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**I

R E P O R T

by the Committee on the Environment, Public Health and Consumer Protection

on the proposals from the Commission to the Council for directives:

I. 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
(COM(90) 0072 final - C3-0112/90 - SYN 251)

II. 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
(COM(90) 0072 final - C3-0113/90 - SYN 252)

Rapporteur: Mr Raphäel CHANTERIE

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By letter of 6 April 1990 the Council consulted the European Parliament, pursuant to Article 100a of the EEC Treaty, on the Commission 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 and 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.

At the sitting of 14 May 1990 the President of Parliament announced that he had referred these proposals to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Agriculture, Fisheries and Rural Development and the Committee on Legal Affairs and Citizens' Rights for their opinions.

At its meeting of 30 May 1990 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Chanterie rapporteur.

It considered the Commission's proposals and the draft report at its meetings of 26 September and 18 December 1990 and 21 March 1991.

At the last such meeting it approved the draft legislative resolutions by 22 votes in favour with 2 abstentions.

The following took part in the vote: Collins, chairman; Schleicher and Scott-Hopkins, vice-chairmen; Chanterie, rapporteur; Balfe (for Green, pursuant to Rule 111(2) of the Rules of Procedure); Bowe, Diez de Rivera, Icaza, Fernex (for Monnier-Besombes, pursuant to Rule 111(2) of the Rules of Procedure), Florenz, Guidolin, Caroline Jackson, Jensen, Kuhn, Lannoye (for Amendola), Nordmann (for Veil), Oomen-Ruijten, Partsch, Pimenta, Pollack, Quistorp, Roth-Behrendt, Llewellyn Smith, Valverde Lopez and Vernier.

The opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and of the Committee on Agriculture, Fisheries and Rural Development are attached. The Committee on Legal Affairs and Citizens' Rights decided on 28 June 1990 not to deliver an opinion.

The report was tabled on 11 April 1991.

The deadline for tabling amendments will appear in the draft agenda for the part-session at which the report is to be considered.

A.

I. Proposal from the Commission to the Council for a 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

Commission text[1]	Amendments
	(Amendment No. 1) 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 distortion of competition between manufacturers of these products;
	(Amendment No. 2) Recital 2a - new
	whereas freedom of choice with regard to therapy needs to be safeguarded
	(Amendment No. 3) Recital 3a - new
	whereas allopathy, anthroposophy and homeopathy should be regarded as different approaches which each have their own merits and which may in many cases complement each other;

[1] For complete text see COM(90) 0072 final - OJ No. C 108, 01.05.1990, p. 010.

(Amendment No. 4)
Recital 4a - new

Whereas, although these differences in status currently prevent total harmonization of alternative medicines practised within the EEC (particularly with regard to pharmacopoeias, medical practice, reimbursement from social security funds and teaching), this exercise should be undertaken within a reasonable period; whereas, therefore, it is appropriate to recognize certain national homeopathic and anthroposophical traditions without imposing them throughout the Community;

(Amendment No. 5)
Recital 4b - new

Whereas anthroposophical medicine plays a significant role in alternative medicine in some Member States and whereas the interests of patients choosing this type of medicine need to be safeguarded;

(Amendment No. 6)
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;

(Amendment No. 7)
Ninth recital

Whereas, however, the usual rules governing the authorization to market medicinal products should be applied to a homeopathic medicinal product marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect;	Whereas, however, the usual rules governing the authorization to market medicinal products should be applied to a homeopathic medicinal product marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; whereas the necessary provisions for authorization to market homeopathic medicinal products with therapeutic indications should take account of the characteristics of the homeopathic treatment;
whereas those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission;	whereas those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission;

(Amendment No. 8)
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. A homeopathic medicinal product may also contain of a number of different components. 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 or by grinding.	Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions and potentiation. A homeopathic preparation may contain, with the exception of catalysts, only homeopathic stocks in a minimum dilution of 1:10.

(Amendment No. 9)
Article 7(1)

1. Homeopathic medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:	1. Homeopathic medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:
- they are administered orally or externally;	- they are administered in accordance with the methods described in the European Pharmacopoeia, or in the absence thereof, in the official homeopathic pharmacopoeia of a Member State;
- they are marketed without any specific therapeutic indication, whether on the labelling of the product or in any accompanying product information;	- they are marketed without any specific therapeutic indication, whether on the labelling of the product or in any accompanying product information;
- there is a sufficient degree of dilution to guarantee the safety of the preparation; in particular, the preparation shall contain less than one part per million of any active principle which is subject to the requirement of a medical prescription.	- there is a sufficient degree of dilution to guarantee the safety of the preparation per dosage; in particular, the preparation shall contain no more than the quantity permitted per dosage for that method of administration of any active principle which is subject to the requirement of a medical prescription. These maximum permitted quantities shall be specified for each active principle in an annex to this Directive. - in particular, the preparation shall contain no more than one part per thousand of any active principle which is subject to the requirement of a medical prescription.

(Amendment No. 10)
Article 7(2)

In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and packaging of the medicinal products referred to in paragraph 1 shall consist of the following information and no other information:	In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and packaging of the medicinal products referred to in paragraph 1 shall consist of the following information and no other information:
- the scientific name of the stock followed by the degree of dilution, using the symbols used in the official pharmacopoeia of the Community,	- name and address of the person responsible for marketing, and of the manufacturer, - method of administration,

- expiry date, in plain language, - special storage precautions, if any, - manufacturer's batch number, - registration number.	- the scientific name of the of the homeopathic stock <u>or stocks</u> followed by the <u>strength or strengths</u>, using the symbols used in the official pharmacopoeia of the Community, - name and address of the person responsible for marketing, and of the manufacturer, - method of administration, - expiry date, in plain language, - special storage precautions, if any, - manufacturer's batch number, - registration number.

(Amendment No. 11)
Article 7(2)
Seventh indent <u>(new)</u>

	<u>- a sentence advising the user to consult a competent homeopathic therapist whilst using the medicinal product if the symptoms persist.</u>

(Amendment No. 12)
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 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 <u>or stocks</u>. 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 <u>or stocks</u>, together with a mention of the various routes of administration, pharmaceutical forms and <u>strengths</u> 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 <u>homeopathic stock or stocks is/are</u> obtained and controlled, and justifying its 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 <u>and potentiation</u>;
- 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.

(Amendment No. 13)
Article 9(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.	Homeopathic and anthroposophical 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, whilst taking due account of the basic principles and special nature of homeopathic or anthroposophical medicine.

(Amendment No. 14)
Article 10(2)a (new)

	The Commission is instructed, within 5 years of the entry into force of this Directive, to take all measures necessary to ensure that the status of alternative medicine is harmonized, particularly in the following respects: - adoption of a European Pharmacopoeia, - adoption of a Directive on the legitimate practice of alternative medicines, - arrangements for social security organizations to refund the cost of services and medicinal products, - organization of officially recognized teaching;

(Amendment No. 15)
Article 10(2b) (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.

A.

DRAFT LEGISLATIVE RESOLUTION

(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission 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 veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0072 final - SYN 251)[1],

- having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-0112/90),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Agriculture, Fisheries and Rural Development (A3-0093/91),

1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;

2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;

3. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;

4. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;

6. Instructs its President to forward this opinion to the Council and Commission.

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[1] OJ No. C 108, 1.5.1990, p. 10

II. **Proposal from the Commission to the Council for a Directive widening the scope of Directive 85/851/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**

Commission text[1]	Amendments
	(Amendment No. 16) 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 distortion of competition between manufacturers of these products;
	(Amendment No. 17) Recital 2a (new)
	whereas freedom of choice with regard to therapy needs to be safeguarded
	(Amendment No. 18) Recital 4a (new)
	Whereas, although these differences in status currently prevent total harmonization of alternative medicines practised within the EEC (particularly with regard to pharmacopoeias, medical practice, reimbursement from social security funds and teaching), this exercise should be undertaken within a reasonable period;

[1]For full text see COM(90) 0072 final - OJ C 108, 01.05.1990, p. 013

(Amendment No. 19)
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;

(Amendment No. 20)
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 pharmacopoeia 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. A homeopathic medicinal product may also contain of a number of different components.
Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions or by grinding.	Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions and potentiation. Homeopathic preparations may, contain with the exception of catalysts, only homeopathic stocks, in a minimum dilution of 1:10.

(Amendment No. 21)
Article 7(1)

Homeopathic veterinary medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:	Homeopathic veterinary medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:
- they are administered orally or externally;	- they are administered orally or externally or parenterally;
- they are marketed without any specific therapeutic indication, whether on the labelling of the medicinal product or in any accompanying product information;	- they are marketed without any specific therapeutic indication, whether on the labelling of the medicinal product or in any accompanying product information;
- there is a sufficient degree of dilution to guarantee the safety of the preparation, and in the case of homeopathic veterinary medicinal products intended for administration to food producing animals, to guarantee the absence of harmful residues in foodstuffs produced from these animals; in particular, the preparation shall contain less then one part per million of any active principle which is subject to the requirement of a veterinary prescription.	- there is a sufficient degree of dilution to guarantee the safety of the preparation per dosage, and in the case of homeopathic veterinary medicinal products intended for administration to food producing animals, to guarantee the absence of harmful residues in foodstuffs produced from these animals; in particular, the preparation shall contain not more than the quantity permitted per dosage for that method of administration of any active principle which is subject to the requirement of a veterinary prescription.
	- in particular, the preparation shall contain no more than one part per thousand of any active principle which is subject to the requirement of a medical prescription. These maximum permitted quantities shall be specified, for each active principle, in an annex to this Directive.

(Amendment No. 22)
Article 7(2), second indent

- the scientific name of the stock followed by the degree of dilution, using the symbols used in the official pharmacopoeia of the Community,	- the scientific name of the stock or stocks followed by the strength or strengths, using the symbols used in the official pharmacopoeia of the Community,

(Amendment No. 23)
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 <u>or stocks</u>. 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 <u>dilutions</u> to be registered;	- scientific name of the homeopathic stock <u>or stocks, together with a mention of the various routes of administration, pharmaceutical forms and strengths</u> to be registered;
- dossier describing how the stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate homeopathic bibliography;	- dossier describing how the stock<u>/stocks</u> is<u>/are</u> obtained and controlled, and justifying its<u>/their</u> 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 <u>and potentiation</u>;
- 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.
	<u>- 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;</u>

(Amendment No. 24)
Article 9(1)

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 in accordance with the provisions of Articles 43 to 50 of Directive 81/851/EEC, whilst taking due account of the basic principles and special nature of homeopathic or anthroposophical medicine;

(Amendment No. 25)
Article 9(1)

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 in accordance with the provisions of Articles 43 to 50 of Directive 81/851/EEC. The product shall be clearly labeled 'homeopathic veterinary medicinal product'.

(Amendment No. 26)
Article 10(2)a - (new)

	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.

A

DRAFT LEGISLATIVE RESOLUTION
(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission 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

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0072 final - SYN 252)[1],

- having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-0113/90),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Agriculture, Fisheries and Rural Development (A3-0093/91),

1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;

2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;

3. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;

4. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;

6. Instructs its President to forward this opinion to the Council and Commission.

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[1] OJ No. C 108, 1.5.1990, p. 13

B

EXPLANATORY STATEMENT

1. Introduction

After remaining constant a long time, interest in alternative medicines, and not only homeopathy, has increased markedly in recent years. At Community level no success has yet been achieved in drawing up common arrangements for (trade in) alternative medicinal products. Directives 87/22/EEC[1] and 75/919/EEC[2] established Community legislation covering medicinal products, but a few categories (immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood and homeopathic and other alternative medicinal products) were excluded.

Three of these four gaps have now been filled by various directives.[3] After several attempts that failed due to the very divergent national standpoints on this sensitive subject, the Commission now proposed to regulate the trade in homeopathic medicinal products.

2. Alternative medicines in Europe

A study for the European Commission by Mr G. Sermeus of the Belgian Consumers' Association investigated the issue of alternative medicines, covering seven Community Member States (Belgium, Denmark, France, Federal Republic of Germany, Italy, the Netherlands and the United Kingdom) and also Finland and Switzerland.

The most significant of its findings were:

- Between 18 and 75% of the population, depending on the country, have consulted practitioners of alternative medicine at least once;

- Between 6 and 24% of the population of the countries in question had consulted an alternative medical practitioner during the previous 12 months.

- One in four Belgians consulted a practitioner of alternative medicine at least once a year. In France and Finland, one in six people did so, in Denmark, the UK and West Germany, one in 11, in the Netherlands and Switzerland, one in 15;

- Homeopathy has proved to be by far the most significant alternative medicine, followed by acupuncture and manipulations (such as chiropractice and osteopathy), and then by herbal remedies, massage and paranormal

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1 OJ No. L 15, 17.1.1987, p. 38
2 OJ No. L 147, 9.6.1978, p. 13
3 Directive 89/342/EEC, OJ No. L 142, 25.5.1989, p. 14, on immunological medicinal products; Directive 89/343/EEC, OJ No. L 142, 25.5.1989, p. 16, on radiopharmaceuticals; Directive 89/381/EEC, OJ No. L 181, 28.6.1989, p. 45, on medicinal products derived from human blood.

methods. There is also anthroposophical medicine, and lastly a number of less frequent method such as iridology, water baths, thalassotherapy, diet therapy, healing, reflexology, etc.;

- Greater use has been made of alternative medicines by adults between the ages of 35 and 60 with a high level of education than by other sections of the population. In general terms, women have made more frequent use of them than men;

3. The Commission proposal

The Commission proposal concerns homeopathic medicinal products excluding medicinal products which are prepared according to magistral or officinal formulae.

First of all, a series of provisions contained in Directive 75/319/EEC[1] are applied to these medicinal products, giving EC consumers solid guarantees regarding the quality and harmlessness of homeopathic medicines. Thus, for example, the same requirements will apply to the manufacture, control, import and export of homeopathic medicinal products as to allopathic medicinal products with effect from 1 January 1993.

The proposal represents the second - and extremely cautious - attempt to liberalize trade in homeopathic medicinal products. The Commission envisages harmonization of the conditions governing authorization for placing on the market. The proposal is still limited to products which come on the market only after 1 January 1993. A significant distinction is drawn between homeopathic medicinal products classified as totally harmless and all other homeopathic medicinal products. In order to belong to the first category, the medicinal product must be administered orally or externally, may not be claimed to have any therapeutic effects and must be diluted to less than one part per million of active principle (= D6). A simplified registration procedure and special labelling arrangements are to apply to these products. All other homeopathic medicinal products are to be authorized and labelled in accordance with the conditions applying to allopathic medicinal products.

4. Proposed amendments to the Commission proposal

The Commission proposal has great merits, but several points need to be formulated more precisely because as it stands many patients and doctors (and healers) are left out of account.

First, it needs to be made clear in the recitals that patients have the right to choose the type of treatment they receive, whether this is allopathic, homeopathic or of some other type. Second, the directive should seek to help in bridging the gap between allopathic and homeopathic treatment, of which much is still currently being made, and to increase the awareness that both types can complement each other.

Furthermore, the directive should incorporate anthroposophical medicine. In the Federal Republic of Germany, in particular, this represents one of the

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[1] OJ No. L 147, 9.6.1975, p. 13

most important alternative medicines, and not incorporating it will mean that an opportunity has been missed that would benefit the countless patients who have chosen this type of medicine.

A fourth shortcoming in the Commission proposal is the failure to incorporate homeopathic and anthroposophical compound medicinal products. These are widely used and ignoring them would jeopardize some branches of homeopathy.

On some other points the Commission has shown excessive caution. Parenteral administration should be included in the simplified registration procedure of Article 7. In the Federal Republic of Germany homeopathic medicinal products are often administered via injections. In the many years that this has been normal practice, there have never been any problems. This form of administration is also normal in homeopathic veterinary treatment, so that suppositories and eye drops should be included in the simplified procedure under Article 7.

The provisions of Article 7 are also too restrictive with regard to the degree of dilution. The proposal sets dilutions of one part per million (D6) as the limit. However, years of experience have shown that almost all dilutions up to 1 part per ten thousand (D4) are totally harmless and satisfy the condition that the product must be guaranteed to be harmless. In place of a single standard or level of dilutions for all preparations, your rapporteur proposes greater differentiation in the regulations so that the permitted quantity of an active principle is determined in accordance with the method of administration and the degree of toxicity.

A further sensitive point is Article 9(2), which lays down that homeopathic medicinal products must be supported by scientific proof such as applies to allopathic medicinal products. This places allopathy on a pedestal. One of the causes of the allopathy-homeopathy controversy is precisely that conventional medical science does not admit the proof adduced by homeopathic doctors. Only rarely are scientific articles about the effectiveness of homeopathic medicine accepted by the publishers of conventional medical journals. The works of Bernard Pointvin[1] and Rigetti[2] provide thorough evidence and contain extensive bibliographical references. Peter Fisher[3] has drawn up a list of some 160 studies on the effects of homeopathy. The proof required by Article 9(1) should therefore take into account the basic principles and special nature of homeopathy.

The same applies to anthroposophical medicine. To apply to these types of treatment the same standard as to allopathic medicine is at variance with the very philosophy behind them. Furthermore, the fact that conventional medicine cannot comprehend homeopathic and anthroposophical medicines does not mean that they do not work. The long experience of tens of thousands of homeopaths and anthroposophy doctors and of millions of patients in and outside the Community is ample proof that these treatments have their merits and are indeed highly effective.

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[1] Bernard Pointvin: Le devenir de l'homéopathie, Doin, Paris, 1987 ISBN 2-7040-053-1

[2] Rigetti: Forschung in der Homepathie, Burgdorf, Göttingen, ISBN 3-922345-39-5

[3] Dr Peter Fisher: Research in Homeopathy - A Bibliography, 5th edition, 1989

The regrettable resistance of conventional medicine to homeopathic and anthroposophical medicine can be explained in part from the Cartesian-Newtonian framework which applies within conventional medicine.

5. Conclusions

The Commission's proposals concerning the placing on the market of homeopathic medicinal products for human use and of homeopathic veterinary products should thus be fully endorsed, provided that some points are clarified.

In the interests of public health and consumer protection it is important for the Commission to submit proposals without delay to regulate the practice of homeopathic and anthroposophical medicine (and indeed all alternative medicines). Since these medicines are enjoying (slightly) rising interest amongst consumers, there is a danger that without legislation amateurs will take over part of the market.

In order to give homeopathic and anthroposophical medicine the same opportunities as allopathic medicine and to safeguard consumer choice of treatment, the companies which reimburse medical expenses must not make a distinction between the therapy chosen. Currently the cost of homeopathic treatment is reimbursed only in France, Germany, the UK and in some cases the Netherlands.

Finally, it is desirable for the EC to contribute to the creation of a European pharmacopoeia and a data bank for homeopathic and anthroposophical medicinal products.

OPINION

(Rule 37 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy

Draftsman: Mrs Brigitte ERNST de la GRAETE

At its meeting of 17 July 1990 the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mrs ERNST de la GRAETE draftsman.

At its meetings of 19-21 September and 15 and 16 October 1990 the committee considered the draft opinion.

At the latter meeting it adopted the conclusions as a whole by 17 votes to 20.

The following took part in the vote: Beumer, chairman; Fuchs, vice-chairman; Ernst de la Graete, draftsman; Bofill Abeilhe, Cassidy, Cox, Herman, Hoff, Metten, Merz, Lulling, Pinxten, Rogalla, Sboarina, Martinez (for Megret), Peter (for Ford), Porto (for Visentini), Titley (For Read) and Van der Waal (for Lataillade).

I. ANALYSIS OF THE SUBSTANCE OF THE PROPOSALS

1. Need for approximation of the laws of the Member States

To date, there have been no measures to harmonize the law on homeopathic medicinal products for human or veterinary use. Discrepancies between existing bodies of legislation applied to homeopathic medicinal products, however, jeopardize the completion of the internal market in that domain.

Although homeopathic medicine has been practised for over 200 years, its status varies from one Member State to another. While some Member States traditionally recognize homeopathy, in others it is merely tolerated or completely ignored.

Yet a demand for alternative medicine exists. A recent study[4] shows that 18 to 75% of the population, depending on the EEC country concerned, use these medicines. The most popular alternative treatments are firstly, homeopathy, then acupuncture, chiropractic and herbal remedies. Those using such medicine are generally adults (from 40 to 60 years old) with a high level of education.

Although almost unanimously rejected by scientific opinion, these methods can appeal to patients disappointed by the impersonal and 'high-tech' nature of modern medicine. They are based on holistic methods of treatment, taking account not only of the patient's physical condition but also of his psychological and spiritual state. They have the further attraction of encouraging the patient to participate more fully in the healing process.

Finally, although homeopathic remedies account for only a small share of the market in pharmaceuticals, that nevertheless represents some half a billion ECU per year[5]

It is appropriate, therefore, from the point of view of both patient safety and the completion of the internal market in the pharmaceutical sector, to seek harmonization in this field, while ensuring that patients have easy access to homeopathic products within the Community area, in accordance with the principle of the free movement of goods.

2. The proposed system

The proposals in question are intended to harmonize the legislation covering homeopathic medicinal products for human or veterinary use.

These proposals apply to homeopathic medicinal products as defined in the European Pharmacopoeia or, failing that, in national pharmacopoeias. They cover only medicines which are widely distributed, in other words those prepared industrially; preparations prescribed in individual cases would not be affected.

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[4] Study by G. Sermus: Alternative Medicine in Europe, Ed. Belgian Consumers' Association, Brussels, November 1987

[5] Moreover, this turnover does not give a true picture of the extent of the homeopathic sector. Given the relatively low price of homeopathic medicinal products, the number of consumers is in fact greater than one would assume from the turnover involved.

(a) Manufacture

In future, homeopathic medicinal products produced in the Community must meet the standards for manufacture and monitoring laid down in Chapter IV of Directive 75/319/EEC: authorization to manufacture, export or import such products will be conditional on possession of suitable premises and equipment; each batch manufactured will have to be monitored by a qualified person; the rules of good manufacturing practice (GMP) will become mandatory.

(b) Patient safety and information

Bringing the preparation of homeopathic medicinal products within the scope of the manufacturing and monitoring rules laid down in Directive 75/319/EEC will offer patients a degree of protection against various sharp practices.

Moreover, Articles 2 and 7 contain provisions to ensure that patients are clearly informed of the fact that the product is a homeopathic remedy, the scientific name of the stock and the degree of dilution.

(c) Marketing of products

Two methods of placing products on the market are proposed.

The first consists of a simplified registration procedure for medicinal products marketed without any specific therapeutic indication, administered orally or externally and in a sufficient degree of dilution to guarantee the safety of the preparation. This means that these products will be subject to the rules of procedure laid down in Articles 5 to 12 of Directive 65/65/EEC, except that proof of therapeutic effect will not be required.

Other homeopathic medicinal products will be subject to the ordinary rules on market authorization, especially criteria of efficacy and safety, that apply to allopathic medicinal products.

However, Member States may decide to apply special rules to homeopathic medicine, in which case (Article 9(2)) they must notify the Commission of the specific rules in force. Finally, the directive, which should be applied by 31 December 1992 at the latest, has no retrospective force.

II. COMMENTS ON THE PROPOSALS

1. Good features of the proposals

We approve the Commission's two proposals to extend to homeopathic medicinal products for human or veterinary use the provisions of Directives 65/65/EEC and 75/319/EEC on allopathic medicinal products. We also consider it reasonable to introduce a simplified registration procedure for a particular category of homeopathic medicinal products that are relatively innocuous in view of their high degree of dilution.

These provisions will offer patients fuller information and increased safety while making the products more easily available inside Community territory in accordance with the objectives of Article 100a.

However, the impact of these measures on homeopathic medicine will remain limited until the Member States harmonize their respective legislation and their approach to alternative medicine in general. It is essential, therefore, to promote the creation of a European homeopathic pharmacopoeia under the auspices of the Council of Europe. Finally, the process of recognizing and organizing homeopathic medical practices at European level should also lead to further reflection both on the status of homeopathic practitioners, who are legally entitled to issue prescriptions, and on whether the cost of homeopathic medicinal products should be reimbursed from social security funds.[6]

The refusal by social security authorities to bear or refund the cost of such medicines constitutes a distortion of competition which is incompatible with the basic principles of the Single Internal Market. This discrimination against homeopathic medicine will become unacceptable once they are covered by European safety standards.

2. Suggested amendments

The text of the Commission's proposal should be amended in various respects.

The wording of Article 7 should be amended to avoid limiting their therapeutic applications and the information provided for patients. The criteria listed in this Article should be regarded as a minimum. The phrase 'by successive dilutions' in the second paragraph of Article 1 should be defined more precisely, while the first paragraph should be expanded.

Article 6 should be expanded by the addition of Article 3, from Chapter III, Article 9(1) of Directive 85/570/EEC of 26 October 1983 to enable the proposed system to be set up more swiftly.
Article 9, also, should be amended. For the sake of consistency and to avoid discriminating against homeopathic products, proof of therapeutic effect, if required, should not be conditional on clinical trials in accordance with allopathic practice. The methods of testing used should be those applied in homeopathic schools of medicine.

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[6] Only France, the FRG and, to some extent, the Netherlands and the United Kingdom allow the cost of homeopathic medicines to be reimbursed by social security bodies.

Finally, the Member States should not be allowed to maintain special rules for pharmacological and toxicological tests and clinical trials of homeopathic medicines. This option would both limit the impact of the directive and lead to discrimination and distortion of competition.

The proposed amendments also apply to the identical text of the proposal for a directive on homeopathic medicinal products for veterinary purposes. We add, however, an additional amendment to Article 7(1) to take account of the frequent use by homeopathic veterinary surgeons of parenteral injections.

PROPOSED AMENDMENTS
COM(90) 72 final - SYN 251

Commission text	Amendments
	Amendment No. 1 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 distortion of competition between manufacturers;
	Amendment No. 2 Article 1, first paragraph
For the purpose 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 purpose of this Directive, 'homeopathic medicinal product' shall mean any medicinal product containing one or more ingredients 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;

Amendment No 3
Article 7(1)

1. Homeopathic medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:	1. Homeopathic medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:
- they are administered orally or externally;	- they are administered in accordance with the methods of administration described by the European Pharmacopoeia or, in the absence thereof, by the official pharmacopoeia of a Member State;
- they are marketed without any specific therapeutic indication, whether on the labelling of the product or in any accompanying product information;	unchanged
- there is a sufficient degree of dilution to guarantee the safety of the preparation; in particular, the preparation shall contain less than one part per million of any active principle which is subject to the requirement of a medical prescription.	- there is a sufficient degree of dilution to guarantee the safety of the preparation; however, the authority responsible for granting authorization may require the submission of documents concerning the toxicological properties of a medicinal product proving its safety when used in normal circumstances if the degree of dilution is such that the preparation contains more than one part per million of any active principle which is subject to the requirement of a medical prescription.

Amendment No. 4
Article 7(2)

2. In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and packaging of the homeopathic medicinal products referred to in paragraph 1 shall consist of the following information and no other information:	2. In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and packaging of the homeopathic medicinal products referred to in paragraph 1 shall consist of at least the following information:
- the scientific name of the stock followed by the degree of dilution, using the symbols used in the official pharmacopoeia of the Community,	- the scientific name of the stock(s) followed by the degree(s) of dilution, using the symbols used in the official pharmacopoeia of the Community,
(rest unchanged)	- galenic form and presentation;
	(rest unchanged)

PROPOSALS FOR AMENDMENTS

COM(90) 72 final - SYN 252

Amendments Nos. 1, 2 and 4 are identical

Amendment No. 3
Article 7(1)

1. Homeopathic veterinary medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:	1. Homeopathic veterinary medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:
- they are administered orally or externally;	- they are administered orally, externally or parenterally;
(rest unchanged)	(rest unchanged)

CONCLUSIONS

1. Homeopathy, a form of alternative medicine that is generally fairly inexpensive and sometimes complementary to allopathic (i.e. orthodox) medicine, meets a distinct need since between 18 and 75% of the population make use of this form of medicine, which has an annual turnover of about half a billion ECU.

2. It is, therefore, necessary to ensure, in accordance with Article 100a of the Treaty, the free movement of such products while providing that the best possible safety guarantees exist for patients.

3. This is the objective of the Commission's proposals, which seek to make homeopathic medicinal products for human or veterinary use subject to the rules laid down in Directives 65/65/EEC and 75/319/EEC on monitoring and controlling the manufacture of medicines and the conditions in which they are freely available in the Community.

4. Further, the Commission's proposals lay down a simplified registration procedure which is justified in the case of those homeopathic medicinal products which are relatively innocuous in view of their high level of dilution and the method by which they are administered.

5. However, these proposals should be amended to enhance patient safety and information (Articles 1 and 7).

6. The two proposals for directives should, therefore, be approved, subject to the above proposals for amendments, which the Committee on the Environment, Public Health and Consumer Protection is requested to take into account.

OPINION

OF THE COMMITTEE ON AGRICULTURE, FISHERIES AND RURAL DEVELOPMENT

Letter from Mr COLINO SALAMANCA, chairman of the Committee on Agriculture, Fisheries and Rural Development, to Mr K.D. COLLINS, chairman of the Committee on the Environment, Public Health and Consumer Protection

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Brussels, 17 October 1990

Subject: 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

and

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
(COM(90) 72 final - Doc. C3-112/90 and Doc. C3-113/90)

Dear Mr Chairman,

At its meeting of 15/16 October 1990[7], the Committee on Agriculture, Fisheries and Rural Development considered the above proposals, on which your committee is currently drawing up a report.

These two proposals for directives are aimed at harmonizing the market in homeopathic medicines for both human and animal use, which were provisionally excluded from Community pharmaceutical legislation in 1975.

In fact, two different conceptions of medicine are involved:

- allopathic medicine, the dominant tradition in Western Europe, is based on the concept of 'curing by opposites' - a maxim attributed to Galen, which underlies the use of 'anti'-drugs such as antibiotics, anti-inflammatory agents and painkillers;

- homeopathic medicine 'makes use of substances which produce systems similar to those of the illness concerned in healthy individuals'. The term 'homeopathy', coined by the German Hahnemann (1755-1843) and first used in 1810, derives from the Greek words homoios (equal) and pathos (suffering).

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[7] The following took part in the vote: COLINO SALAMANCA, chairman; GRAEFE ZU BARINGDORF, vice-chairman; BLANEY, CARVALHO CARDOSO, DOMINGO SEGARRA, GARCIA, GÖRLACH, LIVANOS, MARCK, ORTIZ CLIMENT, PARTSCH (for FALQUI), Feruccio PISONI (for Nino PISONI), SONNEVELD, VERBEEK, VOHRER

Homeopathic medicines are prepared from substances which cause similar reactions to the symptoms of the illness concerned but are diluted at a ratio of 1 to 10^{12} so that the solution no longer contains a single molecule of the original substance, while retaining its dynamic agency. The active capacity of such diluted preparations is questioned by conventional medicine, especially as they do not permit the use of the statistical methods of clinical tests.

Homeopathic medicine is officially recognized in some Member States; homeopathic medicines account for approximately 2% of the market in pharmaceuticals.

The implementation of these directives will provide the Community consumer with a guarantee of the quality and safety of homeopathic medicines, in line with the existing requirements for other medicines. In the veterinary field, there is a further requirement that homeopathic treatment of animals should not leave harmful residues in food products.

The accepted manufacturing procedures are those set out in the official pharmacopoeias of individual Member States, given the lack of a European Pharmacopoeia.

Parliament has given its favourable opinion on the package of measures for the completion of the internal market, aimed at the elimination of obstacles to intra-Community trade while safeguarding human and animal health.

The Committee on Agriculture, Fisheries and Rural Development considers that these two proposals for directives represent a further necessary step in the completion of the process, and therefore favours their adoption.

Yours faithfully

Juan Luis COLINO SALAMANCA