COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 245 final - SYN 229/230/231/273

Brussels, 18 July 1991

Amendment to the proposal for a

SYN 229

COUNCIL DIRECTIVE

on the wholesale distribution of medicinal products for human use

---

Amendment to the proposal for a

SYN 230

COUNCIL DIRECTIVE

on the legal status for the supply of medicinal products for human use

---

Amendment to the proposal for a

SYN 231

COUNCIL DIRECTIVE

on the labelling of medicinal products for human use and on package leaflets

---

Amendment to the proposal for a

SYN 273

COUNCIL DIRECTIVE

on advertising of medicinal products for human use

(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

Amendment to the proposal for a

COUNCIL DIRECTIVE

on the wholesale distribution

of medicinal products for human use

EXPLANATORY MEMORANDUM

At its plenary session on 12 June 1991 the European Parliament approved the Commission proposal on the wholesale distribution of medicinal products for human use (COM(89)607 final, SYN 229 of 26 January 1990).

Pursuant to Article 149(3) of the EEC Treaty, the Commission has decided to make 11 amendments to its proposal.

First, the Commission has included Parliament's amendments concerning the public service obligations of wholesalers supplying pharmacies. Since not all the Member States apply this system, it was found inappropriate to introduce it throughout the Community. On the other hand, the new rules must allow the Member States which practise this system to retain it.

Many of the amendments adopted by Parliament are designed to tighten up the obligations imposed on all wholesale distributors of medicinal products. The Commission feels that these obligations come under the guidelines on good distribution practices. The Commission has accepted Parliament's amendment calling for these guidelines to be published within two years of adoption of the Directive and the amendment requiring all wholesale distributors of medicinal products to give an undertaking to comply with them.

The Commission has not accepted the amendments stipulating that all wholesale distributors of medicinal products must have a pharmacist at their disposal. This requirement would have posed serious problems in at least half the Member States and cannot be justified on public health grounds.

Amendment to the proposal for a

COUNCIL DIRECTIVE

on the wholesale distribution SYN 229

of medicinal products for human use

(Presented by the Commission in accordance with Article 149 paragraph 3 of the EEC Treaty)

Original proposal	Amended proposal
Titel and visas unchanged	
First recital unchanged	
First recital a (new)	Whereas, according to Article 100a, the completion of the internal market must be based on the highest possible level of environmental, public health and consumer protection;
Second recital	
Whereas the wholesale distribution of medicinal products for human use is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products may cover simultaneously several Member States;	Whereas the wholesale distribution of medicinal products for human use is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products cover and will increasingly cover simultaneously several Member States;
Third recital unchanged	
Fourth recital	
Whereas any person involved in the wholesale distribution of medicinal products should be in possession of a special authorization; whereas pharmacists and persons authorized to supply medicinal products directly to the public, and who confine themselves to this activity, should be exempt from obtaining this authorization; whereas it is always necessary in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to deliver medicinal products to the public keep records showing entry transactions;	Whereas any person involved in the wholesale distribution of medicinal products should be in possession of a specific authorization; whereas the definition of distribution does not cover dividing up, packaging and presentation operations referred to in Article 16 of Directive 75/319 and in the amendments thereto or operations linked to direct supply to the public;

4

Original proposal	Amended proposal
Fourth recital a (new)	
	Whereas it is necessary to lay down uniform rules applicable throughout the Community with a view to establishing the conditions for obtaining authorization, arrangements in connection with transport, personnel and premises, and the procedures for the checks to be carried out by the Member States;
Fifth recital unchanged	
Article 1 paragraph 1 and 2 unchanged	
Article 1(2a)(new)	
	2a. For the purposes of this directive 'public service obligations' shall include the obligation for wholesalers to guarantee a constant range of medicinal products to meet the needs of a geographically determined territory and to ensure the supply at very short notice of the products requested throughout the territory in question.
Articles 2, 3 and 4 unchanged	

Original proposal	Amended proposal
Article 5 (a) and (b) unchanged	
Article 5 (c)	
(c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 6.	(c) they must undertake to comply with sound distribution practices and to establish that they have the requisite means at their disposal to apply them in practice.
Article 6 (a) unchanged	
Article 6 (b)	
(b) to obtain medicinal products only from persons who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2);	(b) to obtain medicinal products only from persons who hold an authorization as referred to in Article 16 et seq of Directive 75/319/EEC, or who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2);
Article 6 (c) unchanged	
Article 6 (d)	
(d) to have an emergency plan which allows participation in any action of withdrawal from the market ordered by the competent authorities or initiated by the manufacturer of the medicinal product concerned;	(d) to accept an emergency plan which allows participation in any action of withdrawal from the market ordered by the competent authorities of the Member State or initiated by the manufacturer/importer of the medicinal product concerned;
Article 6 (e), (f) and (g) unchanged	

Original proposal	Amended proposal
Article 7	
With regard to the supply of medicinal products to pharmacists and persons authorized to supply medicinal products to the public, Member States shall not impose upon the holder of an authorization referred to in Article 3 (1), which has been granted by another Member State, any obligation stricter than those they impose on persons which they have themselves authorized to carry out equivalent activities.	The public service obligations imposed by certain Member States on wholesalers established in their territories shall not be affected by this directive.
Articles 8 and 9 unchanged	
Article 10	
If appropriate, the Commission shall publish guidelines on good distribution practices. In that case the pharmaceutical committee instituted by Council Decision 75/320/EEC[1] shall be consulted.	Within a period of two years from the date of adoption of this directive, the Commission shall publish guidelines on good distribution practices. It shall update this publication annually. It shall consult for this purpose the pharmaceutical committee instituted by Council Decision 75/320/EEC.
Articles 11 and 12 unchanged	

Amendment to the proposal for a

COUNCIL DIRECTIVE

on the legal status for the supply

of medicinal products for human use

EXPLANATORY MEMORANDUM

At its plenary session on 12 June 1991 the European Parliament approved the Commission proposal concerning the legal status for the supply of medicinal products for human use (COM(89)607 final, SYN 230 of 26 January 1990).

Pursuant to Article 149(3) of the EEC Treaty, the Commission has decided to make 13 amendments to its proposal.

In its opinion, Parliament proposed a system for the classification of medicinal products very different to the system envisaged by the Commission. The Commission has decided to accept Parliament's suggestion and has therefore included all the amendments concerning the classification system. The title of the proposal for a Directive has also been amended, as requested by Parliament. As a result, the suggested amendments to Article 4 of the Commission's original proposal are no longer necessary since the classification criteria are now included in Article 3 of the amended proposal.

The Commission has also accepted Parliament's amendments allowing a time limit of five years from the date of adoption of the Directive to draw up a list of the medicinal products available without medical prescription and a list of products available on medical prescription only.

Amendment to the proposal for a

COUNCIL DIRECTIVE

SYN 230

on the legal status for supply

of medicinal products for human use

(Presented by the Commission in accordance with

Article 149 paragraph 3 of the EEC Treaty)

Original proposal	Amended proposal
Titel	
Proposal for a Council directive concerning the legal status for the supply of medicinal products for human use.	Proposal for a Council directive concerning the legal status for the supply of medicinal products for human use and their classification.
Visas and three first recitals unchanged	
Fourth recital	
Whereas, moreover, persons moving around within the Community have the right to carry a reasonable quantity of medicinal products legitimately obtained for their personal use; whereas it must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use; whereas it is important therefore to harmonize the conditions of delivery of medicinal products to the public;	Whereas, moreover, persons moving around within the Community have the right to carry a reasonable quantity of medicinal products legitimately obtained for their personal use; whereas it must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use;
Fifth and sixth recitals unchanged	

10

Original proposal	Amended proposal
Article 1	
1. This Directive concerns the legal status for the supply of medicinal products for human use in the Community.	1. This Directive concerns the legal status for the supply of medicinal products for human use and their classification in the Community as: - medicinal products subject to medical prescription, - medicinal products not subject to medical prescription.
2. For the purpose of this Council Directive, the definition of 'medicinal product' in Article 1 of Council Directive 65/65/EEC shall apply.	2. For the purpose of this Council Directive, the definition of 'medicinal product' set out in Article 1 of Council Directive 65/65/EEC shall apply. In addition, 'medical prescription' shall mean: any prescription emanating from a professional qualified to prescribe medicinal products.

M

Original proposal

Amended proposal

Article 2

1. When a marketing authorization is granted, the competent authority shall specify the classification of the medicinal product:
- medicinal product subject to medical prescription,
- medicinal product not subject to medical prescription.

To this end the criteria laid down in Article 3(1) shall apply.

2. The competent authorities shall specify the subcategories of medicinal products which can only be supplied on medical prescription. In this case they shall use the following classification:

(a) medicinal products available on renewable or non-renewable medical prescription.
(b) medicinal products subject to special medical prescription.
(c) medicinal products available on restricted medical prescription reserved for certain specialized areas.

Original proposal	Amended proposal
Article 3	
1. When a marketing authorization is granted, the competent authority shall specify the legal status for the supply of the medicinal product: — medicinal product not subject to medical prescription, — medicinal product subject to medical prescription, mentioning one of the categories referred to in Article 2. To this end, the criteria laid down in Article 4 shall apply.	1. Medicinal products hall be subject to medical prescription where: - they present a danger; directly or indirectly, even under normal conditions of use if taken without medical supervision or - they are used frequently and to a very large extent under the wrong conditions and this is likely to cause a direct or indirect danger to health or - they contain substances or preparations based on substances whose effects and/or side effects require more detailed research or - they are, with certain exceptions, administered parenterally or - they are administered parenterally or - they cause addiction and/or dependence.
2. All medical products containing a new chemical shall be subject to medical prescription, and classed in one of the categories referred to in Article 2.	2. Where Member States specify a subcategory of medicinal product subject to special medical prescription, account shall be taken of the following elements: - the presence in the medicinal product of a non-exempted dosage of a substance classified as a psychotropic or a narcotic substance within the meaning of the relevant international conventions (United Nations Conventions of 1961 and 1971) or - the possibility that the medicinal product could, if improperly used, give rise to major risks of medicinal abuse, cause addiction or be misused for illegal purposes, or

Original proposal	Amended proposal
	- the presence in the medicinal product of a substance which, because of its novelty or properties, could be included in that category as a precautionary measure.
	2a. In cases where Member States specify a subcategory of medicinal products subject to limited medical prescription, they shall take account of the following elements - medicinal products which, by reason of their pharmacological characteristics or their novelty or in the interest of public health, are reserved for use in treatments which can only be carried out in hospitals, - medicinal products employed in the treatment of illnesses which require diagnosis in a hospital or other institution with adecuate facilities for diacnosis, but where administration and follow-up can be carried out outside the hospital or in establishments equipped with adecuate diagnostic facilities. - medicinal products for use by out-patients which could produce severe adverse effects and which therefore call for supervised treatment.
3. The competent authority shall publish at least annually the list of medicinal products subject to medical prescription, specifying the category of classification.	3. The competent authority shall publish at least annually the list of medicinal products subject to medical prescription specifying the category of classification and circulate this list to the medical professionals in their territory.

Original proposal	Amended proposal
Article 4	
1. Medicinal products which contain substances which are likely to present a direct or indirect danger to human health, even under normal conditions of use, shall not be supplied to the public without medical prescription. The following criteria shall be taken into consideration in this respect:	The legal status of supply of a medicinal product shall be set out in the marketing authorization and included in the summary of the product characteristics.
(a) potential risks appearing during the preclinical and clinical tests and trials;	
(b) novelty of the active principle, as stated in Article 3, paragraph 2;	
(c) possibility of serious side effects in normal conditions of use;	
(d) serious risks associated with contra-indications and precautions for use;	
(e) indications requiring a medical diagnosis or special medical supervision;	
(f) harmfulness of constituents under normal conditions of use, taking into account posology, pack size or possible excessively extended treatment;	
(g) parenteral administration, except when very long term illness requires an active participation by the patient in the treatment (for example: diabetes);	
(h) important risk of abuse, addiction or misuse for criminal purposes,	
2. Moreover, medical products which may be available without prescription shall show a substantial safety in use in the treatment of minor ailments or symptoms, usually capable of rapid and spontaneous relief, which are easily identifiable by users and do not justify a medical consultation.	

Original proposal	Amended proposal
Article 5	
1. Within two years of adoption of this Directive, the Member States shall communicate to the Commission and to the other Member States, the list of medicines which are available only on medical prescription on their territory, mentioning the category of classification.	**1. Unchanged**
2. Each year Member States shall communicate to the Commission and to the other Member States the changes that have been made to the list referred to in paragraph 1.	2. Each year Member States shall communicate to the Commission and to the other Member States the list referred to in paragraph 1 and the changes that have been made thereto.
3. Within four years of adoption of this Directive, the Commission shall submit a report to the Council on the application of this Directive. This report will be accompanied, if necessary, by appropriate proposals.	3. Within five years of adoption of this Directive, the Commission shall draw up a list of the medicinal products in all Member States which are available only on medical prescription. The list shall apply to all Member States.
	4. Within five years of adoption of this Directive, the Commission shall draw up a list of the medicinal products in all the Member States which are available without medical prescription. This list shall apply to all the Member States.
Articles 6 and 7 unchanged	

Amendment to the proposal for a

COUNCIL DIRECTIVE

on the labelling of medicinal products for human use

and on package leaflets

EXPLANATORY MEMORANDUM

At its plenary session on 12 June 1991 the European Parliament approved the Commission proposal on the labelling of medicinal products for human use and on package leaflets (COM(89)607 final, SYN 231 of 26 January 1990).

Pursuant to Article 149(3) of the EEC Treaty, the Commission has decided to make 16 amendments to its proposal.

The Commission has accepted the two amendments clarifying the definitions of terms used in the proposal, the amendment stipulating that only the excipients that should be known about to ensure safe and effective use of the medicinal product need appear on the label and the amendment removing the obligation to indicate the name of the manufacturer, if other than the person responsible for placing the product on the market. It has not included the other amendments on labelling, since care must be taken to avoid putting too much on the label and making it impracticable for manufacturers or incomprehensible for consumers.

The Commission has included several of the amendments adopted by Parliament on small outer packaging.

As regards the package leaflet, the Commission has included the amendments made by Parliament to bring the text of the proposal into line with the rules on labelling plus two other major additions: details of the nature and expected effect of using the medicinal product and specification of the date on which the package leaflet was last revised.

Finally, two amendments to the general guidelines have also been accepted.

Amendment to the proposal for a

COUNCIL DIRECTIVE SYN 231

on the labelling of medicinal products for human use and on package leaflets

(Presented by the Commission in accordance with Article 149 paragraph 3 of the EEC Treaty)

Original proposal	Amended proposal
Titels and visas unchanged	
Recitals unchanged	
CHAPTER I Scope and definitions	
Article 1	
1. This Directive deals with the labelling of medicinal products for human use and leaflets inserted in packages of such products.	1. This Directive deals with the labelling of medicinal products for human use and leaflets inserted in packages of such products.
2. For the purposes of this Directive, the definition of 'medicinal product' laid down in Article 1 of Directive 65/65/EEC shall apply. In addition to this:	2. For the purposes of this Directive, the definition of 'medicinal product' laid down in Article 1 of Directive 65/65/EEC shall apply. In addition to this:
- "name of the medicinal product" shall mean the name given to a medicinal product, which may be an invented name or a common chemical name together with a trademark or the name of the manufacturer;	- "name of the medicinal product" shall mean the name given to a medicinal product, which may be an invented name or a common chemical name together with a trademark or the name of the manufacturer; in the case of an invented name, this shall not be confused with the common name;
— 'common name' shall mean the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name,	— 'common name' shall mean the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name,
— 'immediate packaging' shall mean the container or other form of packaging immediately in contact with the medicinal product;	— 'immediate packaging' shall mean the container or other form of packaging immediately in contact with the medicinal product;
— 'outer packaging' shall mean the packaging into which is placed the immediate packaging,	— 'outer packaging' shall mean the packaging into which is placed the immediate packaging;
— 'package leaflet' shall mean a leaflet containing information for the user which accompanies the medicinal product to which it refers.	— 'package leaflet' shall mean a leaflet containing information for the user which accompanies the medicinal product to which it refers.
	- "labelling" shall mean the particulars provided on the outer or immediate packaging;

Original proposal	Amended proposal
Article 2 unchanged	
CHAPTER II	
Labelling of medicinal products	
Article 3	
The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:	The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:
(a) the name of the medicinal product, including or followed by the common name if the product contains only one active ingredient;	(a) the name of the medicinal product, including or followed by the common name if the product contains only one active ingredient;
(b) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;	(b) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
(c) the pharmaceutical form and the contents by weight, by volume or number or doses of the product;	(c) the pharmaceutical form and the contents by weight, by volume or number or doses of the product;
d) a list of the excipients;	d) the excipients that should be known about to ensure an effective use of the medicinal product;
(e) the route and method of administration;	(e) the route and method of administration;
(f) a special warning that the product must be stored out of reach of children;	(f) a special warning that the product must be stored out of reach of children;
(g) the expiry date in clear terms (month/year);	(g) the expiry date in clear terms (month/year);
(h) special storage precautions, if any;	(h) special storage precautions, if any;
(i) special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;	(i) special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;
j) the name and address of the person responsible for placing the medicinal product on the market and, where different, of the manufacturer;	j) the name and address of the person responsible for placing the medicinal product on the market;
(k) the number of the authorization to put the medicinal product on the market;	(k) the number of the authorization to put the medicinal product on the market;
(l) the manufacturer's batch number.	(l) the manufacturer's batch number.

Original proposal	Amended proposal
Article 4	
1. The following particulars shall appear on immediate packagings placed in an outer packaging which complies with the requirements laid down in Article 3:	1. At least the following particulars shall appear on immediate packagings placed in an outer packaging which complies with the requirements laid down in Article 3:
— name of the medicinal product,	— name of the medicinal product,
— quantity of active constituents, using common names,	— quantity of active constituents, using common names,
— route and method of administration,	— route and method of administration,
— expiry date,	— expiry date,
— batch number.	— batch number.
2. Paragraph 1 shall not apply to immediate packagings containing a single dose which are too small to contain all the particulars listed in paragraph 1.	2. Immediate packagings which are too small to carry all the particulars listed in Article 3 shall carry at least the following particulars:
	- name of the medicinal product, - route and method of administration, - expiry date, - batch number, - contents by weight, by volume or by number of doses.
	3. Immediate packagings other than those referred in paragraphs 1 and 2 shall carry the particulars laid down in Article 3.

Original proposal	Amended proposal
Article 5 and 6 unchanged	
CHAPTER III	
User leaflet	
Article 7	
The inclusion in the packaging of medicinal products of a package leaflet for the information of users shall be obligatory unless all the information required by Article 8 is directly conveyed on the outer packaging or on the immediate packaging.	The inclusion in the packaging of medicinal products of a package leaflet for the information of users shall be obligatory unless all the information required by Article 8 is directly conveyed on the outer packaging or on the immediate packaging or unless the medicinal product may be administered only by a health professional.
Article 8	
1. The leaflet shall include, usually in the following order:	1. The leaflet shall be drawn up in accordance with the summary of product characteristics; it shall contain, usually in the following order:
a) for the identification of the medicinal product:	a) for the identification of the medicinal product:
- name of the medicinal product - quantitative and qualitative composition in terms of active ingredients, using the common names,	- name of the medicinal product in accordance with Article 3(a), - full quantitative and qualitative composition in terms of active ingredients and excipients, using the common names,
	- pharmaceutical form and contents by weight, by volume or by dosage units,
- pharmaco-therapeutic group, if there exists a term easily comprehensible for the patient,	- pharmaco-therapeutic group, or type of action, if there exists a term easily comprehensible for the patient, or, if not, an indication of this category in terms of a simple description of what it covers

Original proposal	Amended proposal
— name and address of the holder of the marketing authorization, and, where different, of the manufacturer;	— name and address of the holder of the marketing authorization, and, where different, of the manufacturer;
(b) the therapeutic indications;	(b) the therapeutic indications;
(c) a list of information which is useful before taking a medicinal product:	(c) a list of information which is useful before taking a medicinal product:
— contra-indications,	— contra-indications,
— appropriate precautions for use,	— appropriate precautions for use,
— interactions with other medicinal products and other forms of interaction (for example, alcohol, tobacco) which may affect the use of the medicine,	— interactions with other medicinal products and other forms of interaction (for example, alcohol, tobacco) which may affect the use of the medicine,
— special warnings,	— special warnings,
this list must:	this list must:
— take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions),	— take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions),
— mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,	— mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
— refer to the excipients knowledge of which is important for a safe and effective use of the medicinal product;	— refer to the excipients knowledge of which is important for a safe and effective use of the medicinal product;
d) the necessary instructions for proper use, in particular:	d) the necessary instructions for proper use, in particular:
- the usual dose and maximum dose,	- the usual dose, <u>together with wording indicating that this does not apply for different doses being prescribed, and, if possible,</u> the maximum dose <u>together with a warning that the dose and therapeutic procedure may be modified by the prescriber;</u>
- the method and route of administration,	- the method and route of administration,
- the frequency of administration, specifying if necessary the appropriate time at which the medicinal product should or must be administered;	- the frequency of administration, specifying if necessary the appropriate time at which the medicinal product should or must be administered;
and, as appropriate, depending on the nature of the product	and, as appropriate, depending on the nature of the product

Original proposal	Amended proposal
- the duration of treatment, when it should be limited,	- the duration of treatment, when it should be limited,
	- the nature and expected effect of using the medicinal product,
- the action to undertake in the case of overdose (symptoms, emergency procedures, antidotes),	- the action to undertake in the case of overdose (symptoms, emergency procedures and antidotes where they exist together with an express recommendation not to use them except under medical control),
- the course of action to take when a dose has not been taken,	- the course of action to take when a dose has not been taken,
- the way the treatment should be stopped, if stopping the treatment may lead to withdrawal effects;	- the way the treatment should be stopped, if stopping the treatment may lead to withdrawal effects;
e) a description of the undesirable effects which can occur under normal use of the medicinal product, with indication if possible of their importance, and if necessary the action to be taken in such case; if the medicine is new, the patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or to his pharmacist;	e) a description of the undesirable effects which can occur when the medicinal product is used, with indication if possible of their importance, and if necessary the action to be taken in such case; the patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or to his pharmacist;
(f) a reference to the expiry date indicated on the label, with: — a warning against using the product after this date, — where appropriate, special storage precautions, — if necessary a warning against visible signs of deterioration;	(f) a reference to the expiry date indicated on the label, with: — a warning against using the product after this date, — where appropriate, special storage precautions, — if necessary a warning against visible signs of deterioration;
(g) all other information compatible with the summary of product characteristics of the product, useful for health education, and on condition that it is not of a promotional nature.	(g) all other information compatible with the summary of product characteristics of the product, useful for health education, and on condition that it is not of a promotional nature.
	h) the date on which the package leaflet was last revised

Original proposal	Amended proposal
Article 9	
The package leaflet must be written in clear and understandable terms for the patient, in the official language or languages of the Member State where the medicinal product is put on the market. This provision does not prevent the leaflet being printed in several languages, provided that the same information is given in all the languages used.	The package leaflet must be written in such a way that it is clear, easily legible and understandable for the patient, in the official language or languages of the Member State where the medicinal product is put on the market. This provision does not prevent the leaflet being printed in several languages, provided that the same information is given in all the languages used.
Article 10 unchanged	
CHAPTER IV	
General and final provisions	
Articles 11 and 12 unchanged	
Article 13	
As necessary, the Commission shall publish guidelines concerning:	No later than two years after the adoption of this Directive, the Commission shall publish guidelines for the various leaflet sections, in particular concerning:
— the formulation of certain warnings for certain categories of medicinal products,	— the formulation of certain warnings for certain categories of medicinal products,
— the particular information needs relative to self-medication,	— the particular information needs relative to self-medication,
— the readability of particulars on the labelling and leaflet,	— the readability of particulars on the labelling and leaflet,
— utilization of bar codes for the identification of medicinal products.	— utilization of bar codes for the identification of medicinal products.
	- excipients that must be indicated on the packaging and warnings referring to them that must be carried on the packaging.
For this purpose, the Commission shall consult the Committee for Proprietary Medicinal Products instituted by Directive 75/319/EEC.	For this purpose, the Commission shall consult the Committee for Proprietary Medicinal Products instituted by Directive 75/319/EEC.
Articles 14, 15 and 16 unchanged	

Amendment to the proposal for a

COUNCIL DIRECTIVE

on advertising

of medicinal products for human use

EXPLANATORY MEMORANDUM

At its plenary session on 12 June 1991 the European Parliament approved the Commission proposal on advertising of medicinal products for human use (COM(90)212 final, SYN 273 of 6 June 1990).

Pursuant to Article 149(3) of the EEC Treaty, the Commission has decided to make 19 amendments to its proposal.

The Commission has accepted the amendments prohibiting advertising to the general public of medicinal products which are habit-forming and/or addictive, of performance-enhancing products or of medicinal products subject to reimbursement by the social security system. It has also accepted the amendments prohibiting the distribution of free gifts and bonuses and making it compulsory to include an express instruction to read the label and the package leaflet carefully. The other amendments on advertising to the general public have not been included: the Commission feels that there is no need for a Community Directive to lay down the smallest details on the advertising of medicinal products, where such advertising is allowed.

As regards advertising to health care professionals, the amended proposal includes the amendment omitting the exception for objects of an insignificant intrinsic value and incorporates the rules proposed by Parliament on the sponsorship of scientific congresses. However, the Commission could not accept the procedures advocated by Parliament to monitor this point. As regards the measures to control free samples, the Commission felt that it was inappropriate to replace the quantitative limit which it had proposed by a time limit.

Finally, the Commission has accepted none of the amendments on monitoring and penalties. Since the rules proposed have been harmonized with the existing Community legislation it saw no need to depart from them.

Amendment to the proposal for a

COUNCIL DIRECTIVE

on advertising

of medicinal products for human use

SYN 273

(Presented by the Commission in accordance with Article 149 paragraph 3 of the EEC Treaty)

Original proposal	Amended proposal
Titel and visas unchanged	
Three first recitals unchanged	
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 <u>may</u> affect public health, if it <u>does not satisfy</u> certain essential criteria which ought to be defined;
Fifth, sixth and seventh recitals unchanged	
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 <u>- or other -</u> inducements;

Original proposal	Amended proposal
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;
Tenth and eleventh recitals unchanged	
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;
CHAPTER I	
Scope, definitions and general principles	
Article 1 unchanged	
Article 2	
1. Any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law is prohibited.	1. Any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law is prohibited.
2. All parts of the advertising of a medicinal product must be compatible with the particulars listed in the summary of product characteristics.	2. All parts of the advertising of a medicinal product must conform to the particulars ... (rest unchanged)

Original proposal	Amended proposal
CHAPTER II	
Advertising to the general public	
Article 3	
1. Member States shall prohibit the advertising to the general public of:	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 which contain psychotropic or narcotic substances, within the meaning of the international conventions,
— other medicinal products which are only available on prescription, in accordance with Council Directive .../.../EEC.	— other medicinal products which are only available on prescription, in accordance with Council Directive .../.../EEC.
	— 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,
	— medicinal products which are reimbursed by the social security.
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:	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,	— tuberculosis,
— sexually transmitted diseases,	— sexually transmitted diseases,
— other serious infectious diseases,	— other serious infectious diseases,
— cancer,	— cancer,
— chronic insomnia,	— chronic insomnia,
— diabetes and other metabolic illnesses.	— diabetes and other metabolic illnesses.
3. The prohibition referred to in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.	3. The prohibition referred to in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.
4. The prohibition referred in paragraph 2 shall apply without prejudice to Articles 2, 3 and 14 of Directive 89/552/EEC.	4. The prohibition referred in paragraph 2 shall apply without prejudice to Articles 2, 3 and 14 of Directive 89/552/EEC.
5. Member States shall prohibit the free distribution of medicinal products to the public for promotional purposes.	5. Members States shall prohibit the free distribution of medicinal products to the public for promotional purposes, as well as the offering of gifts or bonuses.

Original proposal	Amended proposal
Article 4	
Without prejudice to Article 3, all advertising to the general public of a medicinal product shall:	Without prejudice to Article 3, all advertising to the general public of a medicinal product shall:
a) be set out in such a fashion that it is clear that the message is an advertisement, and that the product is clearly identified as a medicinal product,	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;
(b) include the following minimum information:	(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 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.	— the information necessary for correct usage of the medicinal product, such as indications for use and special precautions,
	- an express invitation to read the label and the package leaflet carefully.
Article 5	
The advertising of a medicinal product to the general public shall not contain any material which:	The advertising of a medicinal product to the general public shall not contain any material which:
(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
b) suggests erroneously that the effects of taking the medicine are guaranteed, or are better than another treatment;	b) suggests that the effects of taking the medicine are guaranteed, or are better than the effects of another treatment;
(c) suggests that the normal good health of the subject can be enhanced by taking the medicine, or that it could be affected by not taking the medicine;	(c) suggests that the normal good health of the subject can be enhanced by taking the medicine, or that it could be affected by not taking the medicine;
(d) is directed solely or mainly at children;	(d) is directed solely or mainly at children;
(e) refers to a recommendation by scientists or health professionals;	(e) refers to a recommendation by scientists or health professionals;
(f) suggests that the medicinal product is a foodstuff or a cosmetic, or *vice versa;*	(f) suggests that the medicinal product is a foodstuff or a cosmetic, or *vice versa;*
(g) suggests that the safety or efficacy of the medicinal product is due to the fact that it is 'natural'.	(g) suggests that the safety or efficacy of the medicinal product is due to the fact that it is 'natural'.

Original proposal	Amended proposal

CHAPTER III

Advertising to health professionals

Article 6

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:
— the particulars listed in the summary of product characteristics,	— the particulars listed in the summary of product characteristics,
— the legal prescription status of the medicinal product,	— the legal prescription status of the medicinal product,
— the retail price of the various presentations,	— the retail price of the various presentations,
— if appropriate, conditions of coverage by the social security systems.	— if appropriate, conditions of coverage by the social security systems.
2. The advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, if its sole object is to recall to the latter.	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.

Articles 7 and 8 unchanged

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.	1. 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)

Original proposal	Amended proposal
2. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1.	2. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1.
3. The prohibition referred to in paragraph ' applies without prejudice to the regulations of the Member States concerning prices, profit margins and discounts.	3. The prohibition referred to in paragraph ' applies without prejudice to the regulations of the Member States concerning prices, profit margins and discounts.
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.
Article 10	
Where medicinal products are being promoted to persons qualified to prescribe or supply them, free samples shall be provided to such persons only on the following conditions:	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:
(a) two samples at the most may be provided every year to any person qualified to prescribe or to supply medicinal products;	(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;	(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;	(c) the samples shall be identical to the smallest presentation on the market;
d) the samples shall be marked "free medical sample - not for resale" or with another legend of analogous meaning;	d) the samples shall be marked, clearly and indelibly, 'free medical sample - not for resale' or with another legend of analogous meaning;

Original proposal	Amended proposal
(e) the samples shall be accompanied by a copy of the summary of product characteristics;	(e) the samples shall be accompanied by a copy of the summary of product characteristics;
(f) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions may be supplied.	(f) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions may be supplied.

CHAPTER IV

Monitoring of advertising

Articles 11, 12, 13 and 14 unchanged

ISSN 0254-1475

COM(91) 245 final

DOCUMENTS

EN **05**

Catalogue number : CB-CO-91-324-EN-C

ISBN 92-77-74649-1

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