Opinion on the proposal for a Council Directive on advertising of medicinal products for human use [1]

(91/C 60/13)

On 21 June 1990 the Council decided to consult the Economic and Social Committee, under Article 100A of the Treaty establishing the European Economic Community, on the abovementioned proposal.

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 4 December 1990. The Rapporteur was Mr Colombo.

At its 282nd plenary session (meeting of 19 December 1990), the Economic and Social Committee adopted the following Opinion with no dissenting votes and one abstention.

1. Preliminary comments

1.1. The proposal represents a further step in the Commission's drive to harmonize the pharmaceutical sector and eliminate barriers to the free movement of medicinal products in the run-up to an internal market, ensuring a high level of production of public health.

1.2. The proposal forms part of the programme announced in the 1985 White Paper on completing the internal market. It follows the proposals [discussed in the respective Committee Opinions [2]] on:

— wholesale distribution of medicinal products for human use,

— legal status for the supply of medicinal products for human use,

— labelling and package leaflets of medicinal products for human use.

1.3. The proposal seeks to harmonize the rules on advertising of medicinal products to the general public, doctors, and health professionals.

1.4. This is an important matter—the pharmaceutical industry spends considerable sums on advertising to the general public, promotion to health professionals and medicinal information.

1.5. The products of this sensitive sector are designed to improve human health and it is reasonable to introduce Community legislation, without prejudice to the general rules laid down in Directive 84/450/EEC on misleading advertising and Directive 89/552/EEC on television broadcasting.

1.6. All Member States have specific legislation on pharmaceutical advertising.

1.7. Analysis of the situation in the Member States shows significant points of convergence, but also discrepancies as regards both authorization and the systems and levels of advertising control. Community harmonization is thus needed.

1.8. Member States' legislation on the information provided to health professionals presents fewer divergencies. This is partly because of the existence of deontological codes of conduct at both national and EC level, which can provide a useful point of reference.

2. General comments

2.1. The Committee endorses the need for and structure of the proposed Directive, subject to the comments and recommendations which follow.

2.2. Advertising to the public and to health professionals is treated separately because different messages are being conveyed and because current legislation in the two areas differs. While it is common practice in the Member States to include the two areas in a single legal instrument, the Committee is concerned that failure to draw a precise distinction between advertising to the public and information/promotion to health professionals could give rise to ambiguities.

2.3. The ban on public advertising of prescription drugs deserves particular endorsement. However, the

[1] OJ No C 163, 4. 7. 1990, p. 10.
[2] OJ No C 225, 10. 9. 1990.

Committee notes the concern espressed in its Opinion on legal status of medicines, as regards the latitude allowed to the Member States in the classification of prescription and OTC drugs. Differing interpretations of the classification criteria would have an effect on the authorization of advertising to the public.

2.4. The Committee notes the importance of proper health education in order to ensure the 'rational use' of medicinal products with advertising is supposed to encourage under the terms of Article 2(3) of the present proposal.

2.5. Although advertising can be an information vehicle, it is not the main one. In no way can it replace the information on the product's labelling and in the package leaflet, nor that provided by health professionals.

2.6. Lastly, the Committee asks the Commission to examine possible ways and fora for achieving closer harmonization of the instruments and bodies responsible for pharmaceutical advertising.

3. Specific comments

3.1. *Definitions — Article 1(3)*

3.1.1. The definition of advertising in Article 1(3) includes information and promotion for health professionals. There is a danger here of confusing proper scientific information activity with improper incentives to prescribe a particular drug.

3.1.2. For example, it has to be determined whether attendance at congresses is a form of illicit pressure, or whether these provide an updating necessary for the doctor's further training and are potentially in the patient's interest.

3.1.3. The vague reference to 'invitations ... to congresses' in the third indent of Article 1(3) should therefore be deleted, as it seems to imply that any information or training initiatives aimed at health professionals are a form of commercial incitement.

3.2. *Article 2(3)*

The term 'rational use' seems rather vague. The Committee suggests the wording 'appropriate correct use'.

3.3. *Article 4*

3.3.1. In the interests of improved consumer protection, the Committee is concerned at the alternative offered in the second indent, between (a) inclusion of 'the information necessary for correct usage of the medicinal product, such as indications for use and special precautions' and (b) a mere 'invitation to read the package leaflet carefully'.

3.3.2. The package leaflet is of the utmost importance if the consumer is to be fully informed. Advertisements should always include a reminder to read the leaflet. However, it will only be read after the medicine has been purchased; patients could make the wrong purchase if no explicit counter-indications are provided.

3.3.3. Lack of space is no excuse for not providing vital information in a clear and legible form, even if it is not advisable to include a welter of technical and scientific details in advertising targetted to the general public.

3.3.4. However, where the vital information is available on the outer pack, the Committee accepts that, in the case of medicines for which no special precautions are necessary a message to read the label and or the package leaflet is the best alternative means.

3.4. *Article 5(d)*

Drug advertising directed at children should be banned outright. The words 'solely or mainly' could offer a loophole for getting round this ban.

3.5. *Chapter III — Wording of the title*

The term 'advertising' is an oversimplification for describing the complex promotional and information activity aimed at health professionals. The title should include a reference to information activity.

3.6. *Article 3(2)*

This Article should specify that the list of prohibited therapeutic indications is indicative and not exhaustive.

3.7. *Article 8(1)*

3.7.1. Although it is not possible to give a full definition of a 'medical sales representative' in a Directive on drug advertising, the fact remains that the definition given is very vague ('shall be given adequate training and shall have sufficient scientific knowledge') considering the responsibilities which these representatives have.

3.7.2. Provision should be made to ensure that representatives have had higher education and special training and refresher courses from the company, the health authorities or universities on the scientific, legal and deontological aspects of the profession. The position of the medical sales representative within the pharmaceutical business also requires clarification.

3.7.3. These points are important because representatives are required to provide information on the products and promptly report any side effects.

3.8. *Article 8(3)*

3.8.1. It should be specified that the feedback to the company provided by the medical sales representative is not the same as the fourth stage of clinical trials and is subject to different regulations. The information covered by the present Article is provided free of charge by the doctor during normal talks with the sales representative.

3.8.2. Moreover, neither this feedback nor stage four can replace a general drug monitoring service as envisaged by the World Health Organization (WHO).

3.9. *Article 9*

3.9.1. Clarification is needed of the term 'insignificant intrinsic value' in Article 9(1). The Committee suggests the following wording:

> 'objects whose value is not sufficient to induce the health professional to prescribe the drug other than in accordance with good clinical practice.'

3.9.2. If the reference to congresses in Article 1(3) (definitions) is not deleted, the Committee proposes that a clause be inserted in Article 9 to exclude from the ban refresher conferences held solely to inform and train health professionals. The pharmaceutical industry's work in this area should not be discouraged.

3.10. *Article 10*

3.10.1. The maximum of two free samples (obviously per product) per year seems very rigid. It appears to conflict with the need for doctors to familiarize themselves with new drugs and learn to use them better. Furthermore, Article 10(b) requires the doctor to make a written request for the samples, thus assuming direct responsibility for them. The doctor should be given a wider margin of discretion.

3.10.2. The list of products of which samples may not be provided should include thermolabile or otherwise easily perishable products. Representatives do not have proper premises or facilities for storing samples correctly—and these samples are fully-fledged medicinal products.

3.11. *Article 11*

3.11.1. The proposal should identify the body which is to monitor advertising and the relation between image and content of the message, particularly where this exceeds the bounds of proper information and constitutes an incentive to use a particular drug.

3.11.2. It is necessary to harmonize the monitoring systems of the Member States, which range from specific authorization bodies to self-policing arrangements. The free movement which will soon be achieved by the Single Market makes Commission consideration of this point particularly important.

3.11.3. The moves to draw up a European Code of Practice in this sector are to be welcomed. The European pharmaceutical industry has so far only drawn up a code for drugs promotion to health professionals, and this does not lay down sufficient implementing guarantees.

3.11.4. The Committee asks the Commission to investigate possible ways and fora for dealing with this matter at Community level.

3.12. *Article 12*

The in-company scientific service must be headed by a health specialist offering a maximum guarantee of professional skills and legal responsibility. The existence of such a service does not of course preclude the existence of (or indeed, the need for) other information channels for health professionals, such as national or European-level data banks.

3.13. *Article 13*

3.13.1. Further consideration is needed of the clause [Article 13(1)] allowing marketing authorizations to be suspended if the Directive is not observed.

3.13.2. If drugs of proven therapeutic value and novelty had to be withdrawn, this would unfairly deprive patients of a vital drug.

3.13.3. It seems right to impose financial and legal penalties if a company commits a serious offence.

3.13.4. However, the punishment should be in keeping with the severity of the risks engendered for human health.

Done at Brussels, 19 December 1990.

The Chairman

of the Economic and Social Committee

François STAEDELIN

Opinion on the proposal for a Council Directive amending Directive 64/432/EEC as regards the diagnosis of bovine brucellosis and enzootic bovine leukosis

(91/C 60/14)

On 3 December 1990, the Council decided to consult the Economic and Social Committee, under Article 198 of the Treaty establishing the European Economic Community, on the abovementioned proposal.

The Section for Agriculture and Fisheries, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 7 December 1990. The Rapporteur was Mr Proumens.

At its 282nd plenary session (meeting of 18 December 1990), the Economic and Social Committee unanimously adopted the following Opinion.

The Committee fully endorses the proposed Directive, although it feels that certain comments are called for.

1. General comments

1.1. The draft Directive introduces a new diagnostic test, known as ELISA, for bovine brucellosis and enzootic bovine leukosis.

1.2. The draft Directive amends the Annexes to Directive 64/432/EEC in the light of new scientific knowledge on the diagnosis and control of the two diseases.

1.3. A specialist scientific group has studied the matter and carried out a number of international trials, and has recommended that the ELISA method be included as an alternative test.

1.4. The ELISA method uses samples of milk taken from storage tanks, whereas samples previously had to be taken direct from each cow individually.

1.5. The ELISA method is thus quicker, equally efficient, and cheaper for the Member State authorities responsible for testing.