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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council directive amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(12754/1/2003 – C5-0519/2003 – 2002/0008(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Giuseppe Nisticò

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

PROCEDURAL PAGE

At its sitting of 21 November 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive amending the Directive 2001/83/EC as regards traditional herbal medicinal products (COM(2002) 001 – 2002/0008(COD)).

At the sitting of 6 November 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (12754/1/2003 – C5-0519/2003).

The committee had appointed Giuseppe Nisticò rapporteur at its meeting of 19 February 2002.

It considered the Commission proposal and the draft recommendation for second reading at its meetings of 27 November and 2 December 2003.

At the last meeting it adopted the draft legislative resolution unanimously.

The following were present for the vote: Caroline F. Jackson (chairman), Mauro Nobilia, Alexander de Roo and Guido Sacconi (vice-chairmen), Giuseppe Nisticò (rapporteur), Bent Hindrup Andersen (for Hans Blokland), Jean-Louis Bernié, David Robert Bowe, John Bowis, Niels Busk (for Astrid Thors), Dorette Corbey, Chris Davies, Avril Doyle, Saïd El Khadraoui, Marialiese Flemming, Françoise Grossetête, Cristina Gutiérrez Cortines, Karin Jöns (for Béatrice Patrie), Martin Kastler, Hedwig Keppelhoff-Wiechert (for Martin Callanan), Christa Klaß, Bernd Lange, Paul Lannoye (for Marie Anne Isler Béguin), Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Rosemarie Müller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Giacomo Santini (for Robert Goodwill), Karin Scheele, Inger Schörling, María Sornosa Martínez, Catherine Stihler, Robert William Sturdy (for Eija-Riitta Anneli Korhola), Antonios Trakatellis, Phillip Whitehead.

The recommendation for second reading was tabled on 3 December 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a European Parliament and Council directive amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (12754/1/2003 – C5-0519/2003 – 2002/0008(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (12754/1/2003 – C5-0519/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2002) 001)[2],

– having regard to the amended proposal (COM(2003) 161)[3],

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0452/2003),

1. Amends the common position as follows;

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

Council common position	Amendments by Parliament

Amendment 1
RECITAL 11a (new)

	(11a) The present directive allows non-medicinal herbal products, fulfilling the criteria of food legislation to be regulated under food legislation in the Community.

Justification

Many products which are used in traditional therapy are not medicines but fall under food legislation. In many cases they are imported from outside the EU but also produced in the EU. It is important to ensure that these products can continue to fall under food legislation even when regarded as health products.

[1] Texts Adopted, 21.11.2002, P5_TA(2002)0561.
[2] OJ C 126 E, 28.5.2002, p.263.
[3] Not yet published in OJ.

Amendment 2
ARTICLE 1, POINT 2
Article 16f, paragraph 1 (Directive 2001/83/EC)

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.	1. A list of herbal substances, preparations and combinations thereof shall be established in accordance with the procedure referred to in Article 121(2) ***for their use in traditional herbal medicinal products***. 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 ***as a traditional medicinal product***.

Justification

Partial reinstatement of amendment 28 from first reading.

The list to be set up by the Committee for Herbal Medicinal Products should only cover the medicinal use of herbal substances. The same substance may already be regulated for use in food in various Member States and this should not be affected by the proposal.

EXPLANATORY STATEMENT

The value of medicinal plants, and by that of herbal medicinal products, is nowadays widely recognised as an important complement to modern chemical medicines. There is even further scope for the better exploitation of the therapeutic potential of medicinal plants. At the same time it is important to ensure an appropriate use of herbal medicines by adequate quality, safety and efficacy standards.

During its first reading the European Parliament gave support to the general approach chosen by the European Commission for a new legislative framework in relation to traditional herbal medicines. The current legislation for well-established herbal medicines, possibly even supported with modern clinical trials, will be complemented by a category of herbal medicines of traditional use. This does not affect the use of plants in other product categories. Plants will continue to have the possibility to be used in food stuff respectively food supplements depending on the national legislation in the EU Member States, which may be harmonised in the future by an amendment of the EU food supplement directive respectively by the envisaged regulation on food fortification.

While supporting the basic structure for the categorisation of herbal medicinal products, the European Parliament agreed during its first reading on a range of important amendments in order to make the legal requirements for traditional herbal medicines more appropriate. It is with a considerable level of satisfaction that the rapporteur can note that the key points agreed upon in the European Parliament during the first reading have been supported by the European Commission and were also leading to an agreement in the Council of Ministers, which clearly shows the original handwriting coming from the European Parliament. The European Commission and the Council followed the opinion of the European Parliament in particular with regard to the composition of a traditional herbal medicine, the acceptance of non-EU tradition, the mutual recognition of a traditional herbal medicine, the labelling and advertising requirements, the role of the new Committee for Herbal Medicinal Products and the transitional arrangements.

Concerning the composition of a traditional herbal medicine, the European Parliament advocated wider combination possibilities. The Council agreed on the principle and wishes to permit the possibility to include vitamins and minerals provided that the action of the vitamins and minerals is ancillary to that of the herbal active ingredients. As most of the traditional combination products between a herbal and a non-herbal ingredient are indeed combinations with vitamins and minerals, this is an acceptable position from the viewpoint of the rapporteur.

The structure of the legal provisions make it also clear that there are no EU wide legislative provisions which prohibit or restrict the use of herbals in food respectively food supplements. By July 2007, the European Commission will present a report on the advisability to include additional categories of substances into the existing legal provisions for food supplements. Possibly this will be combined with a proposal for extended legislation which may then cover categories such as herbals, aminoacids and fatty acids. Until that time, the national legal provisions continue to prevail. Provided that the respective legal provisions are respected, this will allow the use of plants in medicines as well as in food respectively food supplements.

A particularly sensitive topic during the first reading at the European Parliament was the acceptance of non-European tradition when deciding on the status of traditional herbal medicinal products. The European Parliament agreed that a minimum term of use is needed within the European Community (10 years according to the European Parliament). This is supposed to be part of a time period of use of at least 30 years preceding the date of application. The Council in line with the European Commission insisted on a minimum term of 15 years, however, following the concerns expressed by the European Parliament, the Council could agree to open up an additional route for products with less than 15 years of use in the European Community. After an application for a traditional use registration has been submitted, Member States may refer such an application to the Committee for Herbal Medicinal Products. The Committee shall consider the relevant documentation and decide on the establishment of a community herbal monograph, which then would allow the acceptance on the national markets. This is an acceptable compromise in a very difficult debate and will ensure an open attitude towards tradition from outside the European Union while applying the general quality, safety and efficacy standards as established for this kind of medicines in the European Union.

While the original approach of the European Commission in relation to traditional herbal medicines was primarily looking at the acceptance on national markets, the European Parliament insisted on the possibility of mutual recognition by other Member States also for this kind of products. Both the European Commission and the Council took this request of the Parliament into account and the common position foresees now mutual recognition for all products which are covered by a community monograph respectively a list of herbal substances. This will allow applying the general principles of mutual recognition to a large part of traditional herbal medicines and is therefore a very positive result.

Again in line with the spirit of the amendment adopted in the European Parliament in first reading, both the Commission and the Council agreed on a far more reasonable wording with regard to labelling and advertising of traditional herbal medicines. Contrary to the original proposal advocating a quite negative disclaimer, the agreement of the Council now requires a statement on the labelling and in advertising that the product is for use in the specified indication which is exclusively based upon long standing use. This is an appropriate reflection of the reality and allows the patient and consumer to have the necessary background information on the product concerned. Such a message does not frighten the individual unnecessarily and again it is with a considerable level of satisfaction that the rapporteur can note the move of the other European institutions in the direction advocated by the European Parliament.

Of particular importance for the future evaluation and assessment of herbal medicinal products will be the establishment of an independent Committee for Herbal Medicinal Products within the European Medicines Evaluation Agency. While the original proposal was giving to this Committee a very limited responsibility, the common position now defines a much wider scope of tasks including in particular the final judgement in an arbitration process in cases where a mutual recognition procedure between EU Member States could not be finalised successfully. This enlarged responsibility of the Committee for Herbal Medicinal Products will ensure an appropriate assessment and will also give the confidence to the manufacturers in the area to submit applications as they can now expect that the best available expertise in the sector will judge their products.

Finally, the Council also took into account the considerable concerns the European Parliament with regard to products not covered by the scope of the traditional herbal medicines directive. It is appreciated that the Commission will present not later than 3 years after the date of entry into force of this directive a report to the European Parliament and the Council including an assessment on the possible extension of traditional use registration to other categories of medicinal products. Further on the Council included a transition period of 7 years which allows manufacturers to make appropriate adjustments.

In summary therefore, the common position includes all major points raised by the European Parliament in first reading. The text agreed by the Council based on the amendments suggested by the European Parliament is clearly a considerable improvement in comparison with the original European Commission's proposal. The results may even be regarded as a model for an efficient and adequate cooperation between the European institutions. According to the rapporteur, the European Parliament can be most satisfied with the results of the process.