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****I**

R E P O R T

of the Committee on the Environment, Public Health and
Consumer Protection

on the Commission proposal for a Council directive on
advertising of medicinal products for human use

(COM(90) 0212 final - C3-0185/90 - SYN 273)

Rapporteur: Mrs Ursula SCHLEICHER

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A Series: Reports - B series: Motions for Resolutions, Oral Questions.

- C Series: Documents received from other Institutions (e.g. Consultations)

***** = Consultation procedure requiring a single reading

****II** = Cooperation procedure (second reading) which requires the votes of the majority of the Members of Parliament

****I** = Cooperation procedure (first reading)

******* = Parliamentary assent which requires the votes of the majority of the current Members of Parliament

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By letter of 15 June 1990 the Council consulted the European Parliament, pursuant to Article 100a of the EEC Treaty, on the Commission proposal for a Council directive on advertising of medicinal products for human use.

At the sitting of 9 July 1990 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Legal Affairs and Citizens' Rights for their opinions.

At its meeting of 17 July 1990 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Schleicher rapporteur.

At its meetings of 17 October, 29 October and 18 December 1990, 31 January and 5 April 1991 it considered the Commission proposal and the draft report.

At the last meeting it adopted the draft legislative resolution by 12 votes to 0 with 2 abstentions.

The following took part in the vote: Collins, chairman; Schleicher, vice-chairman and rapporteur; Amendola, Chanterie, Di Rupo, Duarte Cendan (for Avgerinos), Green, Caroline Jackson, Muntingh, Oomen-Ruijten, Pollack, Pompidou (for Fitzsimons), Valverde Lopez and Vernier.

The opinion of the Committee on Economic and Monetary Affairs and Industrial Policy is attached. The Committee on Legal Affairs and Citizens' Rights decided on 19 September 1990 not to deliver an opinion.

The report was tabled on 7 May 1991.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

Commission proposal for a Council directive
on advertising of medicinal products for human use

Commission text¹

Amendments

(Amendment No. 1)
Third recital

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 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 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 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 an exception is made for advertising in professional journals aimed specifically and exclusively at members of the medical profession;

(Amendment No. 2)
Fourth recital

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 advertising to the general public even of non-prescription medicinal products may affect public health, if it does not satisfy certain essential criteria which ought to be defined;

(Amendment No. 3)
Fourth recital a (new)

Whereas regulations on advertising must be established not only for medicinal products, but also for other products, objects, equipment and techniques presented as being good for health;

¹ For full text see COM(90) 0212 final - OJ No. C 163, 4.7.1990, p. 10

(Amendment No. 4)
Fifth recital

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

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

(Amendment No. 5)
Sixth recital

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 scientific information is important in ensuring that medicinal products are used correctly; whereas it is incumbent on the industry to provide all the necessary data for the purposes of correct information; whereas it is the task of the health authorities to ensure that such information is made available, through neutral, objective sources and qualified staff, to those who are authorized to prescribe and dispense medicinal products;

(Amendment No. 6)
Seventh recital

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 medical sales representatives have an important role in the advertising of medicinal products; whereas such information also serves as a means of promotion and medical sales representatives must therefore be qualified to play this role and comply with specific obligations, in particular the obligation to supply the person visited with a summary of all the product characteristics;

(Amendment No. 7)
Eighth recital

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

(Amendment No. 8)
Ninth recital

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 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; these free samples of medicinal products must, of course, not be sold;

(Amendment No. 9)
Ninth recital a (new)

whereas the European Agency for the evaluation of drugs shall be responsible for monitoring scientific information concerning medicinal products;

(Amendment No. 10)
Tenth recital

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 persons qualified to prescribe or supply medicinal products must have access to a neutral objective source of information about products available on the market;

(Amendment No. 11)
Tenth recital a (new)

Whereas in certain situations Member States are entitled to adopt special stricter measures, as appropriate;

(Amendment No. 12)
Tenth recital b (new)

whereas, when implementing this directive, Member States must ensure that its provisions are applied to all parties which may have an influence on prescription practices;

(Amendment No. 13)
Eleventh recital

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 advertising of medicinal products should be subject to effective, adequate monitoring carried out preventively;

(Amendment No. 14)
Twelfth recital

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,

Whereas each undertaking which manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a medicinal product corresponds to the information provided in the summary of the characteristics of the product, as approved by the competent authorities;

(Amendment No. 15)
Article 1(1)

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

This directive aims to regulate the advertising of medicinal products for human use in the Community it being understood that instruction leaflets and labelling shall be subject to the provisions of Directive .../.../EEC.

(Amendment No. 16)
Article 1(2), second indent

- the definition of "medicinal product" shall be that laid down in Article 1 of Council Directive 65/65/EEC
- the definition of 'medicinal product' shall be that laid down in Article 1 of Council Directive 65/65/EEC; the products defined in Articles 1 and 2 of COM(90) 72 final - SYN 251 on homeopathic medicinal products for human use shall also be considered as medicinal products within the meaning of this Directive,

(Amendment No. 17)
Article 1(2), new indent after the second indent

- any person who advertises a medicinal product to a health care professional with a view to promoting the prescription or supply of that product for commercial ends shall be considered to be a medical sales representative.

(Amendment No. 18)
Article 1(2), new indent after the second indent

- all information intended for doctors, pharmacies, other health workers and consumers, for the purposes of ensuring that the products are used correctly, relating to the composition of the medicinal products, their therapeutic effect, side-effects, warnings, instructions for use and the results of controlled clinical tests on the effectiveness and the immediate or long-term toxicity of the product shall be deemed to be 'scientific information',

(Amendment No. 19)
Article 1(3), first indent

- information of a commercial nature for health care professionals, in whatever form, which may promote the prescription or supply of medicinal products;
- information (four words deleted) for health care professionals, in whatever form, which may promote the prescription or dispensing of medicinal products;

(Amendment No. 20)

Article 1(3), new indent after the first indent

- information for the general public, in whatever form, which may promote the consumption of medicinal products;

(Amendment No. 21)

Article 1(3), third indent

- 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.
- 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.

(Amendment No. 22)

Article 2(2)

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

All parts of the advertising of a medicinal product must conform to the particulars ... (rest unchanged)

(Amendment No. 23)

Article 2(3a) (new)

Pending the setting up, under Council Regulation (EEC) No. ..., of a European Community body authorized to provide information for health care professionals, Member States shall ensure that persons authorized to prescribe or supply medicinal products shall have access to information from various sources on medicinal products available on the market.

(Amendment No. 24)

Article 3(1), first indent

- medicinal products which contain psychotropic or narcotic substances, within the meaning of the international conventions,
- medicinal products which contain psychotropic or narcotic substances, within the meaning of Schedules 1 and 2 of the United Nations Single Convention on Narcotic Drugs.

(Amendment No. 25)

Article 3(1), new indents after first indent

- medicinal products and products which are habit-forming and/or addictive,
- any performance-enhancing drug or product, as defined by the Council of Europe and the International Olympic Committee,

(Amendment No. 26)

Article 3(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.

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

Delete

Member States shall be responsible for health education campaigns, targeted at the general public, on the correct use of medicinal products, with particular reference to over-the-counter drugs and those which may lead to abuse or which may become habit-forming.

For the organization of such campaigns, Member States shall collaborate with the Agency referred to in Regulation (EEC) No. and with consumer associations.

(Amendment No. 27)

Article 3(3)

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

The prohibition referred to in paragraph 1 shall not apply to vaccination or public health campaigns run or approved by the competent authorities of the Member States or to research-related campaigns.

(Amendment No. 28)
Article 3(5)

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

Member States shall prohibit the free distribution of prescription-only medicinal products and gifts and bonuses to the public for promotional purposes.

(Amendment No. 29)
Article 4(a)

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,

a) be set out in such a fashion that it is clear that the message is an advertisement, and that the product is clearly presented as a medicinal product;

(Amendment No. 30)
Article 4(b), second indent

- 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.

- the information necessary for correct usage of the medicinal product, such as indications for use, special precautions and possible side effects.

(Amendment No. 31)
Article 4(b), second indent a (new)

- all contra-indications, the main side effects or undesirable effects, appropriate precautions regarding its use, any interactions with other products and any other special warning;

(Amendment No. 32)
Article 4(b), second indent b (new)

- an express invitation to read the label and the package leaflet carefully.

(Amendment No. 33)

Article 4(b), second indent c (new)

- the warning 'any medicinal product can be dangerous if used incorrectly consult your doctor'.

(Amendment No. 34)

Article 4(b), second indent d (new)

- the recommendation that a doctor or pharmacist be consulted.

(Amendment No. 35)

Article 4(b), second indent e (new)

- the pharmacology of the medicinal product,

(Amendment No. 36)

Article 4(1a) (new)

During any television or cinema advertisement for a medicinal product, a box shall be superimposed on the screen containing the references, warnings and contra-indications as well as an express invitation to read the package leaflet carefully. At the end of the advertisement, there will be a voice-over reading out the indication provided for in Article 3(1), third indent (new).

(Amendment No. 37)

Article 4(1b) (new)

At least 20% of all advertising space for a medicinal product shall be reserved for warnings, references and contra-indications.

Furthermore, the advertisement must be clearly identifiable and include the following indication: 'This is an advertisement'.

(Amendment No. 38)
Article 5 b)

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

b) suggests (one word deleted) that the effects of taking the medicine are guaranteed, or are better than the effects of another treatment;

(Amendment No. 39)
Article 5 c)

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;

c) Suggests that the normal good health of the subject (ten words deleted) could be affected by not taking the medicine;

(Amendment No. 40)
Article 5 ca) (new)

ca mentions symptoms of illnesses for which the medicinal product is recommended;

(Amendment No. 41)
Article 5 d)

d) is directed solely or mainly at children;

d) is directed solely or mainly at children or at young people aged under 18;

(Amendment No. 42)
Article 5 da) (new)

da plays on people's distress or on the emotional nature of the advertisement;

(Amendment No. 43)
Article 5 e)

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

e) refers to a recommendation by scientists, health professionals or any other persons who, because they are well-known, are likely to encourage consumption of the medicinal product in question;

(Amendment No. 44)
Article 5 ea) (new)

ea uses pictures showing health care professionals wearing their working uniforms;

(Amendment No. 45)
Article 6(1), first sentence

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

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

(Amendment No. 46)
Article 6(1), third indent

- the retail price of the various presentations,
- deleted

(Amendment No. 47)
Article 6(1) fourth indent

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

(Amendment no. 48)
Article 6(1a) (new)

Persons qualified to prescribe or dispense medicinal products must be given information on the final sales price of each of the various presentations and on the conditions of coverage by the social security systems, in a way which conforms to national requirements.

(Amendment No. 49)
Article 6(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.

The advertising of a medicinal product to persons qualified to prescribe, supply or dispense such products may, notwithstanding paragraph 1 include only the name of the medicinal product, if its sole object is to recall to the latter.

(Amendment No. 50)
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).

Any documentation relating to a medicinal product which is transmitted as part of the advertising of that product to persons qualified to prescribe or supply it shall refer to the data sheets drawn up by the Agency referred to in Regulation (EEC) No.

...

(Amendment No. 51)
Article 7(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.

All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and (one word deleted) complete (rest deleted).

(Amendment No. 52)
Article 7(2a) (new)

A European Data Bank on medicinal products, provided for in Council Regulation (EEC) No. of , to be managed jointly by the Commission and the representatives of the manufacturers and importers concerned, shall centralize all information on all the medicinal products marketed in the European Community. All health care professionals in the Community may have direct access to the data bank by telephone or computer 24 hours a day. Each producer or importer of pharmaceutical products shall pay 0.2% of its turnover in EC territory to the European Data Bank.

(Amendment No. 53)
Article 7(2b) (new)

Within one year of being set up, the Drugs Agency referred to in Regulation (EEC) No. shall draw up regulations for correct information on pharmaceutical products listed according to therapeutic categories.

Within the same period, the Member States shall forward to the Commission the names of medical sales representatives entered in national registers.

(Amendment No. 54)
Article 8(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.

During each visit, medical sales representatives shall provide health care professionals with the summaries of product characteristics in respect of each medicinal product which they present.

(Amendment No. 55)
Article 8(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.

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 advertise especially about adverse reactions, that is reported to them by the persons they visit.

(Amendment No. 56)
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.

In the course of advertising 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. (rest deleted)

(Amendment No. 57)
Article 9a (new)

1. The provisions of Article 9 shall not prevent undertakings which produce or import medicinal products from organizing congresses intended solely for the further scientific training of health care professionals.
2. In this case, the hospitality extended to participants must be subordinate to the main scientific objective of the event during which it is provided. Such hospitality shall be extended only to health care professionals.
3. The undertakings referred to in paragraph 1 shall notify Member States of any congress which they help to organize. They shall provide the following information at least 60 days before the start of the congress:
 - budget details,
 - the identity of the sponsor
 - the aim, duration, programme and location of the congress.

Member States shall make such information available to the Commission and to any other body designated by the Commission for this purpose.

4. Within two years of the adoption of this directive the Commission shall draw up a code of practice regarding the financing by pharmaceutical companies of congresses or other educational or information activities aimed at the medical profession.
5. The Commission shall submit a report on the application of this article to Parliament and the Council by 31 December 1996. Where appropriate, it shall submit suitable amendments in the light of such information.

(Amendment No. 58)
Article 10, first sentence

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:

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

(Amendment No. 59)
Article 10 a)

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

a) samples of medicinal products may be provided only where such products have been on the market for not more than three years. However, subject to the provisions of (f), newly-qualified doctors may request samples of any medicinal products, for a period of three years, irrespective of the date on which such products received market authorization;

(Amendment No. 60)
Article 10 b)

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

b) after the period referred to in Article 10(a), samples may be authorized, following a written request, signed and dated, from the recipient;

(Amendment No. 61)
Article 10 c)

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

c) the content of the samples must be identical to that of the smallest marketed pack and must make it possible to administer at least one initial dose of treatment.

(Amendment No. 62)
Article 10 d)

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

d) the samples shall be marked, clearly and indelibly, 'free medical sample - not for resale' or with another legend of analogous meaning;

(Amendment No. 63)
Article 10 e)

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

e) The samples shall be supplied together with a copy of the summary of product characteristics, in addition to the leaflet intended for patients which is usually included in the pack. They shall be sent in a specific consignment by the company responsible for marketing the product.

(Amendment No. 64)
Article 11(2)

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.

2. (First 9 words deleted) Member States shall confer upon the courts or the administrative authority referred to in paragraph 1 powers enabling them, through emergency procedures:
- (first indent unchanged)
- to 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; in the event of serious infringements, such corrigendum or publication may have the same features (advertising medium, duration, size, circulation or number of publications, etc.) as the advertisement in question.

(Amendment No. 65)
Article 11(3)

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.

3. (First nine words deleted) Member States shall ensure that any decision taken in accordance with paragraphs 1 and 2 shall state in detail ... (rest unchanged)

(Amendment No. 66)
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.

The person who has received market authorization or the person responsible for marketing must have recourse at the very least to a scientific board for medical information, headed by a health care professional, responsible for advertising the medicinal products which he placed on the market.

(Amendment No. 67)
Article 12(2), first sentence

2. The person responsible for marketing shall:

The person responsible for marketing or the person who has received market authorization shall:

(Amendment No. 68)
Article 13(1)

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.

1. Where the provisions of the Directive have not been observed, and a warning notice served on the party concerned has remained without effect within the deadline set by that notice, the competent authorities of a Member State shall decide on penalties pending a sufficient deterrent, and, in the most serious cases, may even go so far as to suspend the authorization to market the medicinal product concerned.

Member States shall introduce into their national legislation the provisions necessary for the application of this article.

DRAFT LEGISLATIVE RESOLUTION

(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission proposal for a Council directive on advertising of medicinal products for human use

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0212 final - SYN 273)²,
 - having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-0185/90),
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (A3-0127/91),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EC Treaty;
 3. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;
 4. Instructs its President to forward this opinion to the Council and Commission.

² OJ No. C 163, 4.7.1990, p. 10

B

EXPLANATORY STATEMENT

1. European legislation on advertising

As long ago as the late 1950s, i.e. long before the existence of the First Community Action Programme on Consumers of 14 April 1975, the Commission deemed there was a need for European legislation on 'unfair competition'. The Commission's ponderous approach to the subject can be seen in the fact that it took almost 20 years to present an initial proposal for a directive on misleading and unfair advertising (COM(77) 724 final of 28 February 1978). This proposal then spent another six years being pulled to pieces and further watered down at various meetings of the Council. Finally, agreement was reached in 1984 but only on misleading advertising. Despite the fact that both the Commission and the Council have repeatedly recognized the need for one, the Commission has still not produced a new proposal concerning unfair advertising. Nor has it yet produced a draft proposal on comparative advertising which is also deemed necessary and which was announced several years ago.

The European internal market will be completed in just on two years time. Industry has already responded by expanding Europe-wide. Advertising law is now hobbling along some three decades behind. Persons intending to advertise in other EC countries need to know and respect the law in force in such countries. This can cause considerable problems. Not only has advertising law developed on different lines in the Member States but it is also, for linguistic reasons, not readily accessible. Framework legislation on advertising needs to be developed as soon as possible, not only to protect consumers but also in the interests of industry.

The development of the internal market and rapid technological changes in communications, in particular the audiovisual media, resulted in the adoption of the 'television directive' in 1989. This directive and the directive on misleading advertising contain legislation which is applicable directly or indirectly to advertising for pharmaceutical products.

In contrast to these two examples of European framework legislation - which urgently need to be expanded to include unfair and comparative advertising - the Commission is increasingly tending to propose detailed and restrictive legislation on advertising for specific products.

The first attempt was the proposal for a directive on the approximation of the laws of the Member States relating to claims made in the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (Doc. 1-224/81 - COM(81) 159 final). Parliament rejected this proposal (Doc. 1-1207/82, PE 79.064/fin., 7.2.1983). Besides specific difficulties concerning the areas to be covered by the legislation, even in 1983 Parliament objected to the fact that various provisions covered the same areas as individual and framework legislation without being formulated in exactly the same terms. Parliament objected to individual directives being proposed without taking into account the underlying issues. It was also concerned about unnecessary and confusing duplication. It called on the Commission to ensure that new proposals were in line with existing proposals.

Despite these objections, the Commission has now submitted two further detailed items of legislation concerning advertising:

- the directive on advertising tobacco products (Parliament's opinion on first reading on 14.3.1990)
- and the present proposal for a directive on advertising of medicinal products for human use.

On the whole, the Commission's proposal for a directive on advertising medicinal products is well-balanced and it represents an appropriate legal framework for the advertising of such products in the Community. It is regrettable, however, that the Commission is once again proposing a detailed directive for a specific group of products without first having proposed framework directives for unfair and comparative advertising. If there were comprehensive legislation on these two areas in the form of a European framework directive, there would be no need for a number of detailed proposals, including some of those in the present text. In fact, the directive on misleading advertising (in force since 1984) and the 1989 directive on television advertising already cover a number of points in the Commission's proposal which are therefore unnecessary. European legislation should always be aimed at laying down appropriate and unambiguous basic conditions embracing uniform criteria for assessment.

It is also questionable whether differences in legislation on advertising of medicinal products really do constitute a barrier to trade. The example quoted by the Commission (judgment of 6 March 1990, Case GB-INNO-BM ./ . CCL) is specifically concerned with mail shots and not with differences in the substance of advertising. This matter - the free distribution of printed matter - is generally covered by the Helsinki and Vienna Agreements and by international postal agreements.

Given the considerable interest in medicinal products and advertising of them, it is understandable for political reasons, however, that the Commission has drawn up a proposal for a directive.

II. Contents of the proposal for a directive

There are already statutory and voluntary restrictions in all Member States on advertising to the general public for non-prescription medical products (including those sold only by pharmacists). The intention is to harmonize the different national schemes in such a way that the properties of the medicinal products are presented objectively in advertising. The proposal specifies what information has to be provided as a minimum requirement in advertising of medicinal products to the general public. Certain advertising claims are banned.

All Member States already prohibit the advertising of prescription-only medicinal products. The Commission proposal incorporates this prohibition. With the exception of specialist literature, the 'advertising' of prescription-only products is permitted only in the form of direct visits to health professionals. The Commission's proposal therefore includes this area, too. Yet it is precisely in this area that it is difficult to draw a distinction between 'advertising' and essential forms of 'information'. The Commission's proposal also regulates the supervision of advertising in the two areas and provides for penalties.

III. Evaluation of the proposal for a directive

1. The role of medicinal products in health care

Medicinal products play a key role in all health care systems in the countries of the European Community. Approximately 80% of all illnesses are alleviated or treated through medicaments. Cost-benefit analyses have clearly shown that for many illnesses medicinal products are by far the cheapest and, in very many instances, the only form of treatment. They are therefore important not only for medical reasons but also on cost grounds.

Conditions for the advertising of medicinal products

By virtue of EC directives dating from 1965 (65/65/EEC) and 1975 (75/318/EEC and 75/319/EEC), which have been continuously updated since then, medicinal products are subject to a strict approval procedure in the countries of the European Community. They are tested for effectiveness, harmlessness and quality. If these criteria are not fulfilled the product is not authorized, or in some cases authorization can be revoked by the competent body.

The free movement of medicinal products will be facilitated by the future EC authorization procedure, the draft of which has been submitted by the Commission (COM(90) 283 final). The product claims approved by the authorization procedure will be the basis for the advertising claims and for the information supplied to specialists.

In contrast to the Commission proposal, the Member States' pharmaceuticals legislation makes a distinction between 'information for specialists' and 'product advertising as such'. The annex contains a survey of national regulations currently in force on information for specialists.

2. Advertising of medicinal products to the general public

Advertising claims

The basic principle is that advertising is permitted only for non-prescription medicinal products. Advertising is intended to make the product and its areas of application known. For manufacturers it is an important means of drawing attention to tested and authorized products. All claims of substance in the advertising are based on the authorization certificate and/or registration by the competent authorization body; i.e. there is a neutral basis. Advertising to the general public is also intended to provide information on specific preventive effects of the product and to indicate ways of overcoming mild feelings of ill-health. This information therefore helps reduce public spending on sickness insurance systems. All the countries of the Community are undertaking efforts to redistribute social insurance resources with a view to targeting the central measures and reducing the financial burden of trivial illnesses. In this context a ban on the advertising of non-prescription reimbursable products will be counter-productive, quite apart from the fact that, as the Commission itself says, this 'grey area' accounts for only a very small proportion of advertised products and it varies from country to country. As long as there are no plans for harmonization of European social insurance systems, a European ban on the advertising of non-prescription reimbursable products would create new inequalities.

Restricting advertising statements for certain illnesses, as proposed by the Commission, reflects national practices.

Furthermore, it is irresponsible if advertising is addressed specifically or exclusively to children and young persons. Further restrictions are needed here.

There are various sources of specialist information on medicinal products and these are an important source of product safety. People are becoming more health-conscious; hence their interest in, and desire for, better information. Responsible advertising should supply this information. However, advertising of medicinal products cannot include every single detail if the information is to remain comprehensible. Nevertheless, a majority of the Committee felt it would be sensible to include in advertising to the general public not only the name of the medicinal product together with the usual general description, but also instructions on use, precautionary measures, contra-indications, the main side-effects and possible interactions with other products and any special information. Advertising to the general public, it was felt, should also include a specific invitation to read the label and package information. A majority of members of the Environment Committee also felt it necessary to point out that every form of advertising should include the following statement: 'Any medicinal product can be dangerous if misused. Consult your doctor or chemist'.

The rapporteur would have considered it enough to include in the advertising to the general public of prescription-only products not only the name of the product and its application but also a compulsory text drawing the attention of consumers to the packaging leaflet and/the labelling. This is not intended as a means of withholding information, but as a means of drawing the consumer's attention to comprehensive sources of information on the product. Pharmacists are available to advise consumers on purchasing products and they can provide information on them. (In Germany, pharmacists are by far the commonest source of information for consumers, followed by doctors and - a long way behind - the media or other sources).

Package leaflets

The main source of consumer information for self-administered products are the package leaflet and the labelling. Another Commission proposal (COM(89) 207 final) proposes that this be standardized Community-wide and presented in a form which the consumer can easily understand.

The important point is that the package leaflet, as a source of information, should be checked and approved by the approval authorities to ensure that the information is neutral and scientifically sound. In many countries there are reference works for patients which provide clear and easily understood information on non-prescription products on the basis of the text contained in the package leaflet. A reference to the package leaflet must therefore be made a standard feature of all forms of advertising.

Forms of advertising

Nine Member States permits advertising of medicinal products in all media. In Denmark there is a general ban on audiovisual media (which also, of course, includes non-prescription products). In Greece there is an absolute ban on pharmaceutical advertising but the importance of this should not be

exaggerated because there are only two substances (aspirin and paracetamol) which can be administered without a prescription. Belgium is the only Member State with a specific ban on the advertising of medicinal products on TV and in the radio. However, in a press release of 27 June 1990 the Deputy Minister of Public Health stated that, in the light of European developments, the Belgian Government was considering removing this restriction which is peculiar to Belgium.

In Greece, too, there is considerable discussion on making an appreciable number of substances prescription-free and, connected with this, the introduction of advertising to the general public.

This means that advertising to the general public in all media for non-prescription products is on the way to being accepted in all countries of the Community. Since advertising is an important feature of liberal economic systems, this development is not surprising in view of the future Common Market. A majority of members of the Environment Committee felt there was a need to add two new paragraphs to Article 4 to cover regulations on advertising on television or in cinemas and on warnings, references and contra-indications.

To summarize, a balanced critical attitude is the most appropriate approach.

3. Information on medicinal products

Medicinal products are a particular type of goods. In contrast to many consumer goods, the correct application of a medicinal product presupposes comprehensive information on the healing properties and the potential risks. This is particularly true of what is in general the complex use of such products for therapeutic purposes. With new products the manufacturer's information, the substance of which is based on the authorization procedure for the product, is of particular importance. In all the countries of Europe there are reference works for specialists based on the product properties as a whole; they constitute an independent source of information (in Germany the reference work is the 'red list' which is updated annually and made available free of charge to health professionals). Besides this standard information, pharmaceutical firms normally provide health professionals with additional, detailed information on request and free of charge.

The information to be provided to health professionals (Chapter III) is exclusively the responsibility of the manufacturer. The retail price-setting and sickness insurance schemes' conditions of coverage will continue to differ widely in accordance with national practice. In the Community, reimbursement systems are state-run, semi-state-run, private, company-based and profession-wide. In some countries the retail prices of certain groups of medicinal products are determined by pharmacists.

The minority felt that, given the considerable system-related differences between the individual countries, it was not possible to impose on manufacturers a set of European 'advertising rules' covering information on the retail price of medicinal products and the sickness insurance schemes' conditions of coverage. However, the majority followed the Commission's approach and made it more explicit. 'Persons qualified to prescribe or dispense medicinal products must be given information on the final sales price of each of the various presentations and on the conditions of coverage by the

social security systems, in a way which conforms to national requirements.' (Amendment No. 48).

At the initiative of the Commission a European database for medicinal products is currently being developed which will also include a summary of the product characteristics of each product. Health professionals will be able to see where there may be possible differences in scientific assessment by the national authorization bodies. The future system of European registration of medicinal products could eliminate and standardize any existing differences. This European database is an additional, independent source of information for health professionals. A majority of the Environment Committee supported including an explicit reference to the European database for medicinal products, together with information on how it operates and how it is funded (Amendment No. 52).

A majority also favoured including a reference to the European Agency for the evaluation of drugs, the subject of a Commission proposal (COM(90) 283 final), and its task of monitoring scientific information concerning medicinal products (Amendment No. 9). The rapporteur believes this is premature in that the details of the Agency's tasks and structure are still the subject of political discussion.

The advertising and sales promotion of medicinal products to health professionals is principally the task of medical sales representatives who therefore play an important part in disseminating medical information. Although the Committee was unable to go as far as the rapporteur - who called for additional, scientifically trained medical sales representatives to provide information to health professionals - the Committee wants them to be 'qualified to play (their) role and comply with specific obligations' (Amendment No. 6).

The whole issue of information on side-effects and the risks of medicinal products is covered in a detailed chapter in the draft 'authorization directive for medicinal products' and, in the rapporteur's opinion, ought not to be covered in the 'advertising directive' in a few lines in the chapter on 'advertising to health professionals'. It would be more appropriate to make reference to the more detailed rules concerned in the authorization directive. This was not the view taken by the majority.

Samples of medicinal products have traditionally been an important means of providing information on a new product. However, limiting the number of samples would seem appropriate on economic grounds and for reasons of health policy. A majority of members of the Committee were of the opinion that the Directive should specify that samples of medicinal products should be supplied only if no more than three years had elapsed since the actual date of marketing the product, with the proviso that newly-qualified doctors might request samples of any medicinal products for a period of three years, irrespective of the date on which such products received market authorization (Amendment No. 59). Samples should also be such as to make it possible to administer at least on initial dose of treatment (Amendment No. 61).

A majority was in favour of upholding the Commission's proposal to ban supplying to doctors samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions. The rapporteur believes such a ban is necessary because:

- the proposal already imposes a general restriction on the numbers of samples;
- doctors also need to familiarize themselves with such products;
- this group of products also includes relatively harmless ones such as cough syrups and
- all the Member States and the international conventions have strict rules on providing written evidence for the supply of such products, and this also applies to samples.

Specialist conferences and information meetings are an important forum for exchanging information on treatment and for acquiring additional knowledge. A large number of these conferences and events are financed or part-sponsored by the pharmaceuticals industry. This is to be welcomed per se since providing information on their products and also on the pathological causes of an illness is an important function of pharmaceuticals firms.

By contrast, however, events at which the dissemination of scientific information merely takes second place to the social or tourist aspects are to be deplored. Although such forms of advertising are not called into question in other areas of the economy, thanks to our free economy, and although academically trained professionals may assume that their performance as doctors is unaffected by such activities, restrictions - including those of a legal nature - would seem justified and necessary, particularly in view of the special nature of medicinal products. However, such restrictions must not lead to a ban on appropriate sources of information where the scientific nature is clearly predominant and where the financial sponsorship is known. Further training is an important opportunity for younger doctors and pharmacists to broaden and deepen their university training in the light of practical experience.

The alternative to the funding of further training events by industry would be recourse to public spending or, possibly, fewer further training opportunities. In this respect the Committee endorsed the rapporteur's view, but insisted on proposing a new Article 9a (Amendment No. 57) to include the conditions under which pharmaceutical firms might organize congresses solely for the further scientific training of health care professionals. The Committee also called on the Commission to draw up a code of practice on the financing of such congresses.

4. Monitoring of advertising

To cover the special nature of pharmaceutical products, approval in principle of advertising involves comprehensive monitoring. The methods available vary from country to country in the Community and they can broadly be divided into three categories:

- a priori monitoring by the state (e.g. France);
- a priori monitoring by self-regulatory bodies (e.g. Britain);
- a posteriori monitoring by the state and/or self-regulatory bodies (e.g. in Germany).

Comparisons between the nature of advertising permitted in the countries of the Community have shown that despite the differences in monitoring bodies

there are virtually no differences in practice. What this means is that the results of monitoring of medicinal products are similar and that no one system can be seen to be significantly better than any other one. In general the Commission proposal is based on this finding and it continues to permit different forms of monitoring which have proved their worth in the individual countries. This is to be welcomed. Monitoring of advertising should continue to be organized on a national basis to permit an adequate assessment of the linguistic presentation of the advertising message. Contrary to the views of the rapporteur, the Committee - in Amendment No. 13 - was of the opinion that advertising of medicinal products should be the subject to preventive monitoring.

5. Penalties

The problem arises, by contrast, in the link between advertising measures and authorization in the context of the proposed penalties. There can be no doubt that substantial penalties are valuable, particularly in the case of persistent infringements of the directive. However, such penalties should be based on the advertising, for example in the form of a ban on advertising or a fine. This is covered by some of the amendments. Revoking authorization could, in the rapporteur's opinion, involve unacceptable consequences for patients if, for example, a vital product were no longer available for a specific period because there was something wrong with the advertising. There is the risk that innocent consumers could suffer from such a measure.

Furthermore, existing penalties have proved effective at the national level. There is no evidence of persistent infringements of laws on advertising.

6. Conclusion

These theoretical considerations justify the amendments proposed by Parliament. Subject to adoption of these amendments, the European Parliament supports the Commission's proposal because on the whole it is well-balanced.

ANNEXE

REGLEMENTATIONS NATIONALES CONCERNANT L'INFORMATION ET LA PUBLICITE
DESTINEE AUX PROFESSIONS DE SANTE

ALLEMAGNE	
<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaires non-officiels</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis Conformes à la section 11a de la 2e Loi de Réforme de la Loi sur les Médicaments du 16/08/86, <u>datées</u>.</p> <p>La "Rote Liste" regroupe les monographies des médica- ments fabriqués industriellement par les laboratoires- membres du BPI, cette liste a une très grande notoriété et se trouve chez tous les médecins.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Loi dans le Domaine de la Publicité du 11/07/65, amendée le 18/10/75 et Code d'éthique.</p> <p style="text-align: center;">*)¹</p> <p>Conforme à l'AMM, elle doit inclure: composition du produit (désignation et quantité des princi- pes actifs), indications, contre-indications, effets secon- daires et mises en garde.</p> <p>PAS DE CONTROLE A PRIORI. Contrôle a posteriori par des comités de contrôle des Länder et par des associations d'autodiscipline.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code d'autodiscipline du Bundesverband der Pharmazeutischen Industrie (BPI). Code FIIM. *)²</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Loi sur les Médicaments amendée en 1978 et 1986, Sect.47 (3 et 4). Fournis sur demande du médecin, en quantités limitées, marqués: "échantillon, ne peut être vendu". Trace de leur distribution doit être gardée.</p>

1 A.M.M. : Autorisation de Mise sur le Marché

* 2 Code F.I.I.M. : codex de la Fédération Internationale de l'Industrie
du Médicamen

BELGIQUE * LUXEMBOURG

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaires non-officiels</p> <p>officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis Conformes Arrêté Royal du 03/07/1969.</p> <p>"Compendium" de l'AGIM,^{*3} publié annuellement. "Medex" information brève, trimestrielle</p> <p>"Répertoire commenté des Médicaments" publié par le Ministère de la Santé.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Arrêté Royal du 09/07/1984 et Code d'éthique. Conforme à l'AMM.</p> <p>La <u>personne responsable</u> (médecin ou pharmacien agréé par le Ministère de la Santé) de l'information pharmaceutique pour tout fabricant ou importateur doit vérifier la conformité avec les lois et réglementations sur l'information et la publicité. En cas de <u>non respect</u> des principes éthiques ou légaux, cette <u>personne peut être révoquée</u>.</p> <p>PAS DE CONTROLE A PRIORI.</p> <p>Contrôle a posteriori par le Ministère non systématique.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code de Conduite de l'AGIM/AVIGI Code FIIM</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Régis par Arrêtés Royaux du 01/12/76, 25/03/77, 04/05/78 et 02/06/78. Ils doivent être enregistrés et sont assujettis aux mêmes règles que les conditionnements normaux.</p>

* 3 A.G.I.M. : Association Générale de l'Industrie du Médicamen

DANEMARK

<p>INFORMATION MÉDICALE Monographies</p> <p>Dictionnaire non-officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis</p> <p>"Laegemiddelkataloget"</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Loi sur les Médicaments, N° 327 du 26/06/75, Art. 31 et Code d'Ethique Conforme à l'AMM</p> <p>Publicité auprès des médecins, pharmaciens, dentistes, vétérinaires et étudiants.</p> <p>Publicité conforme au RCP^{*4}, y compris le <u>prix</u> du produit, <u>remboursement</u>, <u>conditions spéciales de distribution</u>. <u>Imprimés datés</u>.</p> <p>Publicités de rappel abrégées.</p> <p>PAS DE CONTROLE A PRIORI. Un comité d'autoréglementation reçoit un exemplaire au moment de la distribution de la publicité, s'il trouve matière à objection, il règle l'affaire avec la firme, sans faire intervenir les autorités.</p> <p>Possibilité pour le Ministère de la Santé d'exiger des corrections ou additions pour une publicité, dont il pourra définir la forme et le contenu.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code de Pratiques MEFA*/MEDIF*, Comités de contrôle indép. nommés par MEFA et MEDIF. Code FIIM.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Régis par Notification N° 411 du 14/08/85. Fournis aux médecins, dentistes ou vétérinaires, dans le plus petit conditionnement, un par médecin, durant la première année de mise sur le marché au Danemark. Marqués: "échantillon gratuit".</p>

* MEFA : Association de l'Industrie Pharmaceutique Danoise

* MEDIF: Association des Importateurs de Spécialités Pharmaceutiques

* 4 R.C.P. : Registry of Comparative Pathology

ESPAGNE

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaire non-officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis</p> <p>"Vademecum Internacional" contenant résumés etc. Informations pourront être homologuées, le cas échéant, par Ministère de la Santé.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Décret de la Couronne N° 3451 du 1/12/77, section 29 et Code d'éthique</p> <p>Conforme à l'AMM</p> <p>PAS DE CONTROLE A PRIORI pour la publicité dans la presse professionnelle.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code FIIM adopté par la FARMAINDUSTRIA.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Décret de la Couronne N° 3451 du 1/12/77.</p> <p>Fournis aux médecins sur demande préalable, durant deux ans suivant l'AMM. Conditionnements commerciaux, marqués "échantillon".</p>

FRANCE

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaire officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis</p> <p>Conformes à l'AMM (Annexe I), régulièrement mises à jour.</p> <p>Vidal, monographies approuvées par le Ministère de la Santé et actualisées.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Décret du 23/09/1987, N° 87-772, J.O. 24/09/87.</p> <p>Conforme au RCP et aux mentions exigées par la législation sur les <u>prix</u> et la <u>législation sociale</u>.</p> <p>PAS DE CONTROLE A PRIORI.</p> <p>Le <u>pharmacien responsable</u> en matière d'information et de publicité doit vérifier la conformité des éléments publicitaires proposés aux professionnels de la santé. En cas de litiges, il devra défendre son dossier devant la Commission plénière de Publicité, nommée par le Ministère de la Santé.</p> <p>La publicité sera déposée dès sa diffusion auprès des autorités, versement d'une redevance.</p> <p>Contrôle a posteriori par une Commission du Ministère de la Santé non systématique.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code Commun d'Éthique de l'Ordre National des Pharmaciens, de la Section Médicale de l'Union des Annonceurs et du S.N.I.P.*⁽⁵⁾</p> <p>Code FILM.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Article R-5046-2</p> <p>Peuvent être remis aux médecins et sous certaines conditions aux dentistes et sage-femmes pendant toute la durée de la commercialisation.</p> <p>Délivrance interdite dans les enceintes accessibles au public lors de congrès.</p> <p>Conformes aux conditionnements commercialisés et marqués "Echantillon médical gratuit".</p>

* 5 S.N.I.P. : Syndicat National de l'Industrie Pharmaceutique

GRANDE BRETAGNE

<p align="center">INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaire non-officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bls Conformes à "Medicines Act 1968, The Medicines (Data Sheet) Regulations 1972". Conformes à l'AMM</p> <p>^{x/6} "ABPI Data Sheet Compendium", publié régulièrement.</p>
<p align="center">PUBLICITÉ MÉDICALE</p>	<p>"Medicines (Advertising to Medical and Dental Practitioners) Regulation 1978 (SI 1978)" et Code d'éthique.</p> <p>La publicité auprès du médecin doit s'accompagner de la <u>remise ou de l'envoi de la monographie</u>. Publicités conformes aux détails du "Code of Practice for the Pharmaceutical Industry" et les "Advertising Regulations". Tout matériel promotionnel imprimé doit être <u>certifié conforme par deux personnes responsables</u> pour le fabricant, dont un est médecin. Leurs noms sont notifiés par avance aux autorités d'enregistrement.</p> <p>PAS DE CONTROLE A PRIORI.</p> <p>Le "Code of Practice Committee" contrôle les publicités pour s'assurer de leur conformité avec l'AMM et la monographie et publie régulièrement un rapport d'activité.</p>
<p align="center">CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code de Pratiques de l'ABPI. Code FIIM.</p>
<p align="center">ECHANTILLONS MÉDICAUX</p>	<p>Le "Code of Practice for the Pharmaceutical Industry" régit la distribution des échantillons. Ils ne devront être donnés aux médecins que sur demande signée. Les firmes pourront fournir au médecin des cartes de demande pré-imprimées. Cette carte ne s'applique pas aux produits soumis au "Misuse of Drugs Act de 1971". Un échantillon individuel ne devrait pas représenter plus de 4 jours de traitement pour un seul patient.</p>

* 6 A.B.P.I. : Association of the British Pharmaceutical Industry

GRECE

INFORMATION MÉDICALE	
Monographies	Conformes à la D.E. 83/570/CEE, Art. 4bis Conformes à l'AMM
PUBLICITÉ MÉDICALE	Conforme au RCP. <u>Responsable de publicité</u> pour chaque laboratoire signe les documents, gardés 3 ans. Date, code produit, numéro de série. La responsabilité pour la présentation et le contenu de la publicité reste à la firme. PAS DE CONTROLE A PRIORI. Dépot préalable à l'E.O.F. (National Drug Organisation) qui peut exiger la <u>correction ou le retrait</u> d'une publicité parue si elle n'est pas conforme ou si elle est trompeuse.
CODES VOLONTAIRES D'ETHIQUE	Code de Conduite de l'Association des Fabricants Pharmaceutiques. Code FIIM
ECHANTILLONS MÉDICAUX	La distribution d'échantillons médicaux aux médecins n'est pas autorisée.

IRLANDE

INFORMATION MÉDICALE	
Monographies	Conformes à la D.E. 83/570/CEE, Art. 4bis Conformes à l'AMM.
Dictionnaire non-officiel	"Irish Data Sheet Compendium", publié régulièrement par la Fédération de l'Industrie (FICI).
PUBLICITÉ MÉDICALE	Licencing, Advertising and Sales Regulations de 1984 (SI N° 210) et Code de conduite. PAS DE CONTROLE A PRIORI. Pas de dépôt préalable.
CODES VOLONTAIRES D'ETHIQUE	Code of Marketing Practice for the Pharmaceutical Industry" de la Federation of Irish Chemical Industries (FICI), contrôlé par un comité nommé par la Div. Pharm. de la Fédération. Code FIIM.
ECHANTILLONS MÉDICAUX	Le Code de Pratiques définit leur distribution. Pas de restrictions légales, mais la circulation d'échantillons non sollicités est découragée.

ITALIE

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaires non officiel</p> <p> officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis Conformes à l'AMM.</p> <p>"Prontuario" réactualisé et publié régulièrement.</p> <p>"Informatore Farmaceutico"</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Circulaires D.M. 23/06/81, D.M. 23/11/82, D.M. 26/02/85.</p> <p>Un RCP doit accompagner le matériel promotionnel.</p> <p>L'accent doit être mis sur les contre-indications, les mises en garde et les effets indésirables.</p> <p>Le nom générique du médicament doit également apparaître dans la publicité.</p> <p>ENVOI 45 JOURS AVANT PUBLICATION, au Ministère de la Santé, de toute publicité. La règle de "silence vaut accord tacite" s'applique.</p>
<p>CODES VOLONTAIRES D'ÉTHIQUE</p>	<p>Code d'Éthique de la FARMINDUSTRIA obligatoire. Un Comité de Contrôle statuera sur les infractions éventuelles. Code FIIM.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Décret Ministériel 23/06/81 et D.M. 23/11/82. Ils peuvent être remis gratuitement aux médecins pendant les 2 premières années suivant le lancement du produit. Après deux ans, ils peuvent être obtenus sur demande écrite. Marqués: "Echantillon médical, ne peut être vendu".</p>

PAYS BAS

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaire non-officiel</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis</p> <p>Conformes à l'AMM</p> <p>"Repertorium" qui regroupe les monographies et qui est actualisé et publié régulièrement.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>L'information et la publicité doivent au moins comporter les éléments suivants, conformes à l'AMM:</p> <ul style="list-style-type: none"> - nom du produit - composition qualitative et quantitative des principes actifs, - forme pharmaceutique, - principales indications, - principaux effets secondaires, - toutes les contre-indications. <p>Il y a allègement pour la publicité de rappel.</p> <p>La promotion pour les indications autres que celles enregistrées ou pour des usages qui ne sont pas directement liés au champ d'indications enregistrées, n'est pas permise. Pas de publicité comparative.</p> <p>PAS DE CONTROLE A PRIORI</p>
<p>CODES VOLONTAIRES D'ETHIQUE</p>	<p>Code de Conduite Néerlandais, édité par NEFARMA, contient dans son intégralité le Code FIIM.</p> <p>Le Conseil de la Promotion des Médicaments contrôle et applique ce Code et intervient en cas de plaintes.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Réglementation de Février 1980. Les échantillons gratuits sont autorisés pendant les 2 ans suivant la date d'AMM, seulement deux paquets du plus petit conditionnement commercialisé et uniquement aux médecins. Obligation de garder trace de la distribution.</p>

PORTUGAL

<p>INFORMATION MÉDICALE</p> <p>Monographies</p> <p>Dictionnaires non-officiels</p>	<p>Conformes à la D.E. 83/570/CEE, Art. 4bis</p> <p>Conformes à l'AMM</p> <p>"Simposlum Terapêutico" et "Indice Nacional Terapêutico, édités tous les ans.</p>
<p>PUBLICITÉ MÉDICALE</p>	<p>Décret 157/88, du 19/06/88, N° 7.</p> <p>Conforme au RCP.</p> <p>La publicité doit expressément comprendre:</p> <ul style="list-style-type: none"> - nom générique joint au nom de marque du produit, - coût journalier du traitement, - prix de vente au public, - remboursement. <p>PAS DE CONTROLE A PRIORI.</p> <p>Contrôle a posteriori effectué par la Direction Générale des Affaires Pharmaceutiques (DGAF).</p>
<p>CODES VOLONTAIRES D'ETHIQUE</p>	<p>Code de Pratiques APIFARMA, basé sur le Code FIIM.</p>
<p>ECHANTILLONS MÉDICAUX</p>	<p>Distribution uniquement aux médecins. Pas de limite dans la quantité et le temps de distribution. L'échantillon <u>peut ne pas être identique</u> (en contenance) au modèle-vente; ceci est de la responsabilité du laboratoire.</p>

OPINION

(Rule 120 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy
for the Committee on the Environment, Public Health and Consumer Protection

Draftsman: Mr DI RUPO

At its meeting of 16 October 1990, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr DI RUPO draftsman.

At its meetings of 18-20 December 1990 and 5-7 February 1991, it considered the draft opinion.

At the latter meeting it adopted several amendments to the proposal for a directive; voting 21 in favour and 21 against, it did not adopt the conclusions as a whole.

The following took part in the vote: Beumer, chairman; Desmond, vice-chairman; Fuchs, vice-chairman; di Rupo, rapporteur; Barton, Beazley, Bernard Reymond, Bofill Abeilhe, Cassidy, Caudron, Cox, de Donnea, Donnelly, Friedrich, Herman, Hoff, Lataillade, Mattina, Metten, Merz, Patterson, Pinxten, Read, Ferreira Ribeiro, Rogalla, Roumeliotis, Seal, Siso Cruellas, Tongue, von Wogau, Wettig, Braun-Moser (for Gallenzi), Daly (for Steven), David (for Christiansen), Fitzgerald (for Ruiz Mateos), Nielsen (for Visentini), Peijs (for Sboarina), van Hemeldonck (for Mihr) and Arias, Green, Sarlis and Zavvos pursuant to Rule 111.

I. THE ECONOMIC IMPORTANCE OF THE PHARMACEUTICALS SECTOR

The twelve Member States of the European Community together comprise one third of the world market in pharmaceuticals. The United States' share is roughly equivalent, while Japan accounts for some 18% of the market.

Europe's balance of trade in medicinal products has been in surplus since the beginning of the 1980s (with an annual growth rate of 4.6% from 1980 to 1987), doubling in 8 years to reach a balance of trade surplus with the rest of the world of over 3.8 billion ECU.

The pharmaceutical companies' turnover on the European market more than doubled between 1980 and 1988, rising from 19 bn to 46 bn ECU.

As regards employment, the pharmaceutical industry provided jobs for almost 450 000 people inside the European Community in 1989, of whom over 10% worked in the research sector. A further 1.2 m people are employed in jobs generated indirectly by the industry.

Products for self-medication account for almost 30% of the total market in the United States. In Europe, on the other hand, they currently represent only 15% of the market. Specialists forecast, however, that products for self-medication will eventually account for 30% of the Community market also.

II. PROS AND CONS OF THE PROPOSAL

1. Need for Community rules on the advertising of pharmaceutical products

All the Member States apply regulations concerning the advertising of pharmaceuticals. Yet those regulations vary from one Member State to another, particularly with regard to advertising to the general public. All the Member States prohibit the advertising of prescription-only products, but certain states (such as Belgium and Denmark) prohibit any radio or television advertising of pharmaceutical products, or any advertising of such products to the general public whatsoever (Greece). The standards for and constraints on advertising of pharmaceuticals vary from one Member State to another. Similarly, the advertising of pharmaceuticals is subject either to retrospective regulation by the courts (as in Germany and Belgium) or to prior monitoring, either by a public regulatory body (as in France, Spain, Italy, Denmark, Portugal and Luxembourg) or by the industry's own self-regulatory bodies (as in the United Kingdom, Ireland and the Netherlands).

Furthermore, certain medicinal products require a medical prescription in some Member States, but not in others while in certain Member States the cost of products that do not require a prescription may still be reimbursed if obtained on prescription. These conflicting rules are liable to impede the free movement of medicinal products.

It is also necessary to secure freedom to provide advertising services, since in future advertising campaigns for medicinal products will cover several Member States at the same time. The completion of the single market will require common rules for the advertising of pharmaceuticals with regard to both consumer protection and the marketing of products.

The Commission proposal does, therefore, meet a need, although it needs to be tightened up.

2. The relatively neutral effect of the proposal

It is, admittedly, difficult to establish with certainty the extent of pharmaceuticals advertising. It accounts for significantly more than the 12 to 15% of pharmaceutical companies' turnover suggested by the Commission and, as the manufacturers' themselves admit, may account for up to 30% of their turnover, compared to a figure of some 15% of turnover for research and development costs.

The marked rise in expenditure on advertising and marketing in general reflects the companies' need to recuperate the very high development costs of such products as swiftly as possible, but also growing competition between pharmaceutical firms as the industry becomes increasingly concentrated.

The Commission's proposal appears to be relatively stringent. In practice, however, it seeks a middle way between the various national regulations currently in force and opts for a more flexible system than that now applied in some Member States. In so doing, the proposed Community legislation reflects a relatively neutral approach to the advertising of pharmaceuticals to the general public, and one wonders whether this is advisable. Should we encourage the constant rise in the pharmaceutical industry's expenditure on advertising (currently double their research budgets)? On the contrary, there are many reasons for seeking to reduce that expenditure.

In the case of OPREN (or BENOXAPROFEM) for example, an anti-arthritis drug produced by ELI LILLY, the aggressive advertising campaign for the product included a three-day cruise on the Rhine for a number of prominent rheumatologists.

This campaign, which seems to have cost more than the product's development costs, cost the British National Health Service £13.5 mn.

It appears that this product caused about 100 deaths and made a further 1500 people ill³.

In 1988, in the United Kingdom, it was demonstrated that the pharmaceutical industry spent 80 times more than the National Health Service on information to doctors.

³ Journal of Consumer Policy 12, pp. 397-414, 1989

Should we leave responsibility for informing the general public and medical practitioners to the manufacturers alone? Would it not be better to compel all the Member States to ensure that neutral and objective sources of information existed in their countries? Such arrangements should, in particular, enable medical practitioners to obtain comprehensive and accurate information about all medicinal products.

Is one much-hyped product really more effective than another? What new health benefits does it offer?

In addition to providing for neutral and objective sources of information at national level, the Commission should set up a European data bank on medicinal products. It appears that such a data bank is currently being considered, particularly in the context of Directive 89/105/EEC on price transparency for medicinal products. The process of setting up this data bank should be accelerated and it should comprise not only data on the price of medicinal products but also all the data contained in their accompanying leaflets and any other information of interest to doctors. This data bank should be funded by the pharmaceutical manufacturers accessible to every doctor in the Community either by telephone or, eventually, by computer.

When it comes to advertising to the general public, as the BEUC (European Bureau of Consumers' Unions) has emphasized, radio and television would not appear to be appropriate media for the promotion of products for self-medication. On the contrary. The brevity of radio or TV commercials and the over-simplified and emotional messages they contain make it impossible to convey the basic information needed by consumers. It is clearly necessary to prohibit all radio or TV advertising of medicinal products.

Furthermore, some countries have very restrictive policies concerning the advertising of medicinal products. The directive should take that into account and allow Member States to apply more restrictive rules if they wish.

General expenditure on marketing to practitioners increases the cost of medicinal products and, albeit insidiously, tends to make the medical profession dependent on the pharmaceutical companies. Finally, advertising campaigns do not necessarily boost sales in general, but increase sales of certain new products to the detriment of older, but often equally effective, products.

The directive does not pay sufficient attention to the role of medical sales representatives. The major international pharmaceutical companies increased the number of such sales representatives by 50% between 1983 and 1988, and they play a crucial role in influencing doctor's decisions. According to the 'Economist' of 27 January 1990, six out of ten doctors stated that they had prescribed medicinal products solely on the basis of information provided by medical sales representatives.

It is necessary, therefore, to ensure that these representatives receive adequate training and are answerable, within their own company, to a medical practitioner. Doctors should have a means of obtaining redress if they are given inaccurate information by medical sales representatives.

While there should be extremely stringent rules on the subject of information for doctors, the provision of purely scientific information by the pharmaceutical industry should, perhaps, be allowed. It should, however, be carefully controlled and should not simply amount to promoting the prescription or sale of a product.

3. Lack of effective regulation

The proposal is not only relatively neutral concerning the advertising of pharmaceutical products, but also fails to ensure that the implementation of its own provisions are monitored effectively.

The proposal should not simply specify obligations; it should also provide for compliance with such obligations to be monitored and penalties imposed.

Yet the proposal leaves the task of monitoring the implementation of Community rules to the Member States, which are required to 'ensure that there are adequate and effective methods to monitor advertising of medicinal products'. These methods may be very diverse, ranging from preliminary or retrospective monitoring by national authorities to self-regulation by the pharmaceutical industry; the Commission does not come down in favour of any particular option. This is liable to produce variations in implementation which could be detrimental to health objectives and lead to distortions of competition.

Given these vague provisions for regulation by the Member States, it seems unlikely that the industry will comply fully with certain obligations contained in the directive (for example, in relation to free samples for doctors, the requirement that firms should issue no more than two samples per year to each doctor, and only in response to a written request).

The proposed sanctions, also, are not particularly convincing. Fines imposed by courts are often insignificant in relation to the size of the companies in question, while the provisions of Article 13 appear to be inappropriate and their application is, in any event, left to the discretion of the Member States.

4. Need for Community regulations concerning para-pharmaceutical products

The directive does not cover para-pharmaceutical products (such as vitamins, dietary products, sun-protection products, etc.), as it is concerned solely with medicinal products proper. However, though on the border-line such products are marketed in such a way as to create the illusion that they possess medicinal properties. Yet they are excluded from all the regulations applied to medicinal products. The Commission should, therefore, also introduce legislation on the advertising of and claims made for para-pharmaceutical products to bring them within the

scope of similar rules to those applied to medicinal products for human use, since such products are often presented as having a beneficial effect on individuals' health or well-being.

The Committee on Economic and Monetary Affairs and Industrial Policy calls on the Committee on the Environment, Public Health and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Commission text

Amendments

(Amendment No. 1)

New recital 2a

Whereas the advertising to the public of non-prescription medicinal products is an important element in the information of patients. In particular, it informs consumers of the methods of treating minor ailments themselves;

(Amendment No. 2)

New recital 10a

Whereas in applying this Directive Member States should ensure that its provisions apply to all parties who may influence prescribing habits;

(Amendment No. 3)

Article 1(2), first indent

2. For the purposes of this Directive

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

2. For the purposes of this Directive,

- the definition of 'advertising' shall be that laid down in Article 2 of Directive 84/450/EEC. Information of a purely, scientific, technical or educational nature shall not be considered as 'advertising' in the sense of this Directive,

Commission text

Amendments

(Amendment No. 4)
Article 1(3), third indent

- 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,

- 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, except when these are of a purely scientific nature.

(Amendment No. 5)
Article 3(1) and (5)

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 medical prescription, in accordance with Council Directive ../... EEC.

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

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,

- medicinal products and doping agents, as defined by the Council of Europe and the International Olympic Committee, that give rise to addictions and/or dependence,

- medicinal products and doping agents, as defined by the Council of Europe and the International Olympic Committee, that give rise to addictions and/or dependence,

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

- Member States shall prohibit the unsolicited distribution of medicinal products to the public for promotional purposes

Commission text

Amendments

(Amendment No. 6)
Article 4(b)

(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.

(b) include the following minimum information:

- the name of the medicinal product,
- the information necessary for correct usage of the medicinal product, i.e. its areas of application and an express invitation to read the package leaflet carefully. The advertising of a medicinal product to the public may, notwithstanding the above, include only the name of the medicinal product, if its sole object is to draw attention to the latter,
- all contra-indications, the principal side-effects or adverse reactions, appropriate precautions for use, possible interaction with other substances and any other special recommendations,
- an invitation to ask the doctor or pharmacist about risks and side-effects.

Commission text

Amendments

(Amendment No. 7)
Article 6(1)

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.

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 when this has been agreed at Community level,

Deleted

Deleted

- persons qualified to prescribe or supply medicinal products should receive information on the retail price of the various presentations and, if appropriate, the conditions of coverage by the social security systems in accordance with national provisions.

Commission text

Amendments

(Amendment No. 8)
Article 9(1) and (2)

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.

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. Notwithstanding the above, it shall be permitted for assistance to be provided to health-care professionals to attend congresses and other meetings of scientific interest provided all such assistance and hospitality is reasonable.

2. As an exception to the provisions of paragraph 1, it shall be permissible to finance medical studies and conferences provided that the existence of such funding is clearly established beforehand, and the identity of the person providing the funds is revealed. any documents relating to the studies or conferences in question must mention the existence of a source of outside funding and the identity of the party supplying those funds.

Commission text

Amendments

(Amendment No. 9)
Article 10(a) to (c)

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;

Deleted

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

b) the samples shall be of a size which is reasonable in relation to the product's actual use;

(Amendment No. 10)
Article 11(1)

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.

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; Member States shall encourage producers to adopt a system of voluntary control of advertising of medicinal products by recourse to self-regulatory codes with effective organs of control.

1a. The judicial or administrative proceedings referred to in paragraph 1 should always be available in the event that voluntary control of advertising of medicinal products by self-regulatory bodies, or recourse to such bodies, proves inadequate.

(Amendment No. 11)

Article 12, paragraph 2, first indent

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|---|---|
| - <u>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;</u> | - <u>retain at the disposal of 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;</u> |
|---|---|

(Amendment No. 12)

Article 13(1)

1. Where the provisions of this 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.

1. Where the provisions of this 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 impose any sanction which may be applied under national law. Decisions concerning the suspension or revocation of marketing authorizations may be made only within the terms of Directive 65/65/EEC.

