COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 313 final - SYN 251 and 252

Brussels, 2 August 1991

Amendment to the proposal for a

COUNCIL DIRECTIVE

widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws of the Member States on medicinal products and laying down additional provisions on homeopathic medicinal products

SYN 251

Amendment to the proposal for a

COUNCIL DIRECTIVE

widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products

SYN 252

(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

EXPLANATORY MEMORANDUM

At its plenary session on 13 June 1991, the European Parliament, on first reading of the co-operation procedure, gave its opinion upon two proposals for Directives relating to homeopathic medicines for human and veterinary use - COM(90)72 of 22.03.90, SYN 251-252.

The Commission has decided, in accordance with Article 149, paragraph 3 of the EEC Treaty, to amend its proposals in order to incorporate into the text 17 out of the 28 amendements adopted by the Parliament.

The primary aims of the amendments accepted by the Commission are :

- to avoid the distortion of competition between manufacturers

- to maintain the principle of a free choice of therapies

- to assimilate anthroposophic medicines as homeopathic medicines when described in an offical pharmacopoeia

- to introduce appropriate references to homeopathic and anthroposophic principles.

By contrast, the Commission rejected other amendments for three principal reasons.

Certain of the amendments go far beyond the limits of those proposals which deal with the free movement of medicines, for example; training for and engaging in professional practice, and the way in which the cost of medicines to the patient is met by public funding.

Some amendments show excessive partiality towards particular medical traditions, bearing in mind that the Commission must remain neutral in the debate between "conventional" and "alternative" medicine.

Other amendments would widen excessively the scope of the simplified registration procedure (Article 7), to the extent that a full marketing authorization (Article 9) would become an exception to the normal rule.

It is worth recalling that since 1965 throughout the Community the normal basis for a marketing authorization has been three standard criteria (quality, safety and efficacy) leading the competent authorities to undertake an evaluation of the risks and benefits expected of the medicament in question.

However, the simplified registration procedure, in the form proposed by the Commission, constitutes rather an administrative notification, adequate for homeopathic medicines which do not present any known risk by virtue of their method of administration (oral) and the low concentration of their active constituents, which is fixed at less than one part per million. Manufacturing quality can be verified from the dossier supplied.

The other routes of administration described by the pharmacopoeias, especially injectibles, or stronger concentrations of active constituents, can, in certain cases, expose patients to potential risks and necessitate because of this a more comprehensive authorization procedure based upon an evaluation of the risks and benefits by the competent authorities in accordance with the provisions of Article 9.

Amendment to the proposal for a

COUNCIL DIRECTIVE

widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws of the Member States on medicinal products and laying down additional provisions on homeopathic medicinal products

SYN 251

(Presented by the Commission in accordance with article 149, paragraph 3 of EEC Treaty)

Original proposal	Amended proposal
Titles and visas unchanged	
First recital	
Whereas differences currently existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic medicinal products within the Community;	Whereas differences currently existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic medicinal products within the Community and thus lead to discrimination and distorsion of competition between manufacturers of these products;
2nd recital unchanged	
Recital 2a (new)	
	Whereas freedom of choice with regard to therapy needs to be safeguarded; whereas, despite considerable differences in the status of alternative medicines in the various Member States, patients should be quaranteed free access to the therapy of their choice, provided all precautions are taken to ensure the quality and safety of products;
3rd recital unchanged	

Original proposal	Amended proposal
	Fourth recital
Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States; whereas, therefore, it is appropriate to recognize certain national homeopathic traditions without imposing them throughout the Community;	Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States;
	5th, 6th and 7th recitals unchanged
	Eighth recital
Whereas, having regard to the particular characteristics of these medicinal products, such as their very low content of active principles and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is appropriate to provide a simplified registration system for those traditional homeopathic medicinal products which are placed on the market without specific therapeutic indications in a preparation which does not present a risk for the patient;	Whereas, having regard to the particular characteristics of these medicinal products, such as their very low content of active principles and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is appropriate to provide a simplified registration system for those traditional homeopathic medicinal products which are placed on the market without specific therapeutic indications in a preparation and dosage which does not present a risk for the patient;
	9th recital unchanged

Original proposal	Amended proposal
Article 1	
For the purposes of this Directive "homeopathic medicinal product" shall mean any medicinal product prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, or in the absence thereof, by the official pharmacopoeia of a Member State.	For the purposes of this Directive "homeopathic medicinal product" shall mean any pharmaceutical preparation prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, or in the absence thereof, by the official pharmacopoeia of a Member State.
	For the purposes of this Directive anthroposophical medicinal products described by an official pharmacopoeia shall be treated as equivalent to homeopathic medicinal products.
Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions.	Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions and potentiation. A homeopathic medicinal product may also contain a member of different components.
	A homeopathic preparation may contain, with the exception of catalysts, only homeopathic stocks in a minimum dilution of 1:10.
Articles 2, 3, 4, 5 and 6 unchanged	
Article 7, paragraph 1 unchanged	
Article 7 (2)	
Seventh indent a (new)	
	- a sentence advising the user to consult a competent therapist whilst using the medicinal product if the if the symptoms persist.
Rest of the article unchanged	

Original proposal	Amended proposal
Article 8, introductory phrase and first three indents	
An application for a simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch consistency of the products concerned :	An application for a simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch consistency of the products concerned :
- scientific name of the homeopathic stock, together with a mention of the various routes of administration, pharmaceutical forms and dilutions to be registered;	- scientific name of the homeopathic stock or stocks, together with a mention of the various routes of administration, pharmaceutical forms and strengths to be registered;
- dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate homeopathic bibliography;	- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate homeopathic or anthroposophical bibliography;
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution;	- manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
Rest of the article unchanged	

Original proposal	Amended proposal
Article 9 (1)	
1. Homeopathic medicinal products other than those referred to in Article 7 shall be authorized and labelled in accordance with the provisions of Articles 5 to 21 of Directive 65/65/EEC and Articles 1 to 7 of Directive 75/319/EEC, including the provisions concerning proof of therapeutic effect.	1. Homeopathic and antroposophical medicinal products other than those referred to in Article 7 shall be authorized and labelled pursuant to the provisions of Articles 5 to 21 of Directive 65/65/EEC and Articles 1 to 7 of Directive 75/319/EEC, including the provisions concerning proof of therapeutic effect, in accordance with the basic principles and special nature of homeopathic or anthroposophical medicine.
Article 9(2) unchanged	
Article 10 (1) and (2) unchanged	
Article 10 (3) (new)	
	3. Not later than 31 December 1995 the Commission shall present a report to the Council and to the European Parliament concerning the operation of this Directive.
Article 11 unchanged	

Amendment to the proposal for a

COUNCIL DIRECTIVE

widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products

SYN 252

(presented by the Commission in accordance with Article 149, paragraph 3 of the EEC Treaty)

Original proposal	Amended proposal
First recital	
Whereas differences currently existing between the provisions laid down by law, regulation or administrative action by the Member States may hinder trade in homeopathic medicinal products within the Community;	Whereas differences currenlty existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic medicinal products within the Community and thus lead to discrimination and distorsion of competition between manufacturers of these products;
2nd recital unchanged	
Recital 2a (new)	
	Whereas freedom of choice with regard to therapy needs to be safequarded;
3rd recital unchanged	
Fourth recital	
Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States; whereas, therefore, it is appropriate to recognize certain national homeopathic traditions without imposing them throughout the Community;	Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States;
5th, 6th and 7th recitals unchanged	

Original proposal	Amended proposal
Eighth recital	
Whereas, having regard to the particular characteristics of these medicinal products, such as their very low content of active principles and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is appropriate to provide a simplified registration system for those traditional homeopathic veterinary medicinal products which are placed on the market without specific therapeutic indications in a preparation which does not present a risk for the animal or the consumer of animal products;	Whereas, having regard to the particular characteristics of these medicinal products, such as their very low content of active principles and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is appropriate to provide a simplified registration system for those traditional homeopathic veterinary medicinal products which are placed on the market without specific therapeutic indications in a preparation and dosage which does not present a risk for the animal or the consumer of animal products;
9th recital unchanged	
Article 1	
For the purposes of this Directive "homeopathic veterinary medicinal product" shall mean any veterinary medicinal product prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, or in the absence thereof, by the official pharmacoposia of a Member State.	For the purposes of this Directive "homeopathic veterinary medicinal product" shall mean any pharmaceutical preparation prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, or in the absence thereof, by the official pharmacopoeia of a Member State.
Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions.	Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions and potentiation. A homeopathic medicinal product may also contain a number of different components.

Homeopathic preparations may contain, with the exception of catalysts, only homeopathic stocks, in a minimum of 1:10.

Articles 2, 3, 4, 5, 6 and 7 unchanged

Original proposal	Amended proposal
Article 8	
An application for a simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch to batch consistency of the products concerned :	An application for a simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch to batch consistency of the products concerned :
- scientific name of the homeopathic stock, together with a mention of the various routes of administration, pharmaceutical forms and dilutions to be registered;	- scientific name of the homeopathic stock or stocks, together with a mention of the various routes of administration, pharmaceutical forms and strengths to be registered;
- dossier described how the stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate homeopathic bibliography;	- dossier describing how the homeopathic stock/stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate homeopathic bibliography;

- manufacturing and control file for each pharmaceutical form and a description of the method of dilution;	- manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
- manufacturing authorization for the preparations concerned;	- manufacturing authorization for the preparations concerned;
- copies of any registrations or authorizations obtained for the same preparations in other Member States;	- copies of any registrations or authorizations obtained for the same preparations in other Member States;
- one or more specimens or mock-ups of the sales presentation of the preparations to be registered.	- one or more specimens or mock-ups of the sales presentation of the preparations to be registered;
	- documents guaranteeing the safety of the preparation and, in the case of veterinary medicinal products intended for administration to food-producing animals, guaranteeing the absence of harmful residues.

Original proposal	Amended proposal
Article 9	
Homeopathic veterinary medicinal products other than those referred to in Article 7 shall be authorized and labelled in accordance with the provisions of Articles 5 to 15 of Directive 81/851/EEC, including the provisions concerning proof of therapeutic effect, and shall be labelled in accordance with the provisions of Articles 43 to 50 of Directive 81/851/EEC.	Homeopathic veterinary medicinal products other than those referred to in Article 7 shall be authorized and labelled in accordance with the provisions of Articles 5 to 15 of Directive 81/851/EEC, including the provisions concerning proof of therapeutic effect, and shall be labelled pursuant to the provisions of Articles 43 to 50 of Directive 81/851/EEC, in accordance with the basic principles and special nature of homeopathic or anthroposophical medicine.
Article 10, paragraphs 1 and 2 unchanged	
Article 10 (3) (new)	
	3. Not later than 31 December 1995 the Commission shall present a report to the Council and to the European Parliament concerning the operation of this Directive.
Article 11 unchanged	

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DOCUMENTS

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