Opinion on the proposal for a Council Directive widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products[1]

(90/C 332/08)

On 5 April 1990 the Council decided, in accordance with Article 100A of the Treaty establishing the European Economic Community, to consult the Economic and Social Committee on the abovementioned proposal.

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 5 September 1990. The Rapporteur was Mr Rolão Gonçalves.

At its 279th plenary session (meeting of 19 September 1990), the Economic and Social Committee adopted unanimously the following Opinion.

1. Introduction

1.1. While eschewing value judgements, either absolute or relative, on the principles governing allopathic or homeopathic medicine, it is nevertheless the case that homeopathic medicine has been used to treat human beings in several Member States for at least two centuries. Nowadays the percentage of the population accepting this form of medicine varies from 18 % ins ome countries to 75 % in others. Its use has gradually been spreading to domestic animals, be they pets or farm animals.

1.2. Over the last few years, there has been excessive substitution of 'natural' products by 'synthetic' products, sometimes because there has been no alternative, sometimes on economic grounds not always compatible with ensuring the quality of life. Possibly in reaction to this, there has recently been increased demand for traditional and old-fashioned practices and products adapted to the modern day, such as homeopathy and homeopathic medicines.

1.3. It is not easy for the man in the street to distinguish between what is 'genuine' and what is 'fake', between qualified homeopathic practitioners and opportunists. He has the right to expect that the state, as guardian of public welfare, should take the responsibility for sorting things out. This is all the more improtant since foodstuff requirements are becoming increasingly stringent and are moving towards complete rejection of any significant levels of medicinal residues in meat or other products of animal origin.

1.4. Consequently, as in other sectors, there is a need to take steps to guarantee users—in this case the breeder or owner of the sick animal—the requisite safety in terms of both the actual treatment, and impeccable quality of the medicines used. Likewise, the consumer should have access to this form of medicine throughout the Community area, in line with the principles of free circulation of goods.

1.5. Various Member States have already legally recognized the importance of this issue, although they have dealt with it in quite different ways.

2. Principles of the proposal

2.1. While maintaining the neutrality of Community rules, and without interfering in an individual Member State's decision to accept or reject homeopathy, the proposal seeks to align legislation within the Community governing the free circulation of homeopathic remedies for veterinary use; this is to be done at the highest level of health, safety, environmental and consumer protection.

2.2. On the basis of Article 100A of the Treaty establishing the European Economic Community, the proposal seeks to extend the scope of current legislation on medicinal products (Directive 81/851/EEC) to cover homeopathic products also.

2.3. At the same time, it introduces a simplified registration procedure for homeopathic medicines which are considered safer because of their high degree of dilution, the way they are administered (i.e. not injected) and the lack of specific (therapeutic) indications. For other products, however, the existing arrangements for allopathic or traditional medicines will continue to apply. In any case, the simplified registration process will be aligned throughout the Community.

2.4. For magistral preparations prescribed by homeopathic practitioners, the same principles apply as for allopathic medicine equivalents; this covers a high proportion of the homeopathic pharmacopoeia.

[1] OJ No C 108, 1. 5. 1990, pp. 10-13.

2.5. No provisions have been made for revising the registers already in existence on the date the Directive comes into force; these registers will still apply only to those Member States employing them.

3. General comments

3.1. The Committee welcomes the proposal, subject to the following comments:

3.2. The Committee fully understands the difficulties involved in aligning legislation on homeopathic practices in general and the different schools of homeopathy in particular. It does, however, feel that the goals of the proposed Directive would be much better served if steps were taken to secure a convergence of views leading to a joint, non-restrictive agreement on homeopathic practices.

3.3. The Committee likewise considers that the compilation of a European homeopathic pharmacopoeia should be encouraged, under the auspices of the Council of Europe, so as to bring these remedies under general rules on medicines and thus guarantee maximum protection for users.

3.4. The Committee thinks that the rules on the distribution of homeopathic medicines in the broadest sense should be fully clarified, in line with the rules for allopathic medicines.

3.5. The Committee also considers that rules on labelling and accompanying literature should be the same for all medicines of whatever type, the only acceptable exception being for medicines approved under the simplified registration procedure; in this case therapeutic indications may not be given for these medicines.

3.6. Moreover, the Committee feels that it must point out that inconsistencies might appear in the assessment, (for the purposes of the general approval procedure) of therapeutic effects of homeopathic medicines, because the assessment is geared to allopathic medicine and is carried out by allopathic doctors. The possibility of testing homeopathic medicines according to the principles underlying the practices of the homeopathic school should be considered; these medicines are, after all, intended for the practice of homeopathy.

3.7. The Committee believes that failure to solve problems relating to (a) homeopathic practices, (b) official recognition of homeopaths' legal right to prescribe homeopathic medicines and (c) the distribution of these medecines, could jeopardize the intended objective of this proposal, namely the free circulation of homeopathic medicines.

3.8. The Committee notes that, since there is no provision for back-dating, the proposed Directive will not cover current registers for products on sale in Member States which have approved them. It does, however, agree with the Commission's approach, i.e. that, from the date the Directive enters into force, free circulation of homeopathic products outside these Member States throughout the Community will be authorized only if these products are on registers which have been compiled on the basis of principles adopted in line with the present proposal.

4. Specific comments

4.1. *Recital*

The Committee believes that insertion of the following three recitals, which expand on the eighth recital, will provide greater clarity:

> 'Whereas, having regard to the specific characteristics of these medicinal products, such as their very low content of active principles, it is difficult to apply to them the conventional methods used for clinical trials on allopathic medicines;'
>
> 'Whereas it is appropriate to introduce simplified registration arrangements for those traditional homeopathic medicinal products placed on the market without specific therapeutic indications;'
>
> 'Whereas veterinarians frequently administer parenteral injections to animals they are treating.'

4.2. *Article 1*

First paragraph

While endorsing the thrust of the definition, the Committee queries its validity in those Member States whose pharmacopoeia does not cover this sector; it reiterates the need for measures to encourage the compilation of the European homeopathic pharmacopoeia, as mentioned in point 3.2.

In order to avoid misinterpretation, in the French version, the phrase 'd'un État membre' should be replaced by 'd'un des États membres'.

Second paragraph

In the interests of using a more precise technical term, the expression 'by successive dilutions' should be replaced by 'by successive decimal, centesimal and millesimal dilutions', so as to guarantee to the customer that the concentration marked on the labelling is correct.

4.3. *Article 7*

(1)—First indent

In typical veterinary practice, veterinarians frequently treat animals by injection (generally administered by themselves). The Committee considers that this line should read as follows: 'they are administered orally, externally or parenterally.' The Committee recommends that this matter be studied in greater depth by the Commission jointly with relevant technical experts.

(1)—Third indent

The Committee is surprised at the lack of scientific accuracy in determining the minimum dilution limit (1:1 000 000), in view of the considerable variety of the active principles used and therefore the wide variations in toxicity limit values. While understanding the aim of the proposal here, the Committee recommends that this indent be replaced by the following text, or one equivalent in meaning:

'—There is a sufficient degree to guarantee the safety of the preparations, i.e. if the preparation contains less than one part per million of any active principle, which, when used in medicines, requires a medical prescription. If the concentration is higher, the simplified registration procedure can still be used, as long as the above requirements are met, but the competent licensing authority can require appropriate written toxicological evidence of the medicine's safety.'

Article 7(2)

Except where there are therapeutic indications (homeopathic medicines can only be authorized according to the simplified registration procedure if they have no therapeutic indications), the Committee feels that labelling rules for homeopathic products and allopathic products should be identical (*cf.* point 3.4). For this reason, it considers it essential to replace the restriction 'and no other information' at the end of the fourth line by 'at the very least'. Consumer information should not be limited without good reason; on the contrary, manufacturers should be urged to provide as much information as possible.

4.4. *Article 8*

The expression 'batch-to-batch consistency' (fifth line) is rather ambiguous; it should be replaced by 'sustained consistency of batch-to-batch characteristics'.

Done at Brussels, 19 September 1990.

The Chairman

of the Economic and Social Committee

Alberto MASPRONE