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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 the labelling of medicinal products for human use and on package leaflets
(COM(89) 607 final - C3-0050/90 - SYN 231)

Rapporteur: Mrs Adriana CECI

DOC_EN\RR\109304 PE 145.361/fin.
Or. FR

C O N T E N T S

By letter of 13 February 1990, the Council consulted the European Parliament, pursuant to Article 100a of the EEC Treaty, on the Commission proposal for a Council directive on the labelling of medicinal products for human use and on package leaflets.

At the sitting of 12 March 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 Budgets for their opinions.

At its meeting of 23 March 1990, the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Ceci rapporteur.

At its meetings of 30 October, 9 November and 18 December 1990 and 31 January and 2 May 1991, it considered the Commission proposal and draft report.

At the last meeting it adopted the draft legislative resolution unanimously.

The following took part in the vote: Collins, chairman; Schleicher, vice-chairman; Ceci, rapporteur; Alber, Bertens, Bowe, Chanterie, Douste-Blazy, Florenz, Guidolin, Jepsen (for Caroline Jackson), Lannoye (for Amendola), Maher (for Pereira), Monnier-Besombes, Muntingh, Partsch, Pollack, Pronk (for Banotti), Puerta, Randzio-Plath (for Avgerinos), Simmonds, Valverde Lopez, Veil, Vohrer and Wilson (for Bombard).

The opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Budgets are attached.

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

Commission text[1]	Amendments
	(Amendment No. 1) Fifth recital
whereas the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products be used correctly on the basis of complete and comprehensive information;	whereas the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products be used correctly on the basis of complete and comprehensive information, and whereas those provisions should be worded in such a way as to provide clear and intelligible information that can prevent medical products from being used incorrectly and identify possible contra-indications clearly;
	(Amendment No. 2) Fifth recital a (new)
	whereas the provisions should be available to users at all times in the language of their Member State; whereas a translation should be provided if the provisions have been drawn up in a language other than the customary language of the Member State concerned;

[1] For full text see COM(89) 607 final - OJ No. C 58, 8.3.1990, p.21

Commission text	Amendments
	(Amendment No. 3) Seventh recital a (new)
	whereas clear labelling and clear package leaflets do not dispense with the need to protect customers' health, given that responsibility for promoting correct use of medicines remains with the doctor and/or the pharmacist and the health services;
	(Amendment No. 4) Seventh recital b (new)
	whereas medicines available on prescription only and medicines available over the counter require different kinds of information to be provided insofar as there are differences in respect of their particulars, their methods of use and prescribed responsibilities;
	(Amendment No. 5) Seventh recital c (new)
	whereas the necessity to monitor medicinal products does not end in the experimental pre-clinical stage nor when the product is introduced onto the market, and whereas adequate monitoring of medicinal products under the responsibility of authorized persons provides the best guarantee for consumer protection;
	(Amendment No. 6) Seventh recital d (new)
	whereas industry has an obligation to cooperate in providing effective information and monitoring medicinal products, in particular by ensuring that undesired side-effects are made known as widely as possible;

Commission text	Amendments
	(Amendment No. 7) Article 1(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. Its aim is to provide consumers with clear, comprehensible and comprehensive information compiled in such a way as to prevent incorrect use of medicines.
	(Amendment No. 8) Article 1(2), first indent
- "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;
	(Amendment No. 9) Article 1(2), fifth indent a (new)
	- "labelling" shall mean the particulars provided on the outer or immediate packaging;
	(Amendment No. 10) Article 3(a)
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 international common name;
	(Amendment No. 11) Article 3(d)
d) a list of the excipients;	d) the excipients that should be known about to ensure an effective use of the medicinal product;

Commission text	Amendments
	(Amendment No. 12) Article 3(ed) (new)
	ed) special warnings including categories of users for whom the product is unsuitable and potential effects on ability to operate machinery;
	(Amendment No. 13) Article 3(f)
f) a special warning that the product must be stored out of reach of children;	f) a special warning, in a highly visible location provided for this purpose, that the product must be stored out of reach of children;
	(Amendment No. 14) Article 3(g)
g) the expiry date in clear terms (month/year);	g) the period for which extemporaneous preparations may be kept after being reconstituted, and an inset for notes on this by the user;
	(Amendment No. 15) Article 3(ga) (new)
	ga) the length of time and the temperature for storage after being reconstituted for medicinal products presented in multiple doses and prepared extemporaneously;
	(Amendment No. 16) Article 3(h)
h) special storage precautions, if any;	h) special storage precautions, if any, including the length of time the product may be kept after opening;

Commission text	Amendments
	(Amendment No. 17) Article 3(i)
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 <u>whose shelf life has expired</u> or waste materials derived from such products, if appropriate;
	(Amendment No. 18) Article 3(j)
j) the name and address of the person responsible for placing the medicinal product on the market <u>and, where different, of the manufacturer</u>;	j) the name and address of the person responsible for placing the medicinal product on the market;
	(Amendment No. 19) Article 3(1a) (new)
	1a) <u>advice, where appropriate, to 'read the enclosed leaflet'</u>;
	(Amendment No. 20) Article 3(1b) (new)
	1b) <u>the price of the medicinal product 'immediate packaging only'</u>;
	(Amendment No. 21) Article 3(1c) (new)
	1c) <u>the words 'on prescription only' in connection with medicinal products which may be supplied only on prescription from a medical practitioner</u>; <u>the words 'pharmacy only' in connection with medicinal products which may be supplied to the consumer in pharmacies only</u>; <u>the words 'sample - not for sale' in connection with medicinal products which may supplied as a complimentary sample to persons entitled to prescribe or supply the products concerned'</u>;

Commission text	Amendments
	(Amendment No. 22) Article 3(2) and (3) (new)
	2. The Commission shall appoint a European Community body established by Council Regulation (EEC) No. ..... to devise pictograms for inclusion on the outer packaging of medicinal products, in connection with: - psychotropes and narcotics, - any habit-forming and/or addictive medicinal product, - any illicit drug product included on the Council of Europe or International Olympic Committee list.
	3. The body referred to in paragraph 2 shall also be responsible for devising pictograms for inclusion on the outer packaging of medicinal products in connection with special user categories, in particular, children, pregnant or breast-feeding women, the elderly or persons with specific pathological conditions.
	(Amendment No. 23) Article 3a (new)
	3a) Where a medicinal product is available with a number of different doses of the active ingredient or ingredients, the packaging for the variants shall be clearly colour contrasted. The same graphic representations may be used, however.
	(Amendment No. 24) Article 4(1)
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:

Commission text	Amendments
	(Amendment No. 25) Article 4(1), second indent a (new)
	- in the case of products available without prescription, conditions for which the product is intended, and instructions for use;
	(Amendment No. 26) Article 4(1), third indent a (new)
	- special warnings including categories of users for whom the product is unsuitable and potential effects on ability to operate machinery;
	(Amendment No. 27) Article 4(1), third indent b (new)
	- the storage period and temperature for multiple dose extemporaneous medicinal products after they have been reconstituted,
	(Amendment No. 28) Article 4(2)
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.
	(Amendment No. 29) Article 4(2a) (new)
	2a. Immediate packagings other than those referred to in the following paragraphs shall carry the particulars laid down in Article 3.

Commission text	Amendments
	(Amendment No. 30) Article 5(1)
1. The particulars referred to in Articles 3 and 4 shall be easily visible, clearly comprehensible and indelible.	1. The particulars referred to in Articles 3 and 4 shall be easily visible, clearly comprehensible - through the use, if possible, of pictograms and colour coding - and indelible.
	(Amendment No. 31) Article 5(3)
3. The particulars listed in Article 3 shall appear in the official language or languages of the Member State where the product is to be put on the market. This provision shall not prevent these particulars from being indicated in various languages, provided the information given is the same in all languages used.	3. The particulars listed in Article 3 shall appear in the official language or languages of the Member State where the product is to be sold. This provision shall not prevent these particulars from being indicated in various languages, provided the information given is the same in all languages used.
	(Amendment No. 32) Article 6(2), third indent a (new)
	- special warnings for safe and effective use of the medicinal product.
	(Amendment No. 33) 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.

Commission text	Amendments
	(Amendment No. 34) Article 8(1)(a), first and second indents
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,
	(Amendment No. 35) Article 8(1)(a), second indent a (new)
	- pharmaceutical form and contents by weight, by volume or by dosage units,
	(Amendment No. 36) Article 8(1)(a), third indent
- 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
	(Amendment No. 37) Article 8(1)(a), fourth indent
- 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;
	(Amendment No. 38) Article 8(1)(b)
b) therapeutic indications;	b) the therapeutic indications and pharmacological characteristics;

Commission text	Amendments
	(Amendment No. 39) Article 8(1)(d)
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
- the duration of treatment, when it should be limited,	- the duration of treatment, when it should be limited,
	- <u>the nature and expected effect of using the medicinal product</u>,
- 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 <u>and antidotes where they exist together with an express recommendation not to use them except under medical control)</u>,
- 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;

Commission text	Amendments
	(Amendment No. 40) Article 8(1)(d) seventh indent a (new)
	- an emergency telephone number of a toxicology service;
	(Amendment No. 41) Article 8(1)(e)
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;
	(Amendment No. 42) Article 8(1)(e)(new)
	e) the necessary instructions in the event of a mistake in dosage. Clear reference must be made to the risk attaching to overdose or a sudden interruption in treatment especially, if acute withdrawal symptoms can be identified, by recommending an immediate visit to the doctor providing treatment or, if necessary, to the nearest health centre;
	(Amendment No. 43) Article 8(1)(f) third indent a (new)
	- information as to where, following treatment, the organization can collect the unused portion of the medicinal product, with a view to preventing it from dispersing into the environment;
	(Amendment No. 44) Article 8(1)(ga)(new)

Commission text	Amendments
	ga) the date on which the package leaflet was last revised;
(Amendment No. 45) Article 8(2)	
Notwithstanding point 1(b), the competent authorities may decide that certain therapeutic indications will not be mentioned in the package leaflet, when the dissemination of such information might have serious disadvantages for the patient.	Deleted
(Amendment No. 46) 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... (rest unchanged)
(Amendment No. 47) Article 10a (new)	
	Draft labelling and leaflets shall be drawn up under the authority of a medical practitioner and a pharmacist.
(Amendment No. 48) Article 11, before paragraph 1 (new)	
	Member States shall ensure that the marketing authorization authorities avail themselves of the assistance of representatives of the public when examining specimens or mock-ups of the outer packaging, the immediate packaging and the draft package leaflet.

Commission text	Amendments
	(Amendment No. 49) Article 11(1)
1. One or more specimens or mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the competent authorities of the Member State concerned.	1. One or more specimens or mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, compiled in accordance with the summary of product characteristics referred to in Article 4a of Directive 65/65/EEC, shall be submitted to the competent authorities of the Member State concerned.
	(Amendment No. 50) Article 12(1)
1. When the provisions of this directive are not observed, the competent authorities of a Member State may suspend or revoke the authorization to place the medicinal product on the market, until the labelling and leaflet of the medicinal product in question has complied with the requirements of this Directive.	1. When the provisions of this directive are not observed, the competent authorities of a Member State shall, by the deadline specified in that order, impose penalties of a sufficiently deterrent nature, which may even involve, in the most serious instances, suspension of the authorization to place the medicinal product on the market, this to remain in force until the labelling of and/or leaflet for the medicinal product complies with the provisions of this Directive. Member States shall incorporate into their body of law the infringements and penalties required for the application of this article.
	(Amendment No. 51) Article 13, introductory phrase
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:

Commission text	Amendments
	(Amendment No. 52) Article 13, fourth indent, (new)
	- excipients that must be indicated on the packaging and warnings referring to them that must be carried on the packaging.

DRAFT LEGISLATIVE RESOLUTION
(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission proposal for a Council directive on the labelling of medicinal products for human use and on package leaflets

The European Parliament,

- having regard to the Commission proposal to the Council (COM(89) 607 final - SYN 231)[1],

- having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-50/90),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Budgets (A3-0126/91),

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 EEC 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.

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[1] OJ No. C 58, 8.3.1990, p. 21

B

EXPLANATORY STATEMENT

Although the main aim of this directive is to rationalize and harmonize the labelling of medicinal products and on package leaflets, its main effect is to bring about a major innovation in the provision of information.

The traditional package leaflet is basically a rewording of the technical specifications and, as such, is designed for the attention of the doctor. The new leaflet, however, is intended to be of use for the consumer.

However, in its traditional form the leaflet has been shown to be inadequate. This is not the appropriate means for informing the doctor (who needs to be informed at the time of prescribing the medicine and not when the drug is obtained at the pharmacy), nor for the patient for whom 90% of the highly technical information contained in the leaflet is virtually meaningless.

This directive therefore acknowledges a real need for clarity of information and, if nothing else, should encourage good user habits among patients.

Despite the clear advantages of providing information for consumers which is 'clear, comprehensible and able to prevent incorrect use of medicines', it must be remembered that the new leaflet does not dispense with the need for the doctor and/or the pharmacist to provide information since the central role played by them in determining doses and the means for administering them cannot be discounted.

It is surprising that the transformation of the leaflet into an instrument for providing consumers with information has not been matched by measures to harmonize, qualify and control the regulations relating to the scientific information provided for the health services and, in particular, doctors.

Reference to these problems is actually contained in another directive under consideration (COM(90) 212 - SYN 273). This directive deals with the advertising of medicinal products which involves the provision of information for the health services since, as the Commission states, 'advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons' (sixth recital)[2].

This arrangement, and the operational proposals deriving therefrom, are, quite frankly, not tenable.

Publicity and information, insofar as they have totally different aims and objectives, should be clearly and explicitly differentiated and thus regulated separately starting with a clear recognition of their distinct aims.

On the other hand, the subject matter of the two directives under consideration should be viewed basically as a single topic that would be better defined as 'information for correct use of medicines'.

Examining the proposals referred to, it is clear that the one on advertising of medicinal products is general in nature, in other words aimed at the general public, through the traditional means of communication (press, radio,

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[2] OJ No. C 163, 4.7.1990, p. 163

television); the other proposal on labelling and package leaflets is also concerned with information, but is aimed at the user and is therefore concerned with all the information required by the consumer to ensure correct use of medicine.

In the specific case of products for self-medication, the similarity and overlap of information is even more obvious.

Indeed, the main aim of advertising is to draw attention to the fact that the product exists, while the information provided with the packaging (container and leaflets) enables the medicine to be taken with a full knowledge of all its particulars (warnings, precautions for use).

Even scientific information, aimed at the prescribing doctor and dealt with in the context of the directive on advertising, should be viewed as information aimed at promoting proper use.

This information is neither condensed, nor strictly commercial in nature. It must be drawn up in a rigorous scientific manner to ensure that medicinal products are prescribed responsibly and their results monitored.

The role played by the pharmacist in promoting rational use of medicines is just as important. However, in many or in all Community countries, pharmacists are currently facing a professional identity crisis.

This would appear to be due, on the one hand, to the growth of sales outside pharmacies and, on the other hand, to the prevailing view of the pharmacy as a commercial outlet rather than a health centre.

The rapporteur takes the view that it is in the interest of public health and consumers for the pharmacy to retain its health-oriented role, and as self-medication spreads, this role should take on greater significance in a technical and health context.

Finally, information relating to the proper use of medicines should take different forms depending on whether it is aimed at doctors, pharmacists or consumers and depending on whether the medicines are available only on prescription or are available over the counter.

The scope of the present directive concerns information to be provided for consumers on labels and package leaflets.

1. PRODUCTS AVAILABLE ONLY ON PRESCRIPTION

Medicinal products available only on prescription have extremely specific pharmacological properties and are used in well-defined medicinal forms under direct medical control.

1.1. Information for patients

1.1.1. Information for patients by means of the package leaflet

Only essential information should be given on package leaflets. It is therefore up to the doctor to explain the advantages and disadvantages of the medicine that he considers useful to the patient having regard to the psychological and physical characteristics of the person under his care. The doctor is therefore responsible for providing personalized information in the same way that other medical advice (dosage, method of administration, etc.) is indicated on an ad personam basis.

The package leaflet must therefore contain the following headings, in particular:

1.1.1.1. Brief general pharmaco-toxicological explanation. In a few lines the text must contain the chemical and pharmacological characteristics of the medicinal products, without mentioning other similar substances and without providing information liable to encourage the patient to effect self-treatment;

1.1.1.2. Therapeutic indications. The text should mention all the therapeutic indications as authorized by the registering bodies.
In any case, the particulars should refer solely to illnesses, without mention of any possible symptoms.

1.1.1.3. Secondary and collateral effects. Indication of secondary and collateral effects must be strictly limited to those situations: a) which appear frequently; b) which are serious enough to constitute a threat to the patient's life or affect the functioning of his organs and limbs.

1.1.1.4. Contra-indications. The explanation of contra-indications should be limited to those conditions whose epidemiological concomitant with the medical condition for which the medicine is taken can be easily identified.

1.1.1.5. Incompatibility. Particulars must be given of incompatibility with: a) specific foods using a correct, but simple terminology; b) Specific medicines, with particular reference to products that can be purchased over the counter.

1.1.1.6 Quantitative and qualitative composition. This composition must refer solely and only to the active ingredient. In the case of excipients or vehicles only the overall weight (in grams) or volume (in ml) should be indicated generically, without any individual analytical particulars.

1.1.1.7. Pharmaceutical forms, dosage and precautions for use. The particulars in this respect must be clear, but kept to what is absolutely essential so that, in the event of any variations in dosage, method of administration etc., the patient must consult the doctor.

1.1.1.8. Shelf life and storage precautions. This information is useful for the patient and should therefore be explained at length.

1.1.1.9. Other information. As is the case for all medical specialities, the package leaflet should contain:

- the registration number and the issuing authority;
- name and address of the holder of the marketing authorization;
- name and address of the manufacturer;
- date of manufacture and expiry date;
- an indication as to whether the medicine is listed on European (or national) drug tables;
- clear indication in red letters of the system for distributing the medicine to the public with the words 'available only on prescription'.

1.1.2. **Information to patients on the outer packaging and the internal container (bottle, blister pack, etc.).**

It is absolutely essential that this packaging carry information, but it should be such that it does not give rise to confusion about the contents.

1.1.2.1. Outer packaging. On the two largest sides of the outer packaging (or, at any rate, on two sides in the case of a four-sided container) the following particulars must appear:

- the invented name;
- the official name of the active ingredient;
- possibly, the weight of the active ingredient;
- the manufacturer's name;
- a statement in red letters that the medicine is available only on prescription and, possibly, a note to the effect that repeat prescriptions cannot be given.

On the other sides, the following particulars must appear:

- the registration holder;
- the manufacturer's address;
- date of manufacture and expiry date;
- a reminder to the consumer that further information can be found on the enclosed leaflet.

1.1.2.2. Internal container. The following particulars must appear on the internal container:

- the invented name;
- the official name of the active ingredient;
- possibly, the weight of the active ingredient;
- the manufacturer's name;
- statement in red letters that the drug is available on prescription only.

If the internal container is a blister pack, it must show clearly:

- the invented name;

- possibly, the weight of the active ingredient which must be legible regardless of the number of units used by the patient.

2. OVER THE COUNTER PRODUCTS

Certain types of pharmaceutical preparations that can be recommended or requested directly by the pharmacist or requested directly by the patient for self-medication do not require a prescription.

The preparations concerned are mainly antineuralgics, antiseptics, antipruritics, etc.

Contrary to common belief, OTC preparations cannot be used without special precautions. Although such preparations are traditionally free of major risks, they are nonetheless not completely harmless. In the final analysis, consumers should be informed of the risks entailed so that they can control their medication.

Consequently, the information supplied to the consumer should be particularly detailed.

2.1.1. Information for consumers on the package leaflet

The information provided on package leaflets should be kept simple so that consumers can understand it. Obviously, more detailed information can be provided by the doctor or pharmacist.

The package leaflet should therefore contain the following headings and information.

2.1.1.1. Brief general pharmaco-toxicological explanation. In a few lines the text must contain essential information on the chemical and pharmacological characteristics of the medicine, without mentioning other similar substances and without providing information liable to encourage the patient to effect self-treatment involving other medicines.

2.1.1.2. Therapeutic indications. The text should mention all the therapeutic indications as authorized by the registering bodies.
In any case, the particulars should refer solely to symptoms to be treated by the medicine and make no reference whatsoever to possible treatment of acute or chronic conditions.

2.1.1.3. Secondary and collateral. Indication of secondary and collateral effects must be strictly limited to those situations: a) which appear frequently; b) which are serious enough to constitute a threat to the patient's life or affect the functioning of his organs and limbs.

2.1.1.4. Contra-indications. The explanation of contra-indications should be limited to those symptoms whose epidemiological concomitant with the symptomatology for which the medicine is taken can be easily identified.

2.1.1.5. Incompatibility. Particulars must be given of incompatibility with: a) specific foods using a correct, but simple terminology; b) specific medicines, with particular reference to products that can be purchased over the counter;

2.1.1.6. Quantitative and qualitative composition. This composition must refer solely and only to the active ingredient. In the case of excipients or vehicles only the overall weight (in grams) or volume (in ml) should be indicated generically, without any individual analytical particulars.

2.1.1.7. Pharmaceutical forms, dosage and precautions for use. The particulars in this respect must be simple, clear and absolutely essential so that, in the event of any clarification being needed as regards dosage, method of administration etc., the patient must consult the pharmacist or doctor.

2.1.1.8. Shelf life and storage precautions. This information is useful for the patient and should therefore be explained at length.

2.1.1.9. Other information. As is the case for all medical specialities, the package leaflet should contain:

- the registration number and the issuing authority;
- name and address of the holder of the marketing authorization;
- name and address of the manufacturer;
- date of manufacture and expiry date.

In the light of the above, a centralized structure (Agency) should be established to guarantee the suitability of and control over information. The provision for publishing specific guidelines 'as necessary' for certain categories of drugs would appear totally inadequate.

This centralized structure should ensure the necessary measures relating to the monitoring of medicines underlining the need to move away from an ad hoc (as referred to in Article 8(c)) to a structured approach (as called for in the proposal for a directive).

GENERAL REMARKS

The directive puts forward valid measures for improving the use of medicines by consumers.
However, this is not the end of the story.
Consideration should also be given to:

(a) coordinating these measures with other measures already proposed by the Commission (advertising - Agency - legal regulations)
(b) the need to define certain aspects to which attention has already been drawn (scientific information - monitoring of medicines).

The proposed amendments aim to provide a firm basis for this linkage and strengthen the proposal's information/educational role. In this connection, attention should also be given to certain requirements and specific suggestions put forward by the parties concerned (consumers, industry, etc.).

O P I N I O N

(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 SISÓ CRUELLAS

At its meeting of 27 June 1990, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr Sisó Cruellas draftsman.

At its meetings of 26-28 June, 25 and 27 September and 15-16 October 1990, the committee considered the draft opinion. On 15 October, it adopted the conclusions by 20 votes with one abstention.

The following took part in the vote: Beumer, chairman; Fuchs, vice-chairman; Joaquín Sisó Cruellas, rapporteur; Cassidy, Cox, Ernst de la Graete, Herman, Lulling, Merz, Metten, Pinxten, Rogalla, Speciale, Amaral (for Donnea), Martinez (for Megret), Nielsen (for Visentini), Peter (for Ford), Randzio-Plath (for Hoff), Titley (for Seal), Van der Waal (For Lataillade) and Navarro (for Gallenzi), pursuant to Rule 111(2) of the Rules of Procedure.

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

1. Contents of the proposal

The aim of this proposal is to complete and lay down procedures governing labelling and leaflets already dealt with by previous directives[3].

(a) Labelling

Articles 3 to 6 deal in particular with:

- the particulars that must appear on the outer or immediate packaging (ingredients, name, etc.),
- the way in which this information must be presented (legibility, visibility, in one or more languages),
- additional information that a Member State may require (price, reimbursement conditions, etc.).

(b) User leaflet

In the same way, Articles 7 et seq. stipulate the contents of the obligatory leaflet (except in the case where all the information appears on packaging or the immediate packaging) and the method of presentation.

(c) General provisions

Finally, the proposal contains various provisions concerned with the procedure for monitoring labelling and package leaflets (marketing authorization and suspension of marketing authorization). If necessary (Article 13), the Commission will publish guidelines on these matters.

2. Assessment

This last directive completes the work already undertaken to harmonize, at European level, the contents of labels and leaflets. This step, which aims to ensure better information for patients in the Community, ought to be approved in principle. Detailed consultations concerning this proposal have taken place with industry, consumer organizations and representatives of doctors and pharmacists.

Nevertheless, a number of changes would appear necessary in order to reduce certain excessive burdens placed on industry. In particular, it would be advisable to:

- limit the mention of excipients solely to those excipients of which it is necessary to be aware to ensure safe and effective use of the medicine (Article 2),

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[3] Directive 65/65/EEC of 26 January 1965, OJ No. 22, 9.2.1965, p.369/65 and Directive 89/341/EEC, OJ No. L 142, 25.5.1989, p.11

- limit the list of information required for extremely small immediate packagings (Article 4(2)) without making reference to the dose, since the concept of a dose is too vague, and limit this information on blister packs to what is absolutely essential,

- not to mention, in the context of the additional information that Member States could require (Article 6(2)), reimbursement conditions by social security organizations which, because of their complexity, is clearly impracticable.

Furthermore, the invitation to the patient to communicate to his doctor or pharmacist the undesirable effects of a medicinal product should not be restricted to new medicines (Article 8(1)(e)). The concept of a medicine's newness varies from one country to another (depending on the date on which it was marketed) and, in general terms, the need for monitoring applies to all medicinal products. As far as pictograms are concerned (Article 8(3)), their use presupposes that they will be harmonized throughout the Community.

Finally, the sanctions laid down in Article 11(3) and Article 12 in the event of failure to comply with the provisions of the directive, namely a refusal to grant market authorization or the withdrawal or suspension thereof, seem too harsh. A failure to comply with the provisions governing leaflets and labelling may amount to no more than a minor oversight. It is therefore rather harsh to impose a heavy penalty such as the suspension or withdrawal of market authorization, which applies throughout the Community, especially when the infringement has occurred at national level.

In view of the number of pharmaceutical specialities and the complexity of the task, it would also appear that industry requires a transitional period for existing products. In this sense, the directive should be applied with immediate effect only to newly registered medicinal products.

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

(Amendment No. 12)
Article 1(2), first indent

- 'name of the medicinal product' shall mean the name given to a medicinal product, which may be an invented name, a common name together with a trademark or the name of the manufacturer, or a scientific 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, a common name together with a trademark or the name of the manufacturer, or a scientific 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;

(Amendment No. 13)
Article 3(a)(d)(e)(ga) (new), and (j)

(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; when several pharmaceutical specialities are designated by the same medicinal product name, they must be differentiated by placing next to the name the pharmaceutical form preceded by the dose per unit on condition that it contains only one active ingredient and there are distinct doses for each pharmaceutical form;
(d) a list of the excipients;	(d) the excipients that should be known about to ensure safe and effective use of the medicinal product;
(e) the route and method of administration;	(e) the route and method of administration;
	(ga) the length of time and temperature for storage after being reconstituted for medicinal products presented in multiple doses and prepared extemporaneously;

(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 and, where necessary, of the manufacturer;

(Amendment No. 14)
Article 4(2)(3) (new)

2. Paragraph 1 shall not apply to immediate packagings containing a single dose which are too small to carry all the particulars listed in paragraph 1.	2. Paragraph 1 shall not apply to immediate packagings which are too small to carry all the particulars listed in paragraph 1.
	3. In accordance with paragraph 1, blister packs shall bear only the name, concentration (where necessary), expiry date and batch number.

(Amendment No. 15)
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.

(Amendment No. 16)
Article 8(1)(a), fourth indent

- 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 necessary, of the manufacturer;

(Amendment No. 17)
Article 8(1)(d), fifth indent

- 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 <u>where they exist together with an express recommendation not to use them except under medical control</u>),

(Amendment No. 18)
Article 8(1)(e)

(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 a case; <u>when the medicinal product is new</u>, 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 under normal use of the medicinal product, with indication if possible of their importance, and if necessary the action to be taken in such a 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;

(Amendment No. 19)
Article 13, fifth indent (new)

	- <u>the list of excipients to appear on the label</u>

CONCLUSIONS

1. The aim of the three proposals for directives under consideration is the large-scale rationalization of the trade in medicinal products for human use in order to facilitate circulation of these products under conditions that provide maximum safety for the patient.

   In this sense, they comply with the objective of creating a single market in this sector which has so far been relatively closed.

- Labelling and package leaflets

  In order to ensure that patients are given the best information possible and that this information has universal application, the contents of labels and leaflets in respect of medicinal products must be harmonized. This proposal for a directive meets this essential requirement.

  However, this concern over information and safety should not result in placing on the manufacturer a requirement to provide an excessive amount of useless information (e.g. concerning excipients) and must be tailored to the type of packaging involved (e.g. extremely small packagings).

  Subject to the above proposed amendments - which the Committee on the Environment, Public Health and Consumer Protection is requested to take into account - whose basic aim is to ensure that the European pharmaceutical industry, which must remain competitive, is not handicapped by excessive obligations, these three proposals for directives should be approved.

OPINION

of the Committee on Budgets on the
proposals for a Council directives on the rational use of
medicinal products
(COM(89) 607 final - C3-50/90)

Dear Mr Chairman,

At its meeting of 1 June 1990, the Committee on Budgets considered the above-mentioned proposal.

After considering the nature and the financial impact of this proposal, the committee decided to deliver a favourable opinion.

Yours faithfully,

(sgd) Thomas von der VRING

Present: von der Vring, Chairman; Arias Cañete, Böge, Colajanni, Colom I Naval, Elles, Kellett-Bowman, Langes, Lo Giudice, McCartin (for Forte), Miranda da Silva, Pasty, Theato, Tomlinson and Wynn.