医疗应用，是能够满足要求的。如果药物成分的量或数目在该期间已经减少了，同样也是认可的。
 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 Community for Herbal Medicinal Products. The Committee shall analyse whether the other criteria from 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.
 - 4、如果产品在共同体内应用期不足 15 年，接受传统使用注册申请的成员国应将产品提交草药委员会，委员会应评估第 16 条 a 所提及的简易注册的其他条件是否符合，委员会应建立第 16 条 h(3)所提及的共同体草药专论，成员国据此决定是否给予许可。

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.

第 16d 条

在不违反第 16 条 h(1)的情况下，（2001/83/EC 号指令）第三部第 4 章可同样适用于根据第 16 条 a 给予的注册。

Article 16e

1. Traditional use registration shall be refused if the application does not comply with Articles 16a, 16 b 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 16 a,
 - (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 this, with any decision it makes to refuse traditional use registration on safety grounds and the reasons for this.

第 16e 条

- 1、如果申请与第 16a, 16 b 或 16c 条不符, 或是属于下述情况的任何一种, 该传统应用注册将被拒绝。
 - (a) 定性和/或定量组成与声明中不符者;
 - (b) 治疗适应症不符合第 16 a 条规定条件者;
 - (c) 产品在正常条件下使用可能有害者;
 - (d) 传统应用资料不充分, 特别是在长期应用和经验基础上, 其药理作用或疗效不够确切者;
 - (e) 药品的质量没有得到令人满意的说明者;
- 2、成员国主管当局应提供给申请人以基于安全性考虑所作出的否决传统应用注册的任何决议及其否决的原因, 共同体委员会和任何主管当局都要求这一点。

Article 16f

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.
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) (b) (c) and (d) does not need to be provided. Article 16e (1) (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.

第 16f 条

1. 依据 Article 16h, 委员会应建立一个草药物质目录。该目录应包含每个草药物质的治疗适应症, 指定的效价和剂量, 给药途径和任何其他与草药物质的安全使用有关的必要信息。
2. 如果传统应用注册申请与目录(第 1 段中提及的)中的草药物质有关, 就可以不提供第 16c (1) (b) (c) 和(d) 条所指定的资料。第 16e (1) (c) 和 (d)条 将不适用。
3. 如果目录(第 1 段中提及的)中的草药物质被终止, 依照第 2 段注册的、含有该物质的草药药品将被撤回, 除非按照第 16c (1)条的要求, 在三个月内提交相关的细节和文件。

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 Commission Directive 91/356/EEC 11 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 labeling 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/specified indications and that the safety and efficacy of the product rely exclusively on information obtained from its long-term and experience; and
 - (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.

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 the following statement: “the safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience.”.

第 16g 条

1. 用类推的方法, 本指令的第 3 (1)和 (2), 4(4), 12, 17(1), 19, 20, 23, 24, 25, 40 到 52, 70 到 85, 101 到 108, 111(1) 和 (3), 112, 116 到 118, 122, 123, 125, 126 条第二段, 127 条, 以及共同体委员会的 91/356/EEC 指令 11 适用于本章下授予的传统应用注册。
2. 除了第 54 到 65 条规定的条款外, 任何标签和用户包装说明书应包含一个功效的声明:
 - (a) 产品是传统应用的用于指定适应症的草药品, 产品的安全性和功效仅依赖于从长期的应用和经验所获得的信息; 和
 - (b) 在使用药品过程中, 如若症状持续, 或出现说明书中未提及的副作用, 使用者应当向医生或称职的开业医生咨询。成员国应当规定标签和用户包装说明书也应声明该药品的传统本性。
3. 除了第 86 到 99 条规定的条款外, 以本章下注册的任何药品的广告应包含如下声明: “产品的安全性和功效仅依赖于从长期的应用和经验所获得的信息”。

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 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 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.
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.

3. 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.

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.

When new Community herbal monographs are established, the registration holder shall within one year after the date of establishment of such 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.

第 16h 条

1. 草药品委员会据此成立。该委员会是药品评估机构的一部分。

草药品委员会应承担人用药品委员会在成员国植物药品许可和注册方面的工作。

当含有植物成分的其他药品根据（2001/83/EC 号指令）第三部第 4 章提交给药品评估机构时，草药品委员会应适当给出关于其中草药成分的意见。

药品评估机构的执行理事应根据 2309/93 法规的第 55(2)条制定程序，确保（草药品委员会）与人用药品委员会之间的适当合作。

2. 为指定草药品委员会成员，每个成员国应根据他们在草药品评价方面的职责和经验推荐 5 名候选人。

基于成员国的建议，考虑到委员会多学科性质的需要，药品评估机构的执行理事应按一国一人的原则任命成员。这些成员应与成员国主管机构保持适当联系。

根据成员国的推荐指定的成员可以向药品评估机构执行理事推荐 5 名草药品委员会额外人选，这些人选是依据其各自领域的专长。

委员会成员任期 3 年，可连任。委员会应尽可能根据建议与相关人员、患者和本领域的工作人员的组织建立联系。

3、委员会应建立欧共同体关于第[10a] [10(1)(a)(ii)]条申请的草药品和传统草药品专论。委员会应履行进一步的职责，并根据本章条款的规定和其他共同体的法律来协商。

当本段所指的欧共同体草药专论建立后，将作为任何申请的根据。当欧共同体草药专论建立之前，其他合适的专论、出版物或数据可作为参考。

当共同体新草药专论建立后，注册持有人应在该专论建立之后的一年内，对注册档案提出修改，以符合这些专论。注册持有者应把那些修改意见，通报给有关成员国主管当局。

4. 委员会应采用其自己的程序规则。

Article 16i

Not later than three years 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.

The report shall include an assessment on the possible extension of traditional use registration to other categories of medicinal products.”

第 16i 条

自本指令生效日起三年內， 共同體委員會应当向歐洲議會和理事會提交一份依據本章條款申請的報告。該報告应当包括一份傳統應用註冊可能向其它類別藥品擴展方面的評估。

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, they 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 the present Directive within five years after its entry into force.

第 2 條

1. 成員國應採取必要的措施，在 2004 年 12 月 31 日前與本指令相符。他們應當立即就有关情况通知共同體委員會。當成員國採取了上述措施時，應當包含本指令的一個參考資料或官方正式出版時附上這樣的參考資料。
2. 對於那些本指令 第 1 條所指的传统草药产品，如果已经在市场销售需要实施本指令时，主管当局应当在 5 年內按該指令的規定進行管理。

Article 3

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

第 3 條

本指令自在《歐共體官方雜誌》發表之日起生效。

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament For the Council

The President

The President

第 4 條

本指令提交給成員國。

在布魯塞爾完成。

歐洲議會 理事會

議長 主席

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