28 October 1998 A4-0378/98

REPORT

on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 982/74/EEC on homeopathic medicinal products (COM(97)0362 - C4-0484/97)

Committee on the Environment, Public Health and Consumer Protection

Rapporteur: Mr Raphaël Chanterie

C O N T E N T S

By letter of 14 July 1997 the Commission forwarded its report on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products to the European Parliament and the Council.

On 2 October 1997 the President of Parliament announced that he had referred this report to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Agriculture and Rural Development, the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Legal Affairs and Citizens' Rights for their opinions. On 15 December 1997 the President of Parliament announced that he had referred this report to the Committee on Research, Technological Development and Energy for its opinion.

The Committee on the Environment, Public Health and Consumer Protection appointed Raphaël Chanterie rapporteur at its meeting of 8 October 1997.

It considered the draft report at its meetings of 3 September, 13 October and 27 October 1998.

At the last meeting it adopted the motion for a resolution by 24 votes to 4.

The following took part in the vote: Collins, chairman; Dybkjær and Lannoye, vice-chairmen; Chanterie, rapporteur; Blokland, Bowe, Breyer, Cabrol, Correia (for Jensen), Eisma, Florenz, Graenitz, Grossetête, González Álvarez, Hulthén, Jackson, Kokkola, Kuhn, Leopardi, Liese (for Valverde Lopez), Marinucci, McKenna, Needle, van Putten, Roth-Behrendt, Schleicher, Schnellhardt and Tamino.

The opinions of the Committee on Agriculture and Rural Development, the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Research, Technological Development and Energy and the Committee on Legal Affairs and Citizens' Rights are attached.

The report was tabled on 28 October 1998.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

A
MOTION FOR A RESOLUTION

Resolution on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products (COM(97)0362 - C4-0484/97)

The European Parliament,

- having regard to the report submitted by the Commission on 14 July 1997 on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products (COM(97)0362 - C4-0484/97)([1]),

- having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

- having regard to Directive 92/73/EEC widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products,

- having regard to Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products,

- having regard to the decision of the Court of Justice of 12 February 1998 in case C-144/97([2]),

- having regard to the opinions adopted by the European Parliament on 13 June 1991 ([3]) and 8 July 1992 ([4]) on the proposal for a Council directive 92/73/EEC on homeopathic medicinal products,

- having regard to the resolution adopted by the European Parliament on 29 May 1997 on the status of non-conventional medicine (A4-75/97)([5]),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Agriculture and Rural Development, the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Research, Technological Development and Energy and the Committee on Legal Affairs and Citizens' Rights (A4-0378/98),

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([1]) OJ C 325, 27.10.97, p. 8
([2]) ECR, p. I-0613
([3]) OJ C 183, 15.7.91, p. 318
([4]) OJ C 241, 21.9.92, p. 93
([5]) OJ C 132, 28.4.97, p. 5

A. whereas between one fifth and one quarter of the citizens of the European Union make use of homeopathic medicinal products and whereas such products account for one percent of the turnover of the European pharmaceuticals industry,

B. whereas the differences between the Member States concerning the authorization or recognition of homeopathic medicinal products distort competition and the market,

C. whereas the accessibility and reliability of homeopathic medicinal products need to be guaranteed and whereas users need to be assured of information,

D. whereas transposition of Articles 2, 3, 4, 5, 10 and 11 of Directives 92/73/EEC and 92/74/EEC has resulted in a number of problems but no insuperable complaints or objections,

E. whereas transposition of Articles 1 and 8 and of Article 9 of Directive 92/73/EEC has resulted in problems in the registration or authorisation of anthroposophic medicinal products,

F. whereas in a number of Member States homeopathic anthroposophic medicinal products are of considerable importance and whereas they appear in an official pharmacopoeia,

G. whereas Article 6(2)) of both Directives provides for the possibility of refraining from establishing a 'special, simplified registration procedure for homeopathic medicinal products', but whereas the Member States have made no use of this provision which, accordingly, is redundant,

H. whereas transposition of Article 6(3) of Directive 92/73/EEC on advertising for homeopathic medicinal products and Article 9(1) of the two Directives on the authorization and labelling of homeopathic medicinal products other than those covered by a special, simplified registration procedure has not given rise to any particular problems,

Recognition

I. whereas Article 6(1) of the two Directives specifies that Member States 'shall take due account of registrations and authorizations granted by another Member State'; whereas this provision is so unclear *de jure* that transposition differs substantially from one Member State to another and is *de facto* too open-ended to act as an effective bar to distortions of competition; whereas a more uniform provision would, however, result in fewer problems of interpretation and whereas only a binding provision will ensure the free movement of the products in question,

J. whereas separate assessment of every homeopathic medicinal product in each Member State is a considerable waste of time and money and is the cause of barriers to trade because assessment criteria and margins differ and should be carried out in accordance with criteria involving full guarantees of the quality and harmlessness of the product,

Special, simplified registration procedure (SSRP)

K. whereas a number of Member States, in transposing Article 7(1) of the two Directives, have changed the provision in question or included other provisions such that there is a risk of unfair competitive advantages arising,

L. whereas, in accordance with the wording of Directives 92/73/CEE and 92/74/CEE, homeopathic medicinal products are only eligible for the SSRP if the degree of dilution per preparation does not exceed one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles in medicinal products requiring a doctor's prescription, whereas a number of Member States depart from this obligation,and whereas this limiting of the degrees of dilution in which homeopathic active principles may be included in homeopathic medicinal products is entirely arbitrary, taking no account of factors linked to pharmaceutical form, means of administration and the formula of these products; moreover, the result of such a limit would be to withdraw from the market homeopathic medicines which have been on the market for decades, having given proof of their harmlessness, and whereas this would be very detrimental to a number of homeopathic laboratories,

M. whereas Directive 92/73/EEC restricts the SSRP to homeopathic medicinal products for oral or external use, although this does not follow from any generally accepted health and safety rules based on scientific research, and whereas a number of Member States ignore this and allow other forms of use, too; and whereas the safety of the form of dosage is guaranteed, not only by the inclusion of the form of dosage in an official pharmacopoeia, but also through application of the rules of Good Manufacturing Practice,

N. whereas, notwithstanding Regulation 2377/90 on residue limits of veterinary medicinal products in foodstuffs of animal origin, Directive 92/74/EEC reserves the SSRP for homeopathic medicinal products for pet animals or exotic species not intended for human consumption,

Labelling

O. whereas the obligatory use of the scientific name on labels and, possibly, in the package insert does not make for clarity; whereas this is the cause of confusion and errors; and whereas clarity and ease of identification are an important aid for patients and consumers,

P. whereas the dosage provides the patient or consumer with information about the nature and purpose of a specific medicinal products,

Q. whereas the compulsory mention of 'homeopathic medicinal product without approved therapeutic indication' on the label and, where appropriate, in the package insert is applied by the Member States in different ways; whereas specifying therapeutic indications which may or may not be approved is no part of the registration procedure; and whereas this phrase has pejorative overtones which have a clearly discriminatory effect,

R. whereas homeopathic medicinal products intended for humans must contain on the label and, where appropriate, in the package insert a warning to consult a doctor should symptoms persist 'during the use of the medicinal product'; whereas this warning is evidence of a lack

of understanding of how medicinal products work and of the course of treatment or recovery; but whereas late intervention during long-term treatment should be avoided,

Special rules

S. whereas it is at Member States' discretion, with regard to the testing of homeopathic medicinal products for which the SSRP is not applicable, to lay down special rules for the pharmacological, toxicological and clinical tests; whereas some Member States have done so but others have not, whereas this makes it possible to take account of differences between countries and medical cultures, but whereas this also leads to distortions of competition,

1. Notes that, according to Art 10 (3) of Directives 92/73 and 92/74, the Commission should have reported not later than 31 December 1995 to the Parliament and the Council concerning the transposition and application of the Directives by the Member States; deplores the delay occurred, whatever the reasons for this delay;

2. Calls on the Commission, pursuant to the report on homeopathic medicinal products and on the basis of the suggestions made by the European Parliament, to submit a proposal to amend Directive 92/73/EEC and a proposal to amend Directive 92/74/EEC;

3. Calls on the Commission to modify Article 1 of Directive 92/73/EEC in such a way that homeopathic anthroposophic medicinal products described in an official pharmacopoeia are given the same status as homeopathic medicinal products;

Recognition

4. Calls on the Commission to investigate whether, and to what extent, a system of mutual recognition of homeopathic medicinal products can be set up on the basis of binding principles and appropriate standards;

5. Calls on the Commission to lay down rules for the composition of registration requests applicable by all the Member States and carrying full guarantees of quality and harmlessness;

6. Calls on the Commission to look into the desirability and feasibility of a system of recognition of homeopathic medicinal products by a Community body of persons with expertise in this field;

7. Pending the setting up of such a system of coordination or harmonization, calls for Article 6(1) of the existing Directives to be modified in such a way as to create an unmistakable obligation on the part of Member States actually to recognise registrations carried out, or authorizations granted, by other Member States, and to define exactly under which specific conditions national registration should be mutually recognised or endorsed by other Member States;

8. Calls on the Commission to ensure safeguards for a system of coordination or harmonization whereby the quality of registration procedures is monitored;

9. Is, therefore, of the opinion that the application of the mutual recognition principle should be made dependent on the application, including appropriate control mechanisms, of Good

Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) and on provisions which would ensure that no Member State would be forced to lower its standards relating to problematic residues or contamination of the substances used;

10. Is of the opinion that common safety criteria should be defined at EU level and that the Member State in which a homeopathic product first is registered has to evaluate and document compliance with such criteria;

Special, simplified registration procedure (SSRP)

11. Calls on the Commission to investigate whether homeopathic medicinal products administered by means of injection, plaster, spray, drops, suppository or by any other route other than orally or for external use with no risk to the health or safety of the user can be considered for the SSRP and, if so, to make the rules more flexible;

12. Calls on the Commission to investigate ways and means of producing a valid Community list of degrees of dilution determined for the mother tincture and, in the absence of such a list, to revise and, if possible, to increase the existing degrees of dilution;

13. Calls for homeopathic medicinal products for veterinary use to be given access to the SSRP regardless of the species of animal which the product is intended to cure;

Labelling

14. Calls for the lifting of the ban on fantasy names, in particular for combination preparations, on condition that this does not lead to a therapeutic indication being introduced or suggested;

15. Calls for an obligatory indication of the dose on the label and, where appropriate, in the package insert;

16. Calls for an end to the obligation to use the statement 'homeopathic medicinal product without approved therapeutic indications', and calls on the Commission to examine whether the obligation to use the statement 'application in accordance with clinical homeopathic pharmacology (pharmacological picture)' affords a viable alternative;

17. Calls for the obligatory warning, on specific homeopathic medicinal products intended for humans, advising the user to consult a doctor if the symptoms persist 'during the use of the medicinal product' to be modified, and calls on the Commission to propose doing away with the words 'during the use of the medicinal product';

Special rules

18. Calls on the Commission to submit a proposal, with the full participation of experts in homeopathic medicines, obliging Member States to draw up special rules for the pharmacological, toxicological and clinical tests for the testing of homeopathic medicinal products which are not eligible for the SSRP;

19. Calls on the Commission, to submit to the European Parliament and the Council a report, no later than three years after the entry into force of the Directive amended in this way, on the

progress achieved in regard to completion of the market and the free movement of homeopathic medicinal products;

20. Calls on the Commission to report without delay on the studies and surveys conducted on research into the effectiveness of homeopathic and other alternative treatments within the framework of the Community R&D programme for Biomedicine (budget heading B6-7142);

21. As part of the biomedicine section of the Fifth R&D Framework Programme, research activities in the field of alternative medicine should be promoted, on the basis of the report called for in paragraph 9 to look at the individualised and holistic approaches, preventive role and particular features of alternative medical disciplines. These activities should include programmes for basic research into homeopathy, to be carried out by bio-medical institutions, designed in particular to explain the process of homeopathic potentisation and prove the efficacy of homeopathic high-level potencies. They should also include programmes to promote international pooling of the experience of experts in homeopathy;

22. Instructs its President to forward this resolution to the Commission, the Council and the Member States.

B

EXPLANATORY STATEMENT

Homeopathic medicinal products account for 1% of the turnover of the European pharmaceutical industry, but in Germany, France and the Netherlands the share is over 2% in monetary terms and over 5% in terms of volume. 22% of the citizens of Europe make use of homeopathic medicinal products.

The differences between the Member States in terms of recognition and authorization of alternative medicine in general, and homeopathy in particular, have resulted in a distortion of competition and an imbalance in the market. The existing European rules on the application of legislative administrative provisions on medicinal products - Directives 65/65/EEC, 75/319/EEC and 81/851/EEC - have proved inadequate with regard to the freedom of movement of homeopathic medicinal products for human of veterinary use, partly because of the extremely limited concentrations of active principles and partly because of the conventional statistical methods used in the clinical tests.

Accordingly, the European Community adopted two directives - Directive 92/73/EEC and Directive 92/74/EEC - which both contain additional provisions supplementing Directives 65/65/EEC, 75/319/EEC and 81/851/EEC, with the following purposes:

* to ensure the accessibility of homeopathic medicinal products,
* to guarantee the reliability and safety of these products,
* to guarantee information for users of homeopathic medicinal products, and
* to harmonize partially the rules regarding the production and monitoring of these products.

Hence there are numerous reasons, both economic (freedom of the market, freedom of movement, freedom of competition) and social (public health, product safety, consumer information) to establish such rules. It is useful, then, that these two directives exist. But are they good in themselves? And have they been properly transposed in Member States' legislation?

According to the two directives a report was to be submitted, no later than 31 December 1995, on the application of the directives. Given that at the time in question a number of Member States had not submitted reports on full transposition of the directives, the report did not appear until 14 July 1997. Even then a number of Member States had still evidently failed to comply with their obligations. The Commission went to the Court of Justice on the grounds of failure to transpose or to transpose in full the two directives in Belgium and France and one of the directives in Portugal and the United Kingdom.

Articles accepted

The directives themselves are the same in structure and scope.

The first five articles describe homeopathic medicinal products, for human or for veterinary use, on the basis of the raw materials and the manufacturing process, as described in an official European or national pharmacopoeia, and lay down rules for production, imports, exports, monitoring, inspection and penalties.

Transposition of these provisions does not appear to be satisfactory at all times or in all Member States, with ambiguities in a number of cases as the result, but neither the Commission nor the rapporteur has received any complaints justifying a change in the articles.

Article 8 which governs simplified registration appears to have been properly transposed in all but two instances (France and Ireland) and appears to give no grounds for complaint or suggestions for modification, either on the part of the Commission or on the part of the pharmaceutical industry involved with homeopathy.

Articles 10 and 11 ('Final provisions') are not under discussion and are therefore ignored below.

Disputed articles

However, the provisions on marketing homeopathic medicinal products, in particular Article 6, 7 and 9, do prompt a number of comments: this applies to both types of homeopathic medicinal products.

Article 6(1) specifies that 'each Member State shall take due account of registrations and authorizations previously granted by another Member State'. This wording is *de jure* so unclear that transposition of this provision varies substantially from one Member State to another, and *de facto* too open-ended to be an effective means of preventing any distortion of competition. Both the Commission and the rapporteur therefore call for inclusion of a different wording which will provide fewer problems of interpretation while being more binding in nature. This is something which manufacturers of homeopathic medicinal products, along with consumer organizations and doctors' organizations have been calling for.

Homeopathic medicine makes use of some 2 000 base materials. Hence, if each Member State has to assess each medicinal product, this would mean 15 x 2 000 applications. Not only is this an enormous waste of time and money, it also means different evaluation results for the same products, depending on the assessment criteria and the flexibility or rigidity of the assessment. This, in turn, means that there will continue to be barriers to trade between the Member States.

As a means of doing away with this twofold inconvenience, lack of clarity and barriers to trade, your rapporteur proposes modifying the existing provisions so that Member States should not only take account of authorizations granted by other Member States but should also accept and respect, through a new system of mutual recognition, evaluation results already obtained in other Member States. Only then will there be free movement of homeopathic medicinal products, including products for veterinary use, within the European Union. However, there is a need to establish watertight standards and satisfactory criteria in order to make the system of mutual recognition as uniform as possible.

Article 6(2) gives each Member State the option of refraining from establishing 'a special, simplified registration procedure' (SSRP) but has remained a dead letter since no Member State has informed the Commission that it intends to exercise this option.

Article 6(3) of Directive 92/73/EEC concerning the advertising of homeopathic medicinal products presents no specific problems as such.

Article 7(1) makes the SSRP dependent on three conditions to do with use, packaging, package insert and the degree of dilution. Member States have transposed this provision in their own legislation, but in so doing a number of Member States have changed the provision or added additional provisions. Accordingly, there are differences between the Member States in respect of which homeopathic medicinal products are eligible for the SSRP.

Furthermore, the conditions contained in this provision also give grounds for concern.

Firstly, there is the fact that products are restricted to oral or external use. Other forms of administration - such as injection, plasters, sprays, droplets, suppositories etc. - do not, in principle, satisfy the requirements of the SSRP. Yet a number of Member States use an SSRP for certain routes of administration. Once again, there are differences which impede the free movement of homeopathic medicinal products, although these differences do not result from considerations of health and safety, given that homeopathic medicinal products which are healthy and safe for the citizens and animals of one Member State must obviously be healthy and safe for the citizens and animals of another Member State. The Commission proposes explicitly adding to the provision other routes of administration, but without stating which routes would be acceptable and which would not. The manufacturers propose determining the routes of administration in accordance with the rules of a European pharmacopoeia or the pharmacopoeia valid in the relevant Member State, bearing in mind that the health and safety requirements are part of both the authorization to manufacture medicinal products and the operating licence. The rapporteur agrees that more routes of administration should be permitted, but would prefer to wait for a Commission proposal in order to guarantee the health and safety of users of homeopathic medicinal products. The rapporteur therefore invites the Commission to give consideration to such a proposal forthwith.

Secondly, there is the ban on stating specific therapeutic indications on the packaging or in the package insert, although this has not produced any appreciable problems hitherto.

Finally, there is the question of the degree of dilution. This is determined per preparation as a maximum of 1/10 000 of the mother tincture or 1/100th of the smallest dose used in allopathy with regard to active principles of medicinal products available only on prescription. This is an arbitrary cut-off point for which several Member States have substituted product-specific dilution rules ranging from 1/10 to 1/100 000 000, or other conditions such as harmlessness or degree of familiarity, with the result that selecting the homeopathic medicinal products eligible for the SSRP varies from one Member State to another. In order to guarantee both the health and safety of the users and the free movement of homeopathic medicinal products the rapporteur advocates a Community-wide harmonized list of degrees of dilution determined per mother tincture on the basis of scientific research. The Commission goes no further than advocating a modified break-down of the degrees of dilution to be registered, but does not come up with any clear proposal.

Article 7(1) of Directive 92/74/EEC restricts the SSRP to homeopathic medicinal products for pet animals or exotic species not intended for human consumption. However, there is no reason why - in terms of environmental protection, public health or consumer interests - homeopathic medicinal products which are deemed not to be harmful to humans should be a risk to animals intended for consumption, assuming, of course, compliance with the provisions contained in Regulation No 2377/90 on residue limits of veterinary medicinal products in foodstuffs of animal origin. The rapporteur therefore supports simply deleting the restriction in question, provided the degree of dilution takes due account of public health considerations.

Article 7(2) covers labelling and, where appropriate, the package insert of homeopathic medicinal products which are marketed in accordance with the SSRP. Both the Commission and the manufacturers - and doctors and patients, too - are opposed to a number of the requirements. The rapporteur shares the view that four of the provisions need to be reviewed.

Firstly, this article makes it obligatory to mention only the scientific name of the stock. This means, firstly, that a Latin name has to be used and, secondly, that fantasy names may not be used. This is not only incomprehensible as far as patients are concerned, but it is also regarded as a source of confusion and mistakes. Given that it is in patients' interests to have recognisable product designations and clear product descriptions, the rapporteur would prefer to permit fantasy names, in particular for combination preparations, provided that this does not suggest or introduce any therapeutic indication.

Secondly, both the manufacturers and the Commission wonder whether in certain cases there should be an indication of the dosage. The directives are confined to the obligation to state the method of use and, if necessary, the route of administration. The rapporteur therefore supports the proposal to amend the two directives accordingly.

Thirdly, the article imposes an obligation to make explicit that the product is a 'homeopathic medicinal product without approved therapeutic indication'. While the Commission notes that the Member States have transposed this obligation in widely varying ways, the manufacturers say that this statement has a discriminatory effect with regard to other medicinal products and, moreover, is senseless given that the therapeutic indication is not part of the registration procedure. The manufacturers therefore propose replacing the description 'homeopathic medicinal product without approved therapeutic indication' with 'homeopathic medicinal product'. The Commission favours 'homeopathic medicinal product without medical claim'. The rapporteur agrees that 'homeopathic medicinal products without approved therapeutic indication' needs to be changed. 'Homeopathic medicinal product without claims' would appear to be an acceptable compromise. It denies that a homeopathic medicinal product is making specific medical or therapeutic claims; and it removes any negative or pejorative connotations from the product.

Fourthly - and this, of course, does not apply to homeopathic medicinal products for veterinary use - is it really appropriate to provide a warning advising the user to consult a doctor if the symptoms persist 'during the use of the medicinal product'? The alternatives would be to omit this or to advise the user to consult a doctor if symptoms persist 'after completion of the treatment'. While the Commission avoids making a choice, the rapporteur opts for the former, not least to avoid late intervention in the case of long-term treatment.

Article 9(1) on authorization and labelling of homeopathic medicinal products not covered by the SSRP does not create any specific problems.

Article 9(2) proceeds on the assumption that homeopathic medicinal products which are not eligible for an SSRP are evaluated and authorized, or not, pursuant to Directives 65/65/EEC and 75/319/EEC in the case of homeopathic medicine for humans, and Directives 81/851/EEC and 90/687/EEC in the case of homeopathic medicine for animals. According to this article, however, Member States are entitled, but not obliged, to introduce or retain specific rules for the pharmacological, toxicological and clinical trials, in accordance with the principles and characteristics of homeopathy as practised in the Member State. Some Member States have done this; others have not.

While this article appears to be an essential instrument in taking account of differences between both Member States' traditions and medical culture, it causes distortion of competition and hence prevents the free movement of homeopathic medicinal products.

To satisfy the need for special provisions while ensuring free trade in homeopathic medicinal products, the rapporteur advocates obliging Member States to draw up special rules on the testing of homeopathic medicinal products homeopathic medicinal products. The Commission, too, is thinking on these lines. Manufacturers have pointed out that this affects roughly half of all homeopathic medicinal products.

However, one might well ask whether there is any reason why the individual Member States should carry out all this testing, given that there is no harmonization of homeopathic medicinal products with therapeutic indications. Nor is there a system of mutual recognition. We need to look at how much time and energy could be saved, and how many distortions of competition could be avoided, if the testing, assessment, authorization and recognition were to be carried out by a Community body. However - and this is true of national research, too - there need to be guarantees that persons with expert knowledge of homeopathic medicinal products are involved.

In the absence of such an approach, we must make do with the existing directives. However, they need to be amended in such a way that, firstly, application of the statutory and administrative provisions ensure the free movement of homeopathic medicinal products and, secondly, that when the additional rules are drawn up they take account of the peculiar nature of homeopathic medicinal products. In the rapporteur's opinion, proposals to amend the two Directives can only be accepted by the European Parliament if these two conditions are fulfilled.

20 May 1998

OPINION
(Rule 147)

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

on the Commission Report to the European Parliament and Council on the Application of Directives 92/72 and 92/74 relating to homeopathic medicinal products (COM(97)0362 - C4-0484/97 (Chanterie report)

Committee on Agriculture and Rural Development

Draftsman: Mr David Hallam

PROCEDURE

At its meeting of 26 November 1997 the Committee on Agriculture and Rural Development appointed Mr David Hallam, draftsman.

It considered the draft opinion at its meetings of 15/16 April and 19/20 May 1998.

At the last meeting it adopted the following conclusions unanimously.

The following took part in the vote: Colino Salamanca, chairman; Cunha, vice-chairman; Hallam, draftsman; Anttila, Baldarelli (for Campos), Barthet-Mayer, Botz (for Rehder), Cabezón Alonso (for Watts), Fantuzzi, Filippi, Fraga Estévez, Funk, Garot, Goepel, Görlach, Hardstaff, Iversen, Jové Peres, Keppelhoff-Wiechert, Kofoed, Lambraki, Martinez, Mulder, Novo (for Querbes), Otila (for Dimitrakopoulos), Parigi, Rosado Fernandes, Santini, Schierhuber, Sonneveld, Sturdy and Wibe (for Wilson).

BACKGROUND

Homeopathic medicine has been officially recognised in certain Member States for many years, but only tolerated in others. The differences in status of alternative medicines hindered trade and led to discrimination and distortion of competition. By means of Directives 92/73/EEC and 92/74/EEC, a legal framework was created allowing patients access to the products of their choice while providing precautions to ensure the quality and safety of the products, giving clear indications of their homeopathic character, and harmonising rules relating to manufacture, control and inspection. The purpose of the Commission's present report is to review the application of these directives and to identify areas where improvements can be made before a formal Commission proposal is made to amend the directives. There will thus be a further opportunity to make detailed amendments to these directives.

Directives 92/73/EEC and 92/74/EEC of 22 September 1992 were accepted by all concerned groups, as the texts created the same legal basis in all Member States. This was especially important for those countries where no legislation at all existed concerning the market authorisation or registration

of homeopathic medicinal products. For the first time those products were defined as "medicinal products" all over Europe.

However, the Commission report makes clear that the implementation of the directives varies from Member State to Member State. Unfortunately, it is a fact that the harmonisation of the market and the free movement of goods has not yet been achieved. This is a barrier to the single market.

Directive 92/73/EEC applies to homeopathic products for human use, and 92/74/EEC to homeopathic products for veterinary use, but the problems which the Commission highlights apply in many respects to both directives. One area of concern is the wording of Article 6, paragraph 1, of both directives which state that "Each Member State shall take due account of registrations and authorisations previously granted by another Member State". The Commission points out that this formulation is not very clear and has been interpreted in widely different ways so that the recognition of registration in other Member States are not guaranteed, and that a clear and unambiguous obligation should be placed on Member States to define exactly under which specific conditions existing national legislations should be mutually recognised or endorsed by other Member States, ie by the establishment of a system of mutual recognition.

The draftsman is well aware that homeopathy is well established in certain Member States such as Germany and France, but much less so in other countries. Without wishing to go into the question of the effectiveness of homeopathy, this does seem to be an issue which should be left to individual Member States to decide in the fullness of time. To impose, at this stage, a requirement that homeopathic products which are registered and authorised in a country which has a well-established tradition of homeopathy should be accepted in all other countries, may have a counter-productive effect. While there is always a good case for improving transparency and clarity in matters such as these, in order to improve the single market, this process should not be forced on Member States in such as way as to alienate consumers.

Some homeopathic remedies use dangerous chemicals such as mercury, arsenic and silica which naturally must give some concern about residues both on farm land and in the food chain. However, these "mother tinctures" are substantially diluted so it is claimed that they are harmless in use whilst remaining effective. Treatment is often on the basis of trial and error, with constant adjustments during the therapeutic period. How homeopathy works remains a mystery, though some claim that the sustained shaking of the mother tinctures during dilution sets up a molecular reaction in the body.

Most of the evidence in support of homeopathy is anecdotal rather than scientific. During the course of his research, the draftsman felt that the critical factor in the therapeutic programmes may well be linked to the holistic and time consuming diagnosis rather than the simple application of a medicine. The draftsman came across some counter-anecdotal evidence to suggest that homeopathy, whilst having its advocates, does have its detractors and disappointed users.

A second area of concern is Article 7, paragraph 1, of Directive 92/74, relating to the simplified registration procedure for homeopathic products to be administered to food-producing animals. The directives exclude food-producing animals from the simplified registration system and an opinion is sought on whether they should be included. The simplified procedure at present applies to products which are placed on a market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient, ie where quality and safety are beyond any doubt

whatsoever. European legislation on maximum residue levels([1]) declared homeopathic medicinal products in total to be harmless from the degree of dilution of D4 (=1/10.000) and greater. Moreover, the withdrawal period for the application of homeopathic medicinal products for animals has been fixed at zero days. Nevertheless, whereas the patient prescribes the way he wants to be treated, the consumer of milk or meat does not do so for the food before him, and the draftsman believes that until there is scientific proof that homeopathic medicines do not present any risk to humans, the simplified procedure should not be applied to animals in the food chain.

The third proposal is to amend Article 7, paragraph 2 of both directives. The present directives state that there should be a clear mention of the words "homeopathic medicinal product" with certain specified, but no other, information (including the phrase "homeopathic medicinal product without approved therapeutic indication"). Fantasy names for preparations combining a number of substances are therefore not allowed. The Commission is considering allowing fantasy names, and is investigating the possibility of leaving out the clause "without therapeutic indication". This subject is perhaps the most difficult and controversial of all, because scientific proof is a concept which we understand to be evidence achieved in a controlled environment, and it is extremely difficult to establish this proof in homeopathy. The draftsman is not against the use of fantasy names, but advocates extreme caution if there is any suggestion that homeopathic products should be given a scientific credibility which they do not have in the strictest possible sense of the word.

Finally Article 9, paragraph 2, of the directives relating to tests and clinical trials is optional and not binding on Member States. The directives state that Member States are not obliged to introduce specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products. The reason is quite simply that they are considered to be not up to these demands. The Commission is now considering making this provision binding and demanding explicitly that the specific rules for tests and clinical trials in Member States should provide for the involvement of appropriate experts in homeopathic and anthroposophic medicine.

The draftsman is not sympathetic to the objective of making these products subject to tests and clinical trials but it clear that the judgement of these "appropriate experts" will in fact be completely objective evidence in the scientific sense. It may therefore be wrong - and indeed dangerous - to suggest to the public that these medicines have been scientifically proven in the conventional sense.

CONCLUSIONS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Protection, as the committee responsible, to incorporate the following conclusions in its report:

1. Points out that homeopathy, while of growing interest in the European Union, is at very different stages of development in different Member States, and believes that no attempt should be made at this stage to force Member States to adopt uniform standards, or to adopt a system whereby standards in certain Member States have to be accepted in others; believes that this might be counter-productive and alienate consumers;

([1]) Regulation (EEC) 2377/90 No 2796/95; Annex II of 4.12.1995.

2. Is of the view until there is scientific proof that homeopathic medicines administered to animals are harmless to human health, the simplified registration procedure should not be extended to food producing animals. In particular, all mother tinctures should be subject to rigorous scientific tests to establish dilution levels consistent with safety in the food chain, protection from contaminated slurry, ensuring that animals do not suffer unnecessarily for a prolonged period;

3 Is not against the use of fantasy names for combination products, but believes that this must be controlled in order to ensure that no therapeutic claims are made which cannot be justified by evidence under the strictest possible scientific conditions;

4. Assumes that homeopathic remedies are only used on the basis that they are prescribed by skilled and professional veterinarians or by the nationally recognised professional group of non-medical practitioners in the relevant Member State with qualifications recognised by the wider community;

5. Is not convinced that the judgement of experts in homeopathic and anthroposophic medicine constitute scientific evidence in the conventional sense and believes that it would be wrong to attempt to impose a uniform standard of what is essentially a subjective judgement throughout the European Union.

26 May 1998

OPINION
(Rule 147)

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

on the Homeopathic Medicinal Products on the Commission Report to the European Parliament and the Council on the Application of Directives 92/73 and 92/74 (COM(97)0362 - C4-0484/97) (Chanterie report)

Committee on Economic and Monetary Affairs and Industrial Policy

Draftswoman: Mrs Heidi Hautala

PROCEDURE

At its meeting of 12 December 1997 the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mrs Heidi Hautala draftswoman.

It considered the draft opinion at its meetings of 18 March, 15 April and 26 May 1998.

At the last meeting it adopted the following conclusions by 42 votes with 1 abstention.

The following were present for the vote: von Wogau, chairman; Katiforis and Secchi, vice-chairmen; Hautala, draftswoman; Anttila (for Cox), Areitio Toledo, Carlsson, Cassidy (for de Brémond d'Ars), Caudron, Donnelly, Ferrer (for Mather pursuant to Rule 138(2)), Fourçans, Gallagher, Gasòliba i Böhm, Glante, Harrison, Hendrick, Herman, Hoppenstedt, Imbeni, Jarzembowski (for Christodoulou), Kuckelkorn, Konrad, Langen, Larive, Lukas, Lulling, Malerba (for Arroni), Thomas Mann (for Friedrich), McCarthy (for Berès), Metten, Miller, Paasilinna, Peijs, Read, de Rose, Rübig, Scarbonchi, Skinner (for Billingham), Tappin (for Fayot), Thyssen, Torres Marques and W.G. van Velzen (for Ilaskivi).

BACKGROUND

Over the last decades homeopathy has benefitted from growing demand both from doctors and from the public in most European countries. Opinion polls conducted within the EU countries reveal that the majority of the population agrees to treatment with such methods, as the awareness of the risks and side-effects of conventional drugs is increasing. According to the Commission's figures, homeopathic medicinal products currently account for over 1% of gross sales of the EU pharmaceutical industry. In France, Germany and the Netherlands this figure is over 2% in value and 5% in volume.

By definition, a homeopathic preparation is a medicinal agent which has been manufactured according to a certain method of production. The pharmaceutical quality of these preparations is regulated by homeopathic pharmacopoeias in the different countries such as the BHP(British

Homeopathic Pharmacopoeia), HAB (Homöopathisches Arzneibuch) or PhF (Pharmacopée Francaise), and the respective Directives of the EU. Homeopathic medications are utilized not only in classical homeopathy, but also in other schools of therapy, e.g. anthroposophical medicine. Both single-ingredient homeopathic agents and combination preparations are employed within the field of homeotherapy. Homeopathic medicinal products are officially recognized in certain Member States but only tolerated in others. Nevertheless, they are prescribed and used in all Member States and traded across the borders.

In 1992 the Council adopted Directives 92/73 and 92/74 on homeopathic medicinal products, the latter laying down provisions for homeopathics for veterinary use. By adopting these Directives, specific provisions for homeopathic medicinal products were created, in order to overcome differences in the status of alternative medicines which hindered trade in homeopathic medicinal products within the Community and lead to the discrimination and distortion of competition between manufacturers of these products. It was also intended that a legal framework should be created to allow patients access to the medicinal products of their choice, and to harmonize the rules relating to the manufacturing, control and inspection of homeopathic medicinal products to permit their free circulation throughout the Community. Furthermore, the regulatory framework for medicinal products seemed not always appropriate of homeopathic medicinal products.

According to Art. 6 of Directive 92/73, all homeopathic medicinal products put on the market in the European Union must have either a registration or an authorization, and each Member State "shall take due account" of registrations and authorizations previously granted by another Member State. This formulation was interpreted by the Member States - while transposing the Directive into national law - in a wide variety of ways. The Directives 92/73 and 92/74 also provide for the creation of a simplified registration procedure in Member States for homeopathic medicinal products which are placed on the market without therapeutic indications.

According to Art. 10, paragraph 3 of the said Directives, the Commission should present, not later than 31 December 1995, a report to the European Parliament and the Council concerning the evaluation of the transposition and application of the Directives by the Member States. The Commission clearly missed that date by submitting its report only in mid-1997, claiming that the delay was due to delays in some Member States in transposing the Directives into national law which did not allow for a timely evaluation of experiences - a not fully convincing reason, since most of the Member States transposed the Directives in time.

The main concern in the Commission's report, which is based on a study performed by an independent consultant, is that 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 lead to discrimination and distortion of competition between manufacturers. Other fields of concern are the advertising for these products, their eligibility for the simplified registration procedure, and dilutions that may be registered. Since the structure and wording of both Directives are nearly identical, the problems are the same. However, the exclusion of homeopathic products intended for administration to food producing animals from the simplified registration is a specific problem which has to be considered.

The Commission asks the EP to express its view on the above-mentioned problems and the five conclusions drawn thereof:

- to come to a clear definition on the conditions on which existing national registrations should be mutually recognised or endorsed by other Member States (Art. 6(1);
- increase the scope of products subject to a simplified registration procedure (Art. 7 (1) of the Directive 92/73);
- simplified registration to be enlarged to homeopathics for food producing animals (Art. 7(1) Directive 92/74);
- allowing for the use of phantasy names for homeopathic combination preparations (Art. 7 (2) Directives 92/73 and 92/74) and new labelling provisions;
- introducing binding rules for tests and clinical trials with compulsory involvement of appropriate experts in homeopathic and anthroposophic medicine.

Your draftswoman endorses, in general terms, the problems raised and conclusions put forward by the Commission in its communication. However, she would like to make some specific comments clarifying the Parliament's demands concerning the awaited Commission's proposal for an amended legislative text.

The Commission's report concerns the internal market aspects of homeopathics and is, accordingly, to be treated under Article 100 A. It has to be ensured that no discrimination, which cannot be based on overriding public interest, between these products with origin in different Member States occur. The easiest technical way to guarantee non-discrimination is, of course, the unconditioned mutual recognition of national registrations. But the Parliament should follow the Commission down this road only if it can be secured that no Member State will be forced to accept homeopathic products on its market which are produced, tested on their quality and pureness, and registered under lower health and safety conditions than currently applicable in the respective country.

At the same time, it has to be ensured that no competitive disadvantages exist for homeopathics compared to other medicinal products. Therefore, trials for the registration of homeopathic medicinal products have to respect the peculiarities of these medicines and any discrimination in the provisions for their labelling should be avoided. It has to be born in mind that millions of EU citizens see homeopathics as valuable medicines which are also very cheap in relation to "normal" pharmaceuticals.

Finally, anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products.

CONCLUSIONS

The Committee on Economic and Monetary Affairs and Industrial Policy calls on the Committee on the Environment, Public Health and Consumer Protection, as the committee responsible, to incorporate the following conclusions in its report:

1. Welcomes the Commission's report which invites the Parliament to comment on the conclusions therein at an early stage with a view of new legislative proposals, since Parliament repeatedly has emphasised the important role of non conventional medicine for the health of the citizens (most recently in the Lannoye-report on non-conventional medicine A4- 75/97);

2. Notes that, according to Art 10 (3) of Directives 92/73 and 92/74, the Commission should have reported not later than 31 December 1995 to the Parliament and the Council concerning the transposition and application of the Directives by the Member States; deplores the delay occurred, whatever the reasons for this delay;

3. Emphasizes that the producers of homeopathic medicines are mainly SMEs, which suffer from the burden to register their products separately in the different Member States;

4. Is of the opinion that the aim of further legislation in this field should be the mutual recognition of national registrations and authorizations for homeopathic products, provided that the highest health and safety requirements are met by all Member States;

5. Is, therefore, of the opinion that the application of the mutual recognition principle should be made dependent on the application, including appropriate control mechanisms, of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) and on provisions which would ensure that no Member State would be forced to lower its standards relating to problematic residues or contamination of the substances used;

6. Is of the opinion that common safety criteria should be defined at EU level and that the Member State in which a homeopathic product first is registered has to evaluate and document compliance with such criteria;

7. Insists that the above-mentioned requirement is all the more important as it comes to "sensitive" applications (subcutaneous application, nasal sprays) or registerable dilutions of homeopathics; the aim should be not to limit the simplified registration procedure to homeopathics whose application is oral or external, but to allow for the same procedure for nasal sprays, eye drops etc. wherever no evidence can be produced for toxicological or allergic problems;

8. Suggests the amendment of Art. 7 of Dir. 92/74 on veterinary use of homeopathic medicines, in order to offer the possibility of simplified registration of homeopathics also for food-producing animals;

9. Is in favour of amending Art. 9 of Dir. 92/73 (tests and clinical trials) in order not to submit homeopathics to "classical" clinical test and mainstream-medicine approval; new, specific ways of registration should be applied throughout the Union with full participation of experts in homeopathic and anthroposophic medicine;

10. Asks for a more use-oriented redefinition of the current restriction for the application of the simplified registration to dilution of less than 1/10.000 of the mother tincture or less than 1/100 of the smallest dose to use in allopathy (to be prescribed by a doctor) in homeopathic medicinal products, as the current restriction excludes many common products;

11. Asks for the amendment of Art 7 (2), 1 of the present Directives in order to allow for fantasy names for homeopathic medicines which, in accordance with Article 1(2), contain several constituents;

12. Is of the opinion that the present provisions for labelling homeopathic and anthroposophic medicinal products (Art 7(2),11: "homeopathic medicinal product without approved therapeutic indication") are discriminative and should be replaced by a more neutral wording like "registered homeopathic medicinal product".

23 September 1998

OPINION
(Rule 147)

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

Homeopathic Medicinal Products - Commission Report on the Application of Directives 92/73/EEC and 92/74/EEC (COM(97)0362 - C4-0484/97 (Chanterie report)

Committee on Research, Technological Development and Energy

Draftsman: Mrs Hiltrud Breyer

PROCEDURE

At its meeting of 9 December 1997 the Committee on Research, Technological Development and Energy appointed Mrs Hiltrud Breyer draftsman.

It considered the draft opinion at its meetings of 23 June 1998 and 22/23 September 1998.

At the last meeting it adopted the following conclusions unanimously.

The following were present for the vote: Scapagnini, chairman; Quisthoudt-Rowohl, Adam and Lange, vice-chairmen; Breyer, draftsman; Ahern, Argyros, Chichester, Desama, Estevan Bolea, Ferber, Heinisch (for Rovsing), Izquierdo Collado (for Tannert), Linkohr, McNally, Malerba, Marset Campos, Matikainen-Kallström, Mombaur, Plooij-Van Gorsel, Pompidou, Soulier, Stockmann and van Velzen W.G. .

Introduction

Demand for homeopathic medicinal products has grown in recent decades in the majority of European countries (with the result that some 22% of the population now use them). According to the Commission, they account for over 1% of the gross sales of the European pharmaceutical industry, with the figure exceeding 2% in value and 5% by volume in France, Germany and the Netherlands.

In 1992 the Council passed two directives (92/73 and 92/74) on homeopathic medicinal products which were designed to complete the single market in this field. There were considerable differences at that time between the Member States in the rules governing homeopathic drugs, resulting in obstacles to trade and distortions of competition between manufacturers. The directives were therefore intended to harmonise the rules on the manufacture, control and inspection of homeopathic medicinal products for humans and animals and in doing so guarantee patients access to the products of their choice across the EU. It was essential on the one hand to ensure that a clear indication of the homeopathic nature of the drugs was given and on the other hand to guarantee their quality and safety. The directives introduced a simplified registration procedure in the Member States for traditional homeopathic medicinal products which are placed on the market without therapeutic indications and in a form and dosage which do not present a risk. For homeopathic medicinal

products with therapeutic indications or in a form to be administered other than orally or externally, the usual rules governing the market authorisation of medicinal products were to be applied. However, Member States which had a homeopathic tradition were to be allowed to apply particular rules for the evaluation of the results of tests and trials.

The directives were adopted on 22 September 1992 but the Member States were slow to apply them. As a result, the Commission was obliged to bring infringement proceedings against Belgium, France, Portugal and the United Kingdom (by January 1997 some of these countries had still not implemented the directives). The lack of implementation also gave the Commission a pretext for presenting this report 18 months after the scheduled date.

The Commission's observations

The Commission examines in detail the experiences in implementing the directives' main provisions, focussing in particular on:

- the definition of homeopathic medicinal product
- manufacture, control and inspection, and information exchange
- placing on the market, registration and authorisation
- advertising
- eligibility for the simplified registration procedure
- labelling and package insert
- marketing authorisation.

In its conclusions, the Commission describes the degree of harmonisation achieved since the directives entered into force as unsatisfactory. It suggests that the positions of the Council and Parliament may now differ from those stated in 1992 but does not substantiate this. It proposes to amend the directives as follows so as to:

- provide a clear definition of the conditions for mutual recognition of national registrations (Article 6(1) of 92/73 and 92/74);
- increase the range of products covered by the simplified registration procedure (Article 7(1) of 92/73);
- provide for a simplified registration procedure for homeopathic veterinary medicinal products intended for administration to food-producing animals (Article 7(1) of 92/74);
- authorise the use of fantasy names for homeopathic preparations combining substances (Article 7(2) of 92/73 and 92/74);
- introduce specific binding rules for tests and clinical trials whose provisions would be drafted with the involvement of experts in homeopathic and anthroposophical medicine.

Opinion and conclusions

In the opinion of the Committee on Research, Technological Development and Energy, the following conclusions, in particular, should be drawn:

1. The rules on the registration and market authorisation of homeopathic medicinal products are interpreted differently in the different Member States. The legislation should be worded clearly and binding rules on registration and authorisation are needed. This must not lead to a fall in the current standards of safety, health protection or consumer protection in any of the Member

States. The registration of homeopathic medicinal products is already subject to stringent strict rules on quality and safety criteria. Chapters IV and V of Directive 75/319 and the principles and guidelines for good manufacturing and laboratory practice must be applied in full to all homeopathic medicinal products.
Excessive registration costs in some Member States may be obstructing the widespread use of individual medicinal products, and the Community should therefore take steps to harmonise the relevant provisions.

2. It should also be possible to authorise parenteral administration, eye drops and nasal sprays under the simplified registration procedure, whilst retaining the stringent test criteria for quality and safety.

3. The current restriction of the simplified registration procedure to homeopathic medicinal products with a degree of dilution to less than 1 part per 10 000 of the mother tincture, or less than 1/100th of the smallest dose used in allopathy and for which a doctor's prescription is required, should be reconsidered with a view to bringing it more closely into line with practice since the current restriction excludes many common products. The limit of less than 1 part per 10 000 of the mother tincture should only apply to medicinal products for which a prescription is required. The simplified procedure should also apply to harmless mother tinctures that may be used in allopathy without a prescription.

4. Simplified registration must also be made possible for homeopathic veterinary medicinal products to be administered to food-producing animals. This condition is particularly relevant in view of the demand for organically-produced foodstuffs. Most homeopathic substances from the degree of dilution of 1/10 000 have in any case been listed in Annex II to the regulation on maximum residue levels (EEC) 2377/90 and classed as harmless. The fact that some Member States levy higher charges is preventing the widespread use of homeopathic veterinary medicinal products, and the Community should therefore undertake the necessary harmonisation.

5. As regards the possibility of choosing fantasy names for combination preparations and the mention 'homeopathic medicinal product', no objection can be raised to the liberal approach proposed by the Commission.

6. In Article 7(2), eleventh indent, of Directive 92/73 the mention 'without approved therapeutic indications' is mandatory. This discriminates between medicinal products and should be dropped entirely or replaced by a neutral phrase such as 'licensed homeopathic medicinal product'.

7. Traditional clinical tests have proved unsuitable for homeopathic medicinal products in many respects. The Commission should draw up a directive on homeopathic medicinal products, analogous to Directive 318/75 (on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products), taking into account the special features of homeopathy and the experience gained in administering the homeopathic medicinal products in question. Experts in this area of treatment must also be fully involved in the authorisation and registration of the products.

8. The Commission should report without delay on the studies and surveys conducted to research into the effectiveness of homeopathic and other alternative treatments within the framework of the Community R&D programme for Biomedicine (budget heading B6-7142).

9. As part of the biomedicine section of the Fifth R&D Framework Programme, research activities in the field of alternative medicine should be promoted, on the basis of the report called for in paragraph 9 to look at the individualised and holistic approaches, preventive role and particular features of alternative medical disciplines. These activities should include programmes for basic research into homeopathy, to be carried out by bio-medical institutions, designed in particular to explain the process of homeopathic potentisation and prove the efficacy of homeopathic high-level potencies. They should also include programmes to promote international pooling of the experience of experts in homeopathy.

3 June 1998

OPINION
(Rule 147)

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

on Homeopathic Medicinal Products: Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74 (COM(97)0362 - C4-0484/97) (Chanterie report)

Committee on Legal Affairs and Citizens' Rights

Draftsman: Mrs Wilmya Zimmermann

PROCEDURE

At its meeting of 13 and 14 October 1997 the Committee on Legal Affairs and Citizens' Rights appointed Mrs Zimmermann draftsman.

It considered the draft opinion at its meetings of 16-17 March and 2-3 June 1998.

At the latter meeting it adopted the following conclusions unanimously.

The following were present for the vote: De Clercq, chairman; Palacio Vallelersundi, vice-chairman; Zimmermann, draftsman; Barzanti, Berger, Cot, Gebhardt, Habsburg-Lothringen, Janssen van Raay, Lehne, Mosiek-Urbahn, Thors, Verde I Aldea and Wieland.

INTRODUCTION

Council Directives 92/73/EEC and 92/74/EEC of 22 September 1992 were endorsed as legislative acts by the Member States, thereby creating, for the first time, a European legal framework for homeopathic products at Community level and recognizing them as medicinal products.

This was particularly welcome in that some Community Member States had hitherto not had any legal basis in this area. It is regrettable, however, that insufficient consideration was given to the European Parliament's opinion on the matter at the time. Despite this, the directives have helped to ensure that proper account is taken of the status of homeopathic treatment, thus making it possible to introduce uniform rules in the Member States.

The Commission report

The Commission has drawn up a report on the application of Directives 92/73/EEC and 92/74/EEC([1]) against the backdrop of two topics:

(1) the effectiveness of homeopathic medicinal products, and
(2) the fight for market share between the manufacturers of allopathic and homeopathic medicinal products.

The Commission report fulfils the requirement laid down in Article 10(3) of Directives 92/73/EEC and 92/74/EEC and presents an analysis of the application of the directives and their impact on the parties concerned, namely the manufacturers of homeopathic medicinal products, doctors and patients/consumers.

The report is faced with the fundamental problem that allopathic and homeopathic medicine should not compete with each other, but should complement each other, instead.

Irrespective of which medicine is under consideration, its action must be examined in every case in order to avoid harmful effects on patients, while on the other hand the scale of animal tests must be kept to a minimum.

The report makes it quite clear that the directives have not been transposed uniformly in the Member States, but in some cases with major differences concerning individual aspects. The Commission expresses its regret that the objective of the directives, namely harmonization of the market and the free circulation of homeopathic medicinal products, has only been inadequately achieved.

The Commission, working together with five independent consultants, has focused on five practical issues relating to the application of both directives which have a particular bearing on Parliament's opinion, since both directives were enacted on the basis of Article 100a of the EC Treaty:

1. Mutual recognition of registrations or authorizations issued in another Member State (Article 6(1) of both directives).

2. The extension of the scope of the simplified registration procedure for homeopathic medicinal products (for humans). This concerns the inclusion of new routes of administration and a clarification or modifications of the degree of dilution from which the simplified procedure may be used.

3. The extension of the scope of the simplified registration procedure for veterinary medicinal products to cover food-producing animals; previously, only pets or exotic species whose flesh or products are not intended for human consumption were covered.

4. The use of fantasy names on the labelling and package insert of homeopathic medicinal products.

5. The possible introduction in the Member States of specific rules for tests and clinical trials of homeopathic medicinal products and the involvement of experts in homeopathic medicine.

([1]) Homeopathic Medicinal Products: Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74

CONCLUSIONS

In the light of the above, the Committee on Legal Affairs and Citizens' Rights calls on the Committee on the Environment, Public Health and Consumer Protection, as the committee responsible, to incorporate the following conclusions in its report:

The European Parliament,

1. Welcomes the Commission's proposals as a step in the right direction and therefore calls on the Commission to incorporate the five proposals on page 9 of document COM(97)0362, together with additional proposed amendments, into a proposal to amend the two directives;

2. Notes, in addition, that the wording of Article 6(1) (of Directives 92/73/EEC and 92/74/EEC), concerning the registration of homeopathic medicinal products which have already been registered in another Member State, is mostly taken to be non-binding and therefore does not result in the requisite authorization; expresses, therefore, its keen interest in the new version of the directives having binding wording, in order to rule out States exercising arbitrary power where the authorization of medicinal products is concerned;

3. Notes, further, that most homeopathic substances in dilutions of 1/10 000 or more are already included in Annex II([1]) of the regulation on maximum residue levels (EC) No 2377/90([2]) and recommends that the simplified registration procedure should also be extended to veterinary homeopathic medicinal products intended for use in animals providing foodstuffs; considers that a classification under Annex I, II or III of Regulation 2377/90 should be the basis for the necessary consumer protection;

4. Notes that the same treatment of homeopathic and allopathic medicinal products must be achieved with regard to fantasy names;

5. Realizes that the introduction of specific rules for tests and clinical trials of homeopathic medicinal products is a contentious issue, but one which must be settled in a binding manner after consulting committees of experts, in order to ensure free circulation on the market, on the one hand, and eliminate unnecessary trials and rules, on the other, but without ignoring the justified interests of patients and customers;

6. Deems it essential for future Commission proposals in this area also to be submitted to the Committee on Legal Affairs and Citizens' Rights.

([1]) List of substances not subject to maximum residue levels
([2]) As last amended by Regulation (EC) No 121/98