

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 22 March 1990

Proposal for a

SYN 251

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

Proposal for a

SYN 252

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

(presented by the Commission)

EXPLANATORY MEMORANDUM AND REPORT TO THE COUNCIL

I. General remarks

1. When the Council adopted Directive 87/22/EEC¹, and specifically Article 5 thereof, it instructed the Commission to present it with "proposals for Regulations to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of the proprietary medicinal products excluded by Article 34 of Directive 73/319/EEC² and of the veterinary medicinal products referred to in Article 2(2) of Directive 81/851/EEC³".

2. Three of the four kinds of medicines for human use which were provisionally excluded in 1975 have recently been incorporated into Community pharmaceutical legislation, namely:
immunological medicinal products by Directive 89/342/EEC⁴,
radio-pharmaceuticals by Directive 89/343/EEC⁵ and medicinal products derived from human blood by Directive 89/381/EEC⁶.
In the veterinary field, a proposal for a Directive on immunological medicinal products was transmitted to the Council in January 1989⁷. It has proved more difficult to harmonize legislation on homeopathic medicinal products because of the conflicting conceptions of medicine involved.

(1) OJ N° L 15, 17.1.1987, p.38.
(2) OJ N° L 147, 9.6.1975, p.13.
(3) OJ N° L 317, 6.11.1981, p.1.
(4) OJ N° L 142, 25.5.1989, p.14.
(5) OJ N° L 142, 25.5.1989, p.16.
(6) OJ N° L 181, 26.6.1989, p.44.
(7) OJ N° C 61, 10.3.1989, p.20.

3. While homeopathic medicine has traditionally been recognized in some Member States, it has merely been tolerated in others or even ignored by orthodox medicine altogether. Nonetheless, homeopathy has been practised in Europe for more than two centuries and has become increasingly popular with the public in the last decade or so with the rise in "natural" therapies and alternative medicine.
4. It is not for the Commission to take sides for or against a particular style of medical practice. The aim should be rather, in the light of legislative experience in some of the Member States, to provide European consumers with safeguards about the quality and safety of the homeopathic medicines currently available in all Community countries. Proof of therapeutic efficacy cannot be obtained by generally accepted scientific methods or, at the least, is highly contentious.
5. Whether recognized or simply tolerated, homeopathic remedies represent a small but not insignificant share of the pharmaceuticals market, of the order of half a billion (500 000 000) ECU. Trade between Member States is impeded by the differences in regulation and practice at national level. The proposals the Commission is now presenting to the Council, on homeopathic medicinal products for human and for veterinary use, are intended to further the completion of the internal market in the pharmaceuticals sector as provided for in the 1985 White Paper programme.

II. ALTERNATIVE REMEDIES IN EUROPE

6. In 1987 the Commission asked the Belgian Consumers' Association to carry out a study on the market for alternative medicine among European consumers. This study, written by G. Sermus, covers seven Community countries (Belgium, Denmark, Germany, France, Italy, Netherlands, United Kingdom) as well as Finland and Switzerland. It shows that a considerable proportion of the population (from 18% to 75% depending on country) makes use of alternative therapies. Homeopathy is the principal method among them, well ahead of acupuncture and manipulations such as chiropractic, osteopathy and various types of massage. Then come herbal remedies, followed by what one might call "paranormal" methods, including mystical and religious approaches. Finally the author lists what he classifies as fringe methods (in Europe) such as Iridology, anthroposophy, "biomedicine", aroma therapy, cell therapy and hypnotherapy. The author notes that it is generally adults between the ages of 40 and 60 with a high level of education who make most use of alternative medicine.

7. These diverse therapies have little in common except being almost uniformly rejected by science as lacking a rational basis. Whereas conventional or allopathic medicine has made considerable progress through advances in biology, pharmacology and surgical techniques, the various forms of alternative medicine generally adopt an empirical approach backed by what are often obscure explanations. But conventional medicine itself does not meet all the expectations of patients with certain chronic or supposedly "incurable" diseases. Furthermore, patients are often put off by the impersonal and highly technological nature of modern medicine. The alternative medicines, on the other hand, tend to be holistic in the sense that they look at the person as a whole and encourage the patient to participate in the healing process. Although alternative medicine can be sincere in approach and rest on established traditions, it must be admitted that a degree of opportunism has developed to exploit recent fashions, even to the extent of combining methods that are incompatible.

8. Homeopathic remedies represent by far the most important type of alternative medicines used in Europe. For our present purposes, plant-based medicinal products will be considered as belonging to the allopathic or conventional tradition; medicinal herbs are in fact the origin of many modern medicines, either by extraction or by synthesis, although the action of the plant as a whole may be poorly understood. While allopathy treats a condition by tackling the causes or, at second-best, the symptoms, homeopathy is based on the principle of similarity - like cures like - and extreme dilutions. The theory was developed by Samuel Hahnemann (1755-1843) and consists of trying to cure the patient by administering very small doses of a substance which, in a healthy individual, would produce similar symptoms to those observed in the patient. This theory has evolved into various opposing schools: complexists, pluralists ("materialists") and unicists ("dynamists"). Anthroposophy (following Rudolf Steiner) and "biomedicine" (following Dr Schussler), which are more widespread in Germany than in the rest of the Community, make frequent use of homeopathic remedies while being based on other ideas.

9. When the Community's pharmaceuticals directives were being transposed into German law in the "Arzneimittelgesetz 1976", a wide-ranging debate took place about the position of alternative remedies. The quality of homeopathic and anthroposophic medicines is standardized in a separate official pharmacopoeia (Homöopathisches Arzneibuch - HAB); such medicinal products are evaluated by special committees of the Federal Health Office (Bundesgesundheitsamt - BGA). France also has a well-established homeopathic tradition, with special authorization procedures and the inclusion of monographs on homeopathic preparations and 'mother tinctures' or stocks in the French Pharmacopoeia (editions VIII and X). Homeopathic medicinal products are also mentioned, albeit in much less detail, in the pharmaceutical legislation of Belgium, Denmark, the Netherlands, the United Kingdom and Ireland. These countries, as well as Italy and Portugal, are waiting to see what action the Community will take before reviewing their own legislation.

III. CONSULTATIONS AT COMMUNITY LEVEL

10. In the period since 1987, the Commission has put three successive preliminary drafts of a Directive on homeopathic medicinal products to the Pharmaceuticals Committee, which is composed of representatives of the Member States. The reaction to these drafts varied widely according to the different national positions, from official recognition to outright rejection. Since homeopathic medicines are available on all the national markets, there have been suggestions that they be classified as articles for household consumption rather than as medicines. However, this does not seem consistent either with the Community definition of medicinal products or with the instructions given by the Council. While some convergence of views seems possible in the case of traditional homeopathic medicines, the same cannot be said of anthroposophical products, nor of aspects felt to carry too much risk (preparations for injection, for example) or considered hardly compatible with the basic principles of homeopathy (encouragement of self-medication).

11. The preliminary draft Directive on homeopathic medicinal products for human use was distributed widely through several European organizations representing professionals in the field: the pharmaceuticals industry (EFPIA), homeopathic and anthroposophic laboratories, the Association of EEC pharmacists and mutual pharmacies, and homeopaths and anthroposophical practitioners. The overall reaction was positive, since the draft text introduced greater legal security while eliminating various sharp practices which damage the reputation of serious practitioners. At the request of the Commission, the Consumers' Consultative Committee issued an opinion on 16 February 1989; this was favourable, and was accompanied by complete and detailed reference documentation. In addition to this, an international workshop on homeopathic medicines was held in Berlin on 2 and 3 February 1989 at the invitation of the Federal Health Office; 11 health ministries of European countries were represented, as well as the Commission. Most of the participants met again in Strasbourg on 17 and 18 May at the invitation of the Secretary of the European Pharmacopoeia.

12. Several preliminary drafts of a Directive on medicinal products for veterinary use have been submitted to the Committee for Veterinary Medicinal Products. Despite the great differences between countries, most members of the Committee underlined the need to improve standards of quality and safety for this category of medicines, which are being used more and more. The competent authorities would also like to eliminate a number of abuses in the field, in particular the sale of medicines described as homeopathic for collectively treating livestock as part of specific medications for which a therapeutic effect has not been shown.

IV. THE QUALITY OF HOMEOPATHIC MEDICINES

13. Homeopathic medicinal products are defined primarily by the way they are made up, as described in the European Pharmacopoeia if it is extended to include homeopathy or, if not, in national pharmacopoeias (currently those of France and Germany). This "objective" method of definition, which is the one adopted in the German legislation, has the advantage of not taking sides in the argument over the philosophy or rational basis of homeopathy or other traditions using the same products, such as is often the case for anthroposophy. Homeopathic medicines should be clearly identifiable as such for the general public, by means of a special legend on the label, so that there can be no confusion between these, more controversial, homeopathic products and orthodox medicines. The general approach of Community pharmaceutical legislation is followed in that the proposals cover only medicines which are widely distributed, i.e. prepared industrially and thus a major potential risk for the public, in particular by being sold in intra-Community trade. This would not affect in any way the right to prescribe or prepare other alternative therapies in individual cases according to magistral or officinal formulae, within the bounds of current national legislation.

14. The wide distribution of industrially prepared homeopathic medicines means that the first priority must be to harmonize the manufacture and monitoring of them. Apart from having to comply with the European Pharmacopoeia or, if not covered by it, the existing official pharmacopoeias, homeopathic medicines will become subject to all the Community rules safeguarding the quality of medicinal products manufactured in and imported/exported to or from the Community. A consequence is that the authorization to manufacture, export or import such products will be conditional on possession of suitable premises and equipment. All raw materials and each batch manufactured will have to be monitored by a qualified person, who will issue a properly registered certificate of conformity. The rules of good manufacturing practice (GMP) will become mandatory, which is particularly important in the case of highly diluted products. Establishments will also become subject to regular monitoring by pharmaceuticals inspectors. The competent authorities in the Member States will be required to exchange inspection reports and other data relevant to safeguarding the quality and safety of homeopathic medicines.

V. PLACEMENT OF HOMEOPATHIC MEDICINES ON THE MARKET

15. Harmonizing the terms on which homeopathic medicines are to receive market authorization poses more complicated problems. Some Member States, while accepting that it is useful to ensure the quality of homeopathic products, do not want to give them official status and yet are prepared to admit products legally sold in other Member States, within certain constraints. On the other hand, where a Member State wishes to regulate the marketing of homeopathic medicines it will have a choice between two different regimes.

16. The first of these, full harmonization, consists of a simplified registration procedure applicable to medicinal products which, without therapeutic claims being made, are put up in pharmaceutical forms and at dilutions that carry no risk. Such medicines, sold under their common name and bearing a fully harmonized labelling, will usually be prescribed by a practitioner qualified according to the specific features of the case under treatment. Medicines of this type will be considered to belong to the homeopathic tradition and their therapeutic effect is to be assessed in terms of that tradition. Since some of the information would be repetitive, it will be possible to combine dossiers to cover a series of like preparations.

17. The other, and more rigorous, regime cannot be entirely harmonized at this juncture. For homeopathic medicines other than those qualifying for the simplified registration procedure, proof of therapeutic effect balanced against potential risks will have to be provided. Member States will apply either the ordinary rules on market authorization, especially criteria of efficacy and safety, or special rules for homeopathic preparations. In this second case, these special rules will have to be notified to the Commission with a view to later harmonization.

VI. CONCLUSIONS

18. By 1993, with the entry into effect of the Directives, homeopathic medicines sold in the Community will all have to meet the same high quality standards. First-time applications for registration or authorization will be examined under the terms of the Directives. Experience with implementation will lead to a greater convergence of practice as between Member States despite the present wide differences.

In accordance with Articles 8a and 8c of the Treaty establishing the European Economic Community, the Commission calls on the Member States to take the necessary steps to comply with the proposals presented here by 1 January 1993.

19. The Commission has given due consideration to the requirements of Article 8c of the Treaty and has concluded that no special provisions are needed in this case.

The Commission has also looked at the matter of the high level of protection for health, safety, the environment and consumers required by the third paragraph of Article 100a. This review was conducted after consulting concerned parties and after analysing the inherent risks in this area, given current technical capacity within European industry. The proposals take full account of these factors, in the light of the underlying aims of the Treaty.

II

(Preparatory Acts)

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

COM(90) 72 final — SYN 251

(Submitted by the Commission on 23 March 1990)

(90/C 108/05)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

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 the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health;

Whereas the provisions of Council Directive 65/65/EEC ⁽¹⁾ and the Second Directive 75/319/EEC ⁽²⁾, as last amended by Directive 89/341/EEC ⁽³⁾, are not always appropriate for homeopathic medicinal products;

Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States; whereas, therefore, it is appropriate to recognize certain national homeopathic traditions without imposing them throughout the Community;

Whereas even if homeopathic remedies are not always officially recognized, they are nevertheless prescribed and used in all Member States;

Whereas it is desirable in the first instance to provide users of these remedies with a clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

Whereas the rules relating to the manufacture, the control and inspection of homeopathic medicinal products must be harmonized to permit the circulation throughout the Community of preparations which are safe and of good quality;

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, 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 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,

⁽¹⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽²⁾ OJ No L 147, 9. 6. 1975, p. 13.

⁽³⁾ OJ No L 142, 25. 5. 1989, p. 11.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

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.

Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions.

Article 2

1. The provisions of this Directive shall apply to industrially prepared homeopathic medicinal products for human use to the exclusion of homeopathic medicinal products prepared in accordance with a magistral or an officinal formula as defined in Article 1 of Directive 65/65/EEC.

2. The medicinal products referred to in paragraph 1 must be identified by the inclusion on their labels in clearly legible form of the words 'homeopathic medicinal product'.

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter IV of Directive 75/319/EEC shall apply to the manufacture, control, import and export of homeopathic medicinal products.

Article 4

The measures of supervision and the sanctions provided for in Chapter V of Directive 75/319/EEC shall apply to homeopathic medicinal products together with Articles 31 and 32 of the same Directive.

However, the proof of therapeutic effect mentioned in Article 28 (1) (b) of the same Directive shall not be required for homeopathic medicinal products registered in accordance with Article 7 of this Directive.

Article 5

The Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and marketed within the Community, and in particular the information mentioned in Articles 30 and 33 of Directive 75/319/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic medicinal products manufactured and marketed within the Community are registered or authorized in accordance with the provisions of Articles 7, 8 and 9. Each Member State shall take registrations and authorizations previously granted by another Member State into due consideration.

2. A Member State may refrain from establishing any system of registration or authorization for homeopathic medicinal products. A Member State applying this provision shall inform the Commission thereof. The Member State concerned shall allow the use in its territory of homeopathic medicinal products registered or authorized by other Member States in accordance with Articles 7, 8 and 9.

Article 7

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 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.

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:

- 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.

3. The criteria and rules of procedure provided for in Articles 5 to 12 of Directive 65/65/EEC shall apply to the simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic effect.

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:

- scientific name of the homeopathic stock, together with a mention of the various routes of administration, pharmaceutical forms and dilutions 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,
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution,
- manufacturing authorization for the preparations concerned,

- 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.

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.

2. A Member State may lay down specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7. In this case, before the date referred to in Article 10 (1) the Member State concerned shall notify the Commission of the specific rules in force.

CHAPTER IV

Final provisions

Article 10

1. Member States shall take the measures necessary to comply with this Directive by 31 December 1992. They shall inform the Commission thereof forthwith.

The provisions adopted pursuant to the first subparagraph shall make express reference to this Directive.

2. Applications for registration or for marketing authorization for products covered by this Directive lodged after the date set out in paragraph 1 shall comply with the provisions of this Directive.

Article 11

This Directive is addressed to the Member States.

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 — SYN 252]

(Submitted by the Commission on 23 March 1990)

(90/C 108/06)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas differences between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic veterinary medicinal products within the Community;

Whereas the essential aim of any rules governing the production, distribution and use of veterinary medicinal products must be to safeguard human and animal health;

Whereas the provisions of Council Directive 81/851/EEC (*) are not always appropriate for homeopathic veterinary medicinal products;

Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States; whereas, therefore, it is appropriate to recognize certain national homeopathic traditions without imposing them throughout the Community;

Whereas even if homeopathic remedies are not always officially recognized, they are nevertheless prescribed and used in all Member States;

Whereas it is desirable in the first instance to provide users of these remedies with a clear indication of their

homeopathic character and with sufficient guarantees of their quality and safety;

Whereas the rules relating to the manufacture, the control and inspection of homeopathic veterinary medicinal products must be harmonized to permit the circulation throughout the Community of preparations which are safe and of good quality;

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, however, the usual rules governing the authorization to market veterinary medicinal products should be applied to a homeopathic veterinary medicinal product marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; 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 veterinary medicinal products provided that they notify them to the Commission,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

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.

(*) OJ No L 317, 6. 11. 1981, p. 1.

Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions.

Article 2

1. The provisions of this Directive shall apply to homeopathic veterinary medicinal products to the exclusion of products prepared by a pharmacist or a veterinarian in accordance with a magistral or an officinal formula and intended for administration to a single animal or a small number of animals.

2. The medicinal products referred to in paragraph 1 must be identified by the inclusion on their labels in clearly legible form of the words 'homeopathic medicinal products, for animal treatment only'.

3. This Directive shall not apply to immunological homeopathic veterinary medicinal products which shall be authorized by Member States in accordance with the provisions of the Council Directive extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products.

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter V of Directive 81/851/EEC shall apply to the manufacture, control, import and export of homeopathic veterinary medicinal products.

Article 4

The measures of supervision and the sanctions provided for in Chapter VI of Directive 81/851/EEC shall apply to homeopathic veterinary medicinal products.

However, the proof of therapeutic effect mentioned in Article 37 (1) (b) of the same Directive shall not be required for homeopathic veterinary medicinal products registered in accordance with Article 7 of this Directive.

Article 5

The Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic veterinary medicinal products manufactured and marketed within the Community, and in particular the information mentioned in Articles 39 and 42 of Directive 81/851/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and marketed within the Community are registered or authorized in accordance with the provisions of Articles 7, 8 and 9. Each Member State shall take registrations and authorizations previously granted by another Member State into due consideration.

2. A Member State may refrain from establishing any system of registration or authorization for homeopathic veterinary medicinal products. A Member State applying this provision shall inform the Commission thereof. The Member State shall allow the use in its territory of homeopathic veterinary medicinal products registered or authorized by other Member States in accordance with Articles 7, 8 and 9.

Article 7

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 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 food-stuffs produced from these animals; in particular, the preparation shall contain less than one part per million of any active principle which is subject to the requirement of a veterinary prescription.

2. In addition to the clear mention of the words 'homeopathic medicinal product, for animal treatment only', the labelling and packaging of the homeopathic veterinary 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,
- in the case of products intended for administration to food-producing animals, a statement that there is a nil withdrawal period.

3. The criteria and rules of procedure provided for in Articles 8 to 15 of Directive 81/851/EEC shall apply to the simplified registration procedure for homeopathic veterinary medicinal products, with the exception of the proof of therapeutic effect.

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:

- scientific name of the homeopathic stock, together with a mention of the various routes of administration, pharmaceutical forms and dilutions 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,
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution,

- manufacturing authorization for the preparations concerned,
- 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.

Article 9

Homeopathic veterinary medicinal products other than those referred to in Article 7 shall be authorized and labelled in accordance with the provisions of Articles 5 to 15 of Directive 81/851/EEC, including the provisions concerning proof of therapeutic effect, and shall be labelled in accordance with the provisions of Articles 43 to 50 of Directive 81/851/EEC.

CHAPTER IV

Final provisions

Article 10

1. Member States shall take the measures necessary to comply with this Directive by 31 December 1992. They shall inform the Commission thereof forthwith.

The provisions adopted pursuant to the first subparagraph shall make express reference to this Directive.

2. Applications for registration or for marketing authorization for products covered by this Directive lodged after the date set out in paragraph 1 shall comply with the provisions of this Directive.

Article 11

This Directive is addressed to the Member States.

IMPACT ON COMPETITIVENESS AND EMPLOYMENT

1. What is the main reason for introducing the measure?

White Paper on completing the internal market; improvement of protection of public health; instructions from the Council to include in Community legislation all industrially produced medicinal products.

2. Features of the businesses concerned

The market for homeopathic medicines is relatively restricted (2% of the market for pharmaceuticals). Industrial preparation of homeopathic medicines is carried out by about 15 Community companies which are disadvantaged by present legislation and the lack of legal certainty for their activities in some Member States where homeopathy is not recognized. Small manufacturing or dilution runs produced by local homeopathic, dispensing pharmacies are not affected by the proposals.

According to the information available to the Commission, the industrial-scale firms are located particularly in certain areas: France, Germany, United Kingdom; however, their products are already being sold throughout the Community.

3. What direct obligations does this measure impose on businesses?

The measures introduced all seem necessary to protect the consumer and should therefore already be standard practice for a bona fide producer; in particular:

- good pharmaceutical manufacturing practice,
- a qualified person to check and certify each production batch,
- submission of documentation, especially a bibliography, to guarantee the quality and safety of the homeopathic medicines so produced.

Firms must also agree to try to standardize the quality of raw materials and production processes, as has already been achieved in some countries (Germany, France) but which still remain to be harmonized in the context of the European Pharmacopoeia (Council of Europe convention).

4. What obligations are local authorities likely to impose on businesses?

National-level inspection of premises and manufacturing conditions, where this is not already instituted by the national authorities.

5. Do any special measures apply in respect of SMEs?

No, since products manufactured by local pharmacies on a small scale (magistral and officinal preparations) are not covered by the proposed measures.

6. What is the likely effect on:

(a) business competitiveness?

A greater degree of harmonization in the production of homeopathic medicines and the authorization of them could improve the competitiveness of both manufacturers geared to intra-Community trade and producers with an interest in exporting outside the Community.

(b) employment?

No significant effect is foreseen.

7. Have both sides of Industry been consulted?

Apart from the European federations representing manufacturers of homeopathic medicinal products, there has been consultation of associations representing homeopathic pharmacists and practitioners. The result has been general agreement on the principles behind the measures proposed.

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