COUNCIL DIRECTIVE 92/28/EEC

of 31 March 1992

on the advertising of medicinal products for human use

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 (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Directive 84/450/EEC (4) harmonized the laws, regulations and administrative provisions of the Member States concerning misleading advertising; whereas this Directive is without prejudice to the application of measures adopted pursuant to that Directive;

Whereas all Member States have adopted further specific measures concerning the advertising of medicinal products; whereas there are disparities between these measures; whereas these disparities are likely to have an impact on the establishment and functioning of the internal market, since advertising disseminated in one Member State is likely to have effects in other Member States;

Whereas Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (5) prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located; whereas this principle should be made of general application by extending it to other media;

Whereas advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered; whereas advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined;

Whereas, furthermore, distribution of samples free of charge to the general public for promotional ends must be prohibited;

Whereas the advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons; whereas, nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe;

Whereas medical sales representatives have an important role in the promotion of medicinal products; whereas, therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics;

Whereas persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements;

Whereas it should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them;

Whereas persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market; whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation;

Whereas advertising of medicinal products should be subject to effective, adequate monitoring; whereas reference in this regard should be made to the monitoring mechanisms set up by Directive 84/450/EEC;

Whereas each undertaking which manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a medicinal product conforms with the approved conditions of use,

(1) OJ No C 163, 4. 7. 1990, p. 10 and OJ No C 207, 8. 8. 1991, p. 25.
(2) OJ No C 183, 15. 7. 1991, p. 227 and OJ No C 67, 16. 3. 1992.
(3) OJ No C 60, 8. 3. 1991, p. 40.
(4) OJ No L 250, 19. 9. 1984, p. 17.
(5) OJ No L 298, 17. 10. 1989, p. 23.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, definitions and general principles

Article 1

1. This Directive concerns the advertising in the Community of medicinal products for human use covered by Chapters II to V of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (1).

2. For the purposes of this Directive:

— the definitions of the name of the medicinal product and of the common name shall be those laid down in Article 1 of Directive 92/27/EEC (2);

— the summary of product characteristics shall be the summary approved by the competent authority which granted the marketing authorization in accordance with Article 4b of Directive 65/65/EEC.

3. For the purposes of this Directive, advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

— the advertising of medicinal products to the general public,

— advertising of medicinal products to persons qualified to prescribe or supply them,

— visits by medical sales representatives to persons qualified to prescribe medicinal products,

— the supply of samples,

— the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

— sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,

— sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

4. The following are not covered by this Directive:

— the labelling of medicinal products and the accompanying package leaflets, which are subject to the provisions of Directive 92/27/EEC;

— correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

— factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;

— statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

Article 2

1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

— shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,

— shall not be misleading.

CHAPTER II

Advertising to the general public

Article 3

1. Member States shall prohibit the advertising to the general public of medicinal products which:

— are available on medical prescription only, in accordance with Directive 92/26/EEC (3),

— contain psychotropic or narcotic substances, within the meaning of the international conventions,

(1) OJ No 22, 9. 2. 1965, p. 369/65. Directive last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).
(2) See page 8 of this Official Journal.
(3) See page 5 of this Official Journal.

— may not be advertised to the general public in accordance with paragraph 2.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the invervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Member States shall prohibit the mentioning in advertising to the general public of therapeutic indications such as:

— tuberculosis,

— sexually transmitted diseases,

— other serious infectious diseases,

— cancer and other tumoral diseases,

— chronic insomnia,

— diabetes and other metabolic illnesses.

3. Member States shall also be able to ban on their territory advertising to the general public of medicinal products the cost of which may be reimbursed.

4. The prohibition referred to in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

5. The prohibition referred to in paragraph 1 shall apply without prejudice to Articles 2, 3 and 14 of Directive 89/552/EEC.

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes; they may, however, authorize such distribution in special cases for other purposes.

Article 4

1. Without prejudice to Article 3, all advertising to the general public of a medicinal product shall:

(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;

(b) include the following minimum information:

— the name of the medicinal product, as well as the common name if the medicinal product contains only one active ingredient,

— the information necessary for correct use of the medicinal product,

— an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, according to the case.

2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product if it is intended solely as a reminder.

Article 5

The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 3 (4);

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof;

(l) mentions that the medicinal product has been granted a marketing authorization.