COMMISSION OF THE EUROPEAN C

ORRIGENDUM

a cote du document COM(90) 212 final
ı 6.6.90 doit se lire :
OM(90) 212 final - SYN 273

concerne toutes les versions linguistiques)

COM(90) 212 fin

Brussels, 13 June

Proposal for a

COUNCIL DIRECTIVE

on advertising of medicinal products for humai

(presented by the Commission)

COMMISSION OF THE EUROPEAN COMMUNI

COM(90) 212 final

Brussels, 6 June 1990

Proposal for a

COUNCIL DIRECTIVE

on advertising of medicinal products for human use

(presented by the Commission)

EXPLANATORY MEMORANDUM AND REPORT TO THE COUNCIL

I. GENERAL CONSIDERATIONS

1. In January 1990, the Commission sent the Council and the European Parliament three proposals for directives concerning the rational use of medicinal products (COM(89)607 final of 26.1.1990), thus completing the program announced in the White Paper in 1985. These consist of proposals concerning:
   - 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.

2. Although the present proposal concerning pharmaceutical advertising was not explicitly included in 1985 in the White Paper program, it nevertheless falls within the same framework. The proposal in fact aims to promote the rational use of medicinal products and also to harmonize national legislation in this area, insofar as it is necessary for the completion of the internal Market.

II. REGULATION OF PHARMACEUTICAL ADVERTISING IN THE MEMBER STATES

3. The pharmaceutical industry on average devotes between 12 and 15% of its turnover to advertising and medicinal information (of which more than 2/3 goes on medical sales representatives, in the case of products supplied on prescription).

4. All Member States of the Community have adopted specific rules concerning pharmaceutical advertising over and beyond the general measures concerning misleading or unfair advertising. These rules always distinguish between advertising to the general public and advertising or information intended for health professionals.

5. With regard to advertising to the general public, all the Member States forbid advertising of prescription only medicinal products. Furthermore, several Member States (Belgium, Ireland, United Kingdom, Spain, Portugal and the German Federal Republic) prohibit the advertising of medicinal products aimed at treating certain particular illnesses/conditions. Where it is authorised, pharmaceutical advertising to the general public must conform to certain positive conditions (minimum content) and negative conditions (prohibition of certain forms of advertising).
   In most Member States, advertising through certain media (T.V., Radio) is subject to further specific control. Certain Member States (Belgium, Denmark) prohibit all pharmaceutical advertising through these media. In this regard, it should be noted that Directive 89/552/EEC concerning television broadcasting activities provides, in Article 14, for the prohibition television advertising of medicinal products available only on prescription in the Member State within whose area of competence the broadcasting authority is situated. Article 3 of this Directive however provides that Member States may, with regard to broadcasting authorities situated within their area of competence, provide far stricter or more detailed rules in the areas covered by this directive.

6. National regulations concerning information sent out to health Professionals by pharmaceutical companies are less divergent. It is almost always provided that the information sent out must be either in accordance with the information to be found in the summary of product characteristics, or must reproduce exactly this information. The majority of Member States have imposed restrictions on the distribution of free samples.

7. With regard to the monitoring of pharmaceutical advertising three different approaches are adopted (the monitoring of TV/radio advertising being subject to further specific control as mentioned above).
   In certain Member States (Federal Republic of Germany, Belgium, Luxembourg) pharmaceutical advertising is subject to a posteriori control by the courts and tribunals.
   In other Member States (United Kingdom, Ireland, Netherlands) monitoring of pharmaceutical advertising is undertaken primarily by self regulatory bodies.
   Finally, in several Member States (Denmark, France, Portugal, Spain, Italy) all advertising must be approved in advance by the competent authorities (in general the authorities charged with health matters). It should be noted that in Greece all pharmaceutical advertising to the general public is in fact prohibited so that monitoring of advertising is not necessary.

III. NEED FOR A COMMUNITY DIRECTIVE

8. The Community is competent to adopt all measures necessary for the completion of the internal market, which consists of an area without internal frontiers where the free movement of goods, persons, services and capital is ensured. As the Court of Justice emphasized in its Judgment of 6 March 1990 (case GB-INNO-BM v. CCL), the divergence in national laws restricting or prohibiting certain forms of advertising is capable of hindering the free movement of goods, by affecting the access of goods to the market. Harmonization of national laws concerning pharmaceutical advertising is therefore necessary in so far as differences in the specific rules relating to this form of advertising limit the free movement of pharmaceuticals.

9. All Member States of the Community have indeed adopted, alongside with the general rules concerning advertising, specific measures in respect of pharmaceutical advertising. Though based on common principles, these measures present significant divergences.

10. The harmonisation of the measures taken by the Members States would also appear necessary to ensure the freedom to provide advertising services. In fact, pharmaceutical companies will undoubtedly take more and more advantage of the possibility already open to them in Community law of marketing medicinal products in a member State without being established or represented there. Thus numerous advertisements will be conceived and transmitted in one Member State and destined for people in another Member State. Furthermore, given the integration of markets, in particular in the context of the future system of authorisation of medicinal products, advertising campaigns will be conceived in such a way as to cover several Member States at one time.

11. It is therefore necessary to establish a common framework for pharmaceutical advertising as well as providing for certain requirements to which pharmaceutical advertising must conform where it is authorised, in such a way that all pharmaceutical advertising transmitted within the Community fulfills certain essential criteria, no matter to whom it is addressed within the Community.

IV. CONTENTS OF THE PROPOSAL

12. With the exception of certain common principles and generalities (Article 2) the proposal for a directive provides for separate systems for advertising to the general public and advertising to health professionals.

13. Under a principle common to all Member States, advertising to the general public can only be permitted where it concerns products for self-medication: advertising to the public of medicinal products obtainable only by prescription should therefore, by reference to the recent Commission proposal on the legal status of the supply of medicinal products intended for human, be prohibited (Article 3).

In cases where advertising to the general public is permitted, it must comply with certain positive (Article 4) and negative (Article 5) conditions.

14. Advertising addressed to health professionals must include more extensive information than that addressed to the general public (Article 6). In fact advertising to health professionals must enable the addressee to form his own opinion of the therapeutic worth of the medicinal product; these principles also apply to the documentation provided with regard to promotion of medicinal products (Article 7). Medical sales representatives are thus assigned a positive role and they must supply a summary of product characteristics for each of the products they promote, and report certain pharmacovilligilance information to the firm employing them. Furthermore, the objective information of doctors and pharmacists is incompatible with financial inducements of whatever nature, and as such should be prohibited (Article 9). Finally, even though samples of medicinal products allow doctors and pharmacists to familarise themselves with new medicinal products, the conditions under which such samples can be supplied should be limited (Article 10).

15. Measures concerning the monitoring of pharmaceutical advertising are to a large extent drawn from the system of Directive 84/450/EEC concerning misleading advertising. Thus the role of self-regulatory bodies is expressly recognised (Article 11). As a means of guaranteeing the principles laid down by the Directive, pharmaceutical companies are required to establish within the company a Scientific Service, which would act as a point of contact for all scientific information concerning the medicinal products of the company (Article 12).

V. CONCLUSIONS

16. This proposal has been the subject of several rounds of consultations since July 1989 with the directors of pharmacy within the pharmaceutical Committee (July, October and December 1989), with European associations representing the pharmaceutical industry, advertisers, consumers and the medical and pharmaceutical professions.

17. In accordance with the requirements of Articles 8A and 8C of the Treaty establishing the European Economic Community, the Commission requests the Member States to take the measures necessary to comply with this proposal by 1 January 1992.

The Commission has taken into account the requirements of Article 8C of the Treaty and has concluded that no special provision seems to be justified at this stage.

The Commission has also studied the question from highest level of health, safety, environmental and consumer protection required by the terms of Article 100 A, paragraph 3. It has done so following consultation of the industrial and social partners concerned, and in the light of an analysis of the current technical capabilities of the European industry. The proposals take full account of these considerations in the light of the overall objectives of this provision of the Treaty.

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on advertising of medicinal products for human use

COM(90) 212 final — SYN 273

(Submitted by the Commission on 12 June 1990)

(90/C 163/12)

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 Council Directive 84/450/EEC (1) has harmonized the laws, regulations and administrative provisions of the Member States concerning misleading advertising;

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 (2) 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 prohibiting all advertising of medicinal products which are available only on prescription;

Whereas advertising to the general public even of non-prescription medicinal products could affect public health, if it was 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 achieved 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 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;

(1) OJ No L 250, 19. 9. 1984, p. 17.

(2) OJ No L 298, 17. 10. 1989, p. 23.

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,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, definitions and general principles

Article 1

1. This Directive concerns the advertising of medicinal products for human use in the Community.

2. For the purposes of this Directive,

— the definition of 'advertising' shall be that laid down in Article 2 of Directive 84/450/EEC,

— the definition of 'medicinal product' shall be that laid down in Article 1 of Council Directive 65/65/EEC (1),

— the definitions of the 'name of the medicinal product' and of the 'common name' shall be those laid down in Article 1 of Council Directive .../.../EEC,

— 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 the application of this Directive, the advertising of medicinal products includes, in particular:

— information of a commercial nature for health care professionals, in whatever form, which may promote the prescription or supply of medicinal products,

— visits by medical representatives to persons allowed to prescribe or supply medicinal products,

— any incitement to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, including invitations to travel or to congresses.

Article 2

1. Any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law is prohibited.

2. All parts of the advertising of a medicinal product must be compatible 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, within the meaning of Directive 84/450/EEC.

CHAPTER II

Advertising to the general public

Article 3

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

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

— other medicinal products which are only available on prescription, in accordance with Council Directive .../.../EEC.

2. Member States shall prohibit the mention in advertising to the general public of therapeutic indications for which self-medication is not suitable, in particular:

— tuberculosis,

— sexually transmitted diseases,

— other serious infectious diseases,

— cancer,

— chronic insomnia,

— diabetes and other metabolic illnesses.

3. The prohibition referred to in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.

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

5. Member States shall prohibit the free distribution of medicinal products to the public for promotional purposes.

(1) OJ No L 22, 9. 2. 1965, p. 369/65.

Article 4

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

(a) be set out in such a fashion 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, incorporating or followed by the common name if the medicinal product contains only one active ingredient,

— the information necessary for correct usage of the medicinal product, such as indications for use and special precautions, or, failing this, an express invitation to read the package leaflet carefully.

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 erroneously that the effects of taking the medicine are guaranteed, or are better than another treatment;

(c) suggests that the normal good health of the subject can be enhanced by taking the medicine, or that it could be affected by not taking the medicine;

(d) is directed solely or mainly at children;

(e) refers to a recommendation by scientists or health professionals;

(f) suggests that the medicinal product is a foodstuff or a cosmetic, or *vice versa;*

(g) suggests that the safety or efficacy of the medicinal product is due to the fact that it is 'natural'.

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:

— the particulars listed in the summary of product characteristics,

— the legal prescription status of the medicinal product,

— the retail price of the various presentations,

— if appropriate, conditions of coverage by the social security systems.

2. 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 its sole object is to recall to the latter.

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).

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 and shall have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products which they promote.

2. During each visit, medical sales representatives shall provide the persons visited with the summaries of product characteristics in respect of each medicinal product which they present.

3. Medical sales representatives shall transmit to the scientific service referred to in Article 12 (1), any information about the use of the medicinal products they promote, especially about adverse reactions, that is reported to them by the persons they visit.

Article 9

1. In the course of promoting medicinal products to persons qualified to prescribe them, it shall be prohibited to give, proffer or promise to such persons, directly or indirectly, any gifts, pecuniary advantages or benefits in kind, with the exception of objects of an insignificant intrinsic value.

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

3. The prohibition referred to in paragraph 1 applies without prejudice to the regulations of the Member States concerning prices, profit margins and discounts.

Article 10

Where medicinal products are being promoted to persons qualified to prescribe or supply them, free samples shall be provided to such persons only on the following conditions:

(a) two samples at the most may be provided every year to any person qualified to prescribe or to supply medicinal products;

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

(c) the samples shall be identical to the smallest presentation on the market;

(d) the samples shall be marked 'free medical sample — not for resale' or with another legend of analogous meaning;

(e) the samples shall be accompanied by a copy of the summary of product characteristics;

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

CHAPTER IV

Monitoring of advertising

Article 11

1. Member States shall ensure that there are adequate and effective methods to monitor advertising of medicinal products. Such methods shall 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:

— to order the discontinuance, correction or withdrawal of any advertisement inconsistent with this Directive,

— require either the publication of a corrigendum, or the publication in whole or in part and in a form which it shall deem adequate, of the decision ordering the discontinuance of an advertisement.

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 remedies available at law and the time limit allowed for the exercise of such remedies.

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

Article 12

1. The person responsible for marketing 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 marketing shall:

— make available to the bodies responsible for monitoring advertising of medicinal products a sample of all advertisements emanating from their 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 fulfil the obligations imposed upon them by Article 8 (2) and (3),

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

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

Article 13

1. Where the provisions of the Directive have not been observed, and a warning notice served on the party concerned has remained without effect, the competent authorities of a Member State may suspend the authorization to market the medicinal product concerned, without prejudice to any other sanction which may be applied under national law.

2. All decisions taken pursuant to paragraph 1 shall state in detail the reasons on which they are based. A decision shall be notified to the party affected by it, who shall at the same time be informed of the remedies available at law and the time limit allowed for the exercise of such remedies.

Article 14

1 Member States shall take all the steps necessary to comply with this Directive with effect from 1 January 1992. They shall forthwith inform the Commission thereof.

2. Measures taken in accordance with paragraph 1 shall make express reference to this Directive.

Article 15

This Directive is addressed to the Member States.

COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT

relating to the proposal for a directive
concerning the advertising of medicinal products for human use

I. What is the main reason for introducing the measures ?

Completion of the internal market; improvement of the protection of public health; promotion of the rational use of medicinal products; information of consumers and of health professionnals.

II. Features of the businesses in question ?

Because of the high costs of developping new products, pharmaceutical entreprises are often large companies (multinational or national). There are, however, some smaller and medium sized manufacturers geared at the national market.

III. What direct obligations do these measures impose on businesses ?

- Obligation to conform with the rules relating to advertising to the general public : the proposed measures harmonize existing national rules which are themselves quite stricvt (hence, no additional cost - rationalization of advertising campaigns througout the Community).

- Obligation to deliver systematically the summary of products characteristics : marginal additional cost.

- Obligation to establish a scientific service in charge of medical information : almost every undertaking already has such a service (which, as the cas may be, could consist of just one person).

IV. What indirect obligations are local authorities likely to impose on businessess ?

None.

V. Are there any special measures in respect of SMEs ?

No.

VI. What is the likely effect on :

a) the competitiveness of business ,

The proposed measures will put pharmaceutical undertakings on equal conditions, irrespective of the location of their establishment in the Community and of the destinee of the advertising.

b) employment ?

No significant effect is anticipated.

VII. Have both sides of industry been consulted on these proposals ?

Following interested parties were consulted :
- associations representing consumers,
- associations of the pharmaceutical industry,
- associations of advertisers,
- associations of pharmacists,
- associations of doctors and other health professionals.

FINANCIAL STATEMENT

relating to the proposal for a directive
concerning the advertising of medicinal products for human use

No financial impact

ISSN 0254-1475

COM(90) 212 final

DOCUMENTS

EN **05 15**

Catalogue number : CB-CO-90-230-EN-C
ISBN 92-77-60574-X

PRICE	1 - 30 pages: 3.50 ECU	per additional 10 pages: 1.25 ECU

Office for Official Publications of the European Communities
L-2985 Luxembourg