Basic information

2002/0008(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Traditional herbal medicinal products Amending Directive 2001/83/EC 1999/0134(COD) **Subject** 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	NISTICÒ Giuseppe (PPE-DE)	19/02/2002

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	NISTICÒ Giuseppe (PPE-DE)	19/02/2002

Former committee for opinion	Former rapporteur for opinion	Appointed
JURI Legal Affairs	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2537	2003-11-04
Competitiveness (Internal Market, Industry, Research and Space)	2570	2004-03-11
Health	2440	2002-06-26

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
17/01/2002	Legislative proposal published	COM(2002)0001	Summary

04/02/2002	Committee referral announced in Parliament, 1st reading		
26/06/2002	Debate in Council		
05/11/2002	Vote in committee, 1st reading		Summary
05/11/2002	Committee report tabled for plenary, 1st reading	A5-0365/2002	
20/11/2002	Debate in Parliament	CRE link	
21/11/2002	Decision by Parliament, 1st reading	T5-0561/2002	Summary
09/04/2003	Modified legislative proposal published	COM(2003)0161	Summary
04/11/2003	Council position published	12754/1/2003	Summary
06/11/2003	Committee referral announced in Parliament, 2nd reading		
02/12/2003	Vote in committee, 2nd reading		Summary
02/12/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0452/2003	
16/12/2003	Debate in Parliament	CRE link	
17/12/2003	Decision by Parliament, 1st reading	T5-0579/2003	Summary
11/03/2004	Act approved by Council, 2nd reading		
31/03/2004	Final act signed		
31/03/2004	End of procedure in Parliament		
30/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/0008(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Nature of procedure	Legislation
Legislative instrument	Directive
	Amending Directive 2001/83/EC 1999/0134(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16964

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0365/2002	05/11/2002	
Text adopted by Parliament, 1st reading/single reading		T5-0561/2002 OJ C 025 29.01.2004, p. 0222-0361 E	21/11/2002	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0452/2003	02/12/2003	
Text adopted by Parliament, 2nd reading		T5-0579/2003 OJ C 091 15.04.2004, p. 0134-0375 E	17/12/2003	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	13601/2003	17/10/2003	
Council position	12754/1/2003 OJ C 305 16.12.2003, p. 0052-0060 E	04/11/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2002)0001 OJ C 126 28.05.2002, p. 0263 E	17/01/2002	Summary
Modified legislative proposal	COM(2003)0161	09/04/2003	Summary
Commission communication on Council's position	SEC(2003)1247	05/11/2003	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2004)0114	13/02/2004	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
ESC	Economic and Social Committee: opinion, report	CES1008/2002	18/09/2002	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2004/0024
OJ L 136 30.04.2004, p. 0085-0090 Summary

Traditional herbal medicinal products

2002/0008(COD) - 31/03/2004 - Final act

PURPOSE : to establish a harmonised legislative framework for traditional herbal medicinal products. LEGISLATIVE ACT : Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. CONTENT : this Directive 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 traditional herbal medicines by introducing harmonised rules and procedures and encouraging cross-border trade in these products, which at the moment is very limited. This Directive also 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. However, 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. ENTRY INTO FORCE : 30/04/2004. IMPLEMENTATION : 30/10/2005.

Traditional herbal medicinal products

2002/0008(COD) - 05/11/2003 - Commission communication on Council's position

The Council common position introduces a number of changes in the Commission's amended proposals. However, they are consistent with the objectives and main principles contained in the proposal. The Commission agrees with the text of the common position, adopted by unanimity. The Council and the Commission made the following statement which confirms that medicinal use which has taken place on the territory of a new Member State is to be taken into account for the purpose of application of Article 16c(1)c) even if it has partly or fully occurred before the accession of that State.

Traditional herbal medicinal products

2002/0008(COD) - 04/11/2003 - Council position

The Council's common position, adopted by unanimity, is in accordance with the objectives of the Commission's proposal and accepts in totality or in principle, 17 amendments adopted by the European Parliament in first reading. The amendments taken on board by the Council concern the following issues: - in relation to the Committee for Herbal Medicinal Products' tasks and composition : the Council agrees with the aim of Parliament's amendments which are 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. The council also believes that the aim shall be 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; - concerning allowing 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; - on having mutual recognition for registered traditional herbal medicines : the Council . However, given that products and traditions vary between Member States, the Council believes that it is advisable to make the mutual recognition dependant 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; - registration of herbal medicines : this amendment allows 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). - concerning specified daily doses : the Council has incorporated this amendment but believes that a reference to the strength should be maintained and that it would be appropriate to use thegeneral term "posology" which means dosage schedule, be it a daily schedule or other (Articles 16a (b) and 16f (1)); - the Council accepts the idea contained in the amendment concerning the duration of the minimum use of products. It states 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. - on labelling and packaging : this amendment concerning labelling and package leaflets have been incorporated as these provide for more neutral and concise labelling. The common position incorporates a number of changes, including editorial and linguistic changes. The Council has also introduced changes as to certain provisions, which do not respond directly to an amendment of the European Parliament or a provision of the Commission's proposal. The Council has modified point 31 of Article 1 with a view to clarifying the definition of herbal medicinal products. The Commission supports this amendment, which does not represent a change in substance. The common position provides 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 (under Article 16c(1)(c)). The Commission accepts this amendment, which will permit the application of European expertise in the particular area of longstanding use of herbal medicinal products. The common position clarifies that medicinal use related to other corresponding products than corresponding medicinal products shall be taken into account for the purposes of fulfilling the criteria of longstanding use in Article 16 c (1) c if the corresponding product falls under the definition of Article 16 c (2). The Commission agrees to the wording proposed by the Council, which does not amend the substance of the provision. The Council has amended the scope of the competent authorities' obligation to inform the applicant and the Commission of decisions on refusals of applications for traditional use registration (Article 16e (2)). In particular, it has deleted the reference to "safety grounds", so that the obligation to inform will apply in every case of refusal, whatever the grounds.

Traditional herbal medicinal products

2002/0008(COD) - 21/11/2002 - Text adopted by Parliament, 1st reading/single reading

The European Parliament resolved to adopt the report by Giuseppe NISTICO (EPP-ED, Italy) on herbal medicine. (Please refer to the document dated 5/11/02.) Parliament also inserted an amendment stating that 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 Directive 2001/83/EC.

Traditional herbal medicinal products

2002/0008(COD) - 17/01/2002 - Legislative proposal

PURPOSE : to establish a harmonised legislative framework for traditional herbal medicinal products and to provide a special registration procedure allowing the registration and the marketing of certain traditional herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy (amending Directive 2001/83/EC). CONTENT : the purpose of the proposed Directive is to lay down specific provisions traditional herbal medicinal products in the Community. It brings together the European experience and understanding in the field of traditional herbal medicines with the essential aim of safeguarding public health and satisfying the consumer choice. Trade in traditional herbal medicinal products within the Community is, at present, hindered by disparities between the national requirements and differences in basic traditional use concepts in EU. More specifically, the draft Directive aims to establish a harmonised legislative framework for traditional herbal medicinal products and hence is based on Article 95 of the EC Treaty. Since the differences currently existing between the situation in the Member States constitute an obstacle to the free movement of these goods within the Community, a certain harmonisation on the European level appears necessary and is consistent with the principle of subsidiarity. The draft Directive is limited to those provisions considered indispensable to attain a sufficient degree of harmonisation while ensuring

the full protection of public health and therefore respects also the principle of proportionality. The proposed Directive provides for a special registration procedure allowing the registration and, hence, the marketing of certain traditional herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy. However, the same requirements apply to the manufacturing of these products and their quality. In order to further improve the protection of public health, the Directive provides a special legal framework for traditional herbal medicinal products, thus removing the differences and uncertainties about the status of these products currently existing in the Member States. For reasons of coherence and legibility of the regulatory framework, the specific provisions on traditional herbal medicinal products shall be introduced in the new Community code relating to medicinal products for human use, as contained in Directive 2001/83/EC. In addition, to ensure a full participation and involvement of experts in the field of herbal medicinal products, a new Committee for Herbal Medicinal Products shall be set up within the European Agency for the Evaluation of Medicinal Products. One of the Committee's major tasks will be to establish monographs that further harmonise and facilitate registration applications concerning herbal medicine.

Traditional herbal medicinal products

2002/0008(COD) - 17/12/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Giuseppe NISTICO (EPP-ED, I), making few amendments to the common position. (Please see the summary dated 02/12/03).

Traditional herbal medicinal products

2002/0008(COD) - 09/04/2003 - Modified legislative proposal

The European Parliament adopted twenty-four amendments in total, of which the Commission accepted in full two; thirteen in principle; and rejected ten. The two accepted by the Commission are: - The recognition of herbal medicinal product in cases where a monograph has been established. - Presenting a Commission report to the European Parliament and the Council on the application of the Directive. The Commission can accept in part or in principle amendments relating, inter alia, to: - An extension of responsibilities for the new "Committee for Herbal Medicinal Product". Those responsibilities should include issues relating to national authorisations and registrations of herbal medicinal products, in particular the referral /arbitration procedure for such products. For medicinal products, which contain herbal ingredients without fulfilling the definition of herbal medicinal product, the new Committee for Herbal Medicinal Product should be entitled to give an opinion on the herbal ingredients when deciding on the product in its entirety. - A provision obliging Member States to recognise decisions by other Member States instead of a mere obligation to take due account of such decision. - An extension of the simplified registration procedure to include medicinal products containing non-herbal ingredients (such as vitamins and minerals or other non-biological substances for which there is well documented evidence regarding their safety.) - Amendments 8 and 15 relating to the specified daily dosage. The proposed Directive has been modified by the Commission to refer specifically to "the specified strength and posology" of a product. - On the question of labelling the Commission accepts in principle the amendments proposed by the Parliament though it does seek to clarify the wording 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 use. - A rewording of the provisions requiring users of herbal medicines to consult a doctor should adverse reactions occur - even if they are not mentioned in the leaflet accompanying the product. - The provision of information pointing to possible dangerous interactions with food and/or medicinal products. - On the question of advertising the Commission accepts that herbal medicinal products should include the statement that "the safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience." - The use of monographs, publications or data in a simplified procedure - even if the Committee for Herbal Products has not yet established them. Such information however shall only be used in cases where the Committee for Herbal Medicinal Products has not yet established specific monographs. The amendments rejected by the Commission refer, inter alia, to those: - Allowing Member States to register certain herbal products even though they stem from outside of the Community. - Defining a herbal medicinal product. The definition outlined in the Commission proposal is identical to that of a scientific definition agreed within the Council of Europe. - On therapeutic indications and its classification as a "non-prescriptive" medicine. - Referring to the pharmacological activity of the herbal ingredients. - Regarding the data to be submitted by the applicant. - Requiring the Committee to draw up a classification of herbal medicinal products. - Excluding certain categories of products from the scope of the new Directive. - Allowing Member States to introduce or retain specific national law for traditional medicines other than those of herbal origin.

Traditional herbal medicinal products

2002/0008(COD) - 13/02/2004 - Commission opinion on Parliament's position at 2nd reading

The Commission can accept in full the two amendments to the Council's common position adopted by Parliament. The Council's common position and Parliament's amendments make certain changes to the Commission's amended proposal, which are nevertheless in line with the objectives and general principles on which the proposal is based. The amendments adopted by Parliament serve mainly to clarify the text of the Directive. One amendment confirms that foodstuffs, including plant-based foodstuffs, will continue to be governed by legislation on foodstuffs and the other clarifies the type of herbal substances that the Committee should include in the future list, the purpose of which is to provide a harmonised list of the herbal substances likely to be used in traditional herbal medicinal products.