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.

CHAPTER III

Advertising to health professionals

Article 6

1. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

— essential information compatible with the summary of product characteristics;

— the supply classification of the medicinal product.

Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, if it is intended solely as a reminder.

Article 7

1. Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include as a minimum the particulars listed in Article 6 (1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.

Article 8

1. Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote.

2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 6 (1).

3. Medical sales representatives shall transmit to the scientific service referred to in Article 13 (1) any information about the use of the medicinal products they advertise, with particular reference to any adverse reactions reported to them by the persons they visit.

Article 9

1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion must always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health professionals.

3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by this Article.

Article 10

The provisions of Article 9 (1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality must always be reasonable in level and remain subordinate to the main scientific objective of the meeting; it must not be extended to persons other than health professionals.

Article 11

1. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(a) a limited number of samples for each medicinal product each year on prescription;

(b) any supply of samples must be in response to a written request, signed and dated, from the recipient;

(c) those supplying samples must maintain an adequate system of control and accountability;

(d) each sample shall be identical with the smallest presentation on the market;

(e) each sample shall be marked free medical sample — not for resale or bear another legend of analogous meaning;

(f) each sample shall be accompanied by a copy of the summary of product characteristics;

(g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions may be supplied.

2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.

CHAPTER IV

Monitoring of advertising

Article 12

1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, shall in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Directive may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings.

2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or administrative authorities powers enabling them, in cases where they deem such measures to be necessary taking into account all the interests involved and in particular the public interest:

— to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising,

or

— if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication,

even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.

Member States shall also make provision for the measures referred to in the first subparagraph to be taken under an accelerated procedure:

— either with interim effect, or

— with definitive effect,

on the understanding that it is for each Member State to decide which of the two options to select.

Furthermore, Member States may confer upon the courts or administrative authorities powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:

— to require publication of that decision in full or in part and in such form as they deem adequate,

— to require in addition the publication of a corrective statement.

3. Under the legal provisions referred to in paragraph 1, Member States shall ensure that any decision taken in accordance with paragraph 2 shall state in detail the reasons on which it is based and shall be communicated in writing to the person concerned, mentioning the redress available at law and the time limit allowed for access to such redress.

4. This Article shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.

Article 13

1. The marketing authorization holder shall establish within his undertaking a scientific service in charge of information about the medicinal products which he places on the market.

2. The person responsible for placing the product on the market shall:

— keep available for, or communicate to, the authorities or bodies responsible for monitoring advertising of medicinal products a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination,

— ensure that advertising of medicinal products by his undertaking conforms to the requirements of this Directive,

— verify that medical sales representatives employed by his undertaking have been adequately trained and fulfill the obligations imposed upon them by Article 8 (2) and (3),

— supply the authorities or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities,

— ensure that the decisions taken by the authorities or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.

Article 14

Member States shall take the appropriate measures to ensure that all the provisions of this Directive are applied in full and shall determine in particular what penalties shall be imposed should the provisions adopted in the execution of this Directive be infringed.

Article 15

1. Member States shall take the measures necessary in order to comply with this Directive with effect from 1 January 1993. They shall forthwith inform the Commission thereof.

2. When Member States adopt the said measures, such measures shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS