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**I

R E P O R T

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

on the Commission proposal for a Council directive
concerning the legal status for the supply of medicinal
products for human use

(COM(89) 0607 final - C3-0049/90 - SYN 230)

Rapporteur: Mrs Adriana CECI

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*

= Consultation procedure requiring a single reading

**II

= Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment

**I

= Cooperation procedure (first reading)

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

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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 concerning the legal status of the supply of medicinal products for human use.

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 9 November 1990, 18 December 1990, 31 January 1991 and 25 April 1991 it considered the Commission proposal and draft report.

At the last meeting it adopted the draft legislative resolution by 20 votes to nil with 2 abstentions.

The following took part in the vote: Collins, chairman; Schleicher and Iversen, vice-chairmen; Ceci, rapporteur; Alber, Banotti, Bombard, Bowe, Chanterie, Di Rupo, Florenz, Guidolin, Hadjigeorgiou (for Douste-Blazy), Caroline Jackson, Kuhn, Muscardini, Pimenta, Pollack, Roth-Behrendt, Schwartzberg, Valverde Lopez, Vertemati.

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 30 April 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 concerning the legal status
for the supply of medicinal products for human use

Commission text¹

Amendments

(Amendment No. 1)

Title

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.

(Amendment No. 2)

Second recital a, b and c (new)

Whereas Chapter III of Part 3 of the Annex to Directive 75/318/EEC lays down the special conditions for the supply of medicinal products where advisable in the light of test results;

Whereas the supply of medicinal products is a professional activity which guarantees the protection of the health of consumers and includes the provision of adequate information on the proper use of the medication;

Whereas the conditions for supply of medicinal products must be based on objective criteria established by evaluation of the products under normal conditions of use.

¹For full text see OJ No. C 58, 8.3.1990, p. 19

(Amendment No. 3)
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;

(Amendment No. 4)
Sixth recital

Whereas it is therefore appropriate, in a first stage, to harmonize the basic principles applicable to the legal status for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonization completed within the framework of the United Nations, concerning narcotics and psychotropics,

Whereas, in order to harmonize the legal status for the supply of medicinal products, it is necessary for the Community to define the categories of medicines for which a prescription is compulsory and those which may be sold over the counter; whereas this definition shall take account of the principles already established on this subject by the Council of Europe as well as the work of the United Nations concerning narcotic and psychotropic substances;

(Amendment No. 5)
Sixth recital a (new)

Whereas, in order to guarantee consumer safety and the liability of undertakings, no medicine may be supplied other than by pharmacies or other establishments expressly authorized to do so on the grounds that they provide specific guarantees of safety (as regards storage and hygiene conditions and staff qualified to dispense to the public);

Commission text

Amendments

(Amendment No. 6)

Article 1(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.

(Amendment No. 7)

Article 1(2)

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,

- 'legal status for supply' shall mean: the conditions under which a medicinal product may be supplied to the public by a professional who is qualified under the terms of Directive 85/432/EEC and 85/433/EEC;
- 'medical prescription' shall mean: any prescription emanating from a professional qualified to prescribe medicinal products.

(Amendment No. 8)

Article 1a(new)

1a. A prescription duly issued in one Member State in accordance with its legislation may be presented in any other Member State, except where expressly prohibited in respect of a specific medicinal product.

Commission text

Amendments

2. In order to ensure the general effectiveness of the prescription, avoid errors in prescription and supply and ensure the proper use of the medicinal product, the prescription shall consist of two parts:

- the prescription itself, intended for the pharmacist, which must contain, except for justified reasons, the diagnosis or diagnostic information and basic information concerning the patient's general state of health which might give rise to side effects or contra-indications;
- the set of instructions for the patient consisting of two sections: one to be filled out by the prescribing doctor, including indications relevant to the treatment, and the other to be filled out by the pharmacist, giving the necessary instructions for the proper use and administration of the medicinal product in each case.

(Amendment No. 9)
Article 2

Medicinal products which may only be available on medical prescription, shall be classified at the time of granting the authorization for marketing, in one of the following categories:

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.

(a) medicinal products on prescription, which may be renewed during a period of six months from the date of the prescription, unless otherwise specified;

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

Commission text

Amendments

- (b) medicinal products on prescription, which may not be renewed without the prescriber's express consent;
- (c) medicinal products on special prescription, containing a substance classified as a psychotropic or a narcotic substance within the meaning of the international conventions in force (conventions of the United Nations of 1961 and 1971);
- (d) medicinal products on limited prescription, reserved:
- for use in hospitals,
 - to certain specialists.
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.
3. The medical prescription shall not in itself be considered to be a valid certificate for the purpose of reimbursement by national health services. In any case, national provisions and those operating within the framework of existing Community cooperation agreements (E111) regarding payments and reimbursements in respect of medicinal products, will continue to apply.

Commission text

Amendments

(Amendment No. 10).
Article 3(1)

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 shall 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 administered parenterally or
- they cause addiction and/or dependence.

Commission text

Amendments

(Amendment No. 11)
Article 3(2)

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
- 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.

Commission text

Amendments

(Amendment No. 12)
Article 3(2a)(new)

- 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 adequate facilities for diagnosis, but where administration and follow-up can be carried out outside the hospital or in establishments equipped with adequate diagnostic facilities.
 - medicinal products for use by out-patients which could produce severe adverse effects and which therefore call for supervised treatment.

(Amendment No. 13)
Article 3(3)

3. The competent authority shall publish at least annually the list of medicinal products subject to medical prescription, specifying the category of classification.

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.

Commission text

Amendments

(Amendment No. 14)

Article 3a(new)

3a. Medicinal products not subject to prescription shall be those which do not correspond to the criteria listed in Article 3.

(Amendment No. 15)

Article 4, new paragraph before paragraph 1

The legislation concerning the supply of a medicinal product and its classification shall be set out in the authorization certificate and included with the list of properties of the medicinal product.

(Amendment No. 16)

Article 4(1)

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:

1. Medicinal products which contain substances which are likely to present a serious 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.

(Amendment No. 17)

Article 4(1)(c)

(c) possibility of serious side effects in normal conditions of use;

(c) the possibility and frequency of serious side effects in normal conditions of use;

Commission text

Amendments

(Amendment No. 18)

Article 4(1)(d)

(d) serious risks associated with contra-indications and precautions for use;

(d) serious risks associated with contra-indications and precautions in normal conditions of use, if it is impossible to specify clearly the groups at risk;

(Amendment No. 19)

Article 4(1)(e)

(e) indications requiring a medical diagnosis or special medical supervision;

(e) indications requiring special medical supervision;

(Amendment No. 20)

Article 4(1)(f)

(f) harmfulness of constituents under normal conditions of use, taking into account posology, pack size or possible excessively extended treatment;

(f) harmfulness of constituents under normal conditions of use, taking into account possible limitations in respect of posology, pack size, instructions for use and means of administration;

(Amendment No. 21)

Article 4(1)(g)

(g) parenteral administration, except when very long term illness requires an active participation by the patient in the treatment (for example diabetes);

Deleted

Commission text

Amendments

(Amendment No. 22)
Article 5(1)

1. Within two years of the 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. Within two years of the adoption of this Directive, the competent authorities of the Member States shall publish the list of medicinal products which are available only on medical prescription in their territory, mentioning the category of classification. They shall publish this list annually.

(Amendment No. 23)
Article 5(2)

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.

(Amendment No. 24)
Article 5(3)

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.

(Amendment No. 25)
Article 5(3a)(new)

3a. 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.

Commission text

Amendments

(Amendment No. 26)
Article 5a(new)

5a. No provision of this Directive may result in the monopoly of the distribution of medicinal products to the public granted to pharmacists in certain Member States being challenged.

(Amendment No. 27)
Article 56 (new)

5b. The provisions of this Directive shall have neither the objective nor effect of challenging the rules established by each Member State on the refunding by the social security authorities of the cost of medicinal products.

A

DRAFT LEGISLATIVE RESOLUTION
(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission proposal for a Council directive concerning the legal status for the supply of medicinal products for human use

The European Parliament,

- having regard to the Commission proposal to the Council (COM(89) 0607 final - SYN 230)¹,
 - having been consulted by the Council pursuant to Article 100a of the EEC Treaty (C3-0049/90),
 - 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 (A3-0H114/91),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. 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;
 3. Instructs its President to forward this opinion to the Council and Commission.

¹ OJ No. C 58, 8.3.1990, p. 19

EXPLANATORY STATEMENT

This Directive proposes to harmonize conditions of distribution to patients which at present appear to vary considerably.

The main differences between the Member States lie in:

- (a) the regulations governing the supply of medicinal products to the public on medical prescription,
- (b) the differing provisions on whether medicinal products may be dispensed to the public in pharmacies only or whether they are also available from other establishments including supermarkets.

The reasons for the diversification of the drugs market as outlined above can be attributed only in part to actual medical considerations such as allowing consumers to have more control and greater responsibility and enabling them to obtain rapidly tried and tested drugs with which they are familiar.

Other reasons are attributable to:

- (a) the provisions of the health and social security systems which tend only to reimburse (or supply directly) medicinal products prescribed by medical officers,
- (b) the diversification of industrial production which identifies over the counter drugs as a more dynamic market sector which is less subject to protectionism and more in line with the laws of free competition (advertising, which is usually prohibited in the case of prescription-only medicines, is permitted in respect of over the counter medicines).

The rapporteur considers that a fundamental choice must be made when attempting to rationalize the conditions for administering drugs, namely, that consumer safety must be made paramount, in accordance with Article 100a of the EEC Treaty. In practice, this means fulfilling certain specific criteria, namely:

1. Confirming the ethical nature of pharmacological treatment; this means that the responsibility of the prescribing medical officer, which is a feature of sales of medicinal products compared with other categories of products, must be fully recognized.
2. Ensuring that none of the safety and quality requirements governing the supply of medicinal products is jeopardized at any stage of the distribution chain (for example, through the sale of products in establishments other than pharmacies which are not subject to supervision by qualified staff and which do not provide adequate guarantees as regards storage conditions and hygiene).
3. Ensuring that 'safe' medicinal products are widely available to all Community citizens, by recognizing everywhere the legal value of a medical prescription.

4. Preserving traditional therapeutic practices which have become firmly established in response to specific social and cultural conditions, provided that they do not run counter to the primary objective of safety;
5. Combating abuses relating to over-prescription and self-administration, by laying down special provisions in those sectors in which such abuses are most widespread or most dangerous.

These considerations form the basis of the proposed amendments, and are aimed at ensuring that the supply of medicinal products from pharmacies on presentation of a medical prescription recognized as having a period of validity of 6 months and having legal value throughout the Member States is the standard method of supply to the public.

It is the duty of the medical worker who prescribes the medicinal product to decide (on the basis not only of the type of medicine but also of the pathology and clinical symptoms of the individual patient) whether or not the prescription should be repeated and, if so, how many times within the given period.

It is the duty of the pharmacist to ensure compliance with the prescription and to combat abuses.

This system does not apply to over the counter medicines. In defining such medicines, it appears inadvisable to depart as the Commission does in its proposal from universally-recognized criteria - such as a well-established market and use limited to the treatment of easily recognizable symptoms capable of rapid relief. In particular, it seems inadvisable to introduce a third category of drugs (a 'grey area') which does not correspond to over the counter products but which is defined as a category of medicinal products which can also be obtained without a medical prescription.

This third category cannot be justified on either scientific grounds or on the grounds of consumer safety.

It is indeed necessary to guard against the emergence of a heterogeneous group of medicaments which are dispensed in various Member States without a medical prescription. These, we repeat, have no medical or scientific justification and simply cater to the requirement of cheaper medicines which is now widespread in all the Member States as a result of the uncontrolled expansion of the pharmaceuticals market.

The legal status for the supply of medicinal products and the conditions for reimbursement to the public must therefore remain absolutely separate issues, particularly in the spirit and letter of the Directive in question.

The rapporteur recognizes that the proposed amendments differ substantially in some respects from the Commission proposal.

However, they offer certain advantages:

- Member States are not required to agree on a list, however minimal, of medicinal products obtainable only on a medical prescription based on criteria on which no general agreement has yet been reached;

- no unacceptable changes are made in respect of current prescription practice, while long-established regulations governing particular categories of medicines are maintained;
- mention is made of the future system of registering medicinal products in accordance with the requirement of technical and scientific assessment;
- the marketing of medicinal products is made transparent but not static; it does not penalize the industry's activities but at the same time it ensures total respect for consumer safety.

It is therefore suggested that this important directive be approved, subject to the proposed amendments.

OPINION

(Rule 120 of the Rules of Procedure)

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

Draftsman: Mr SISO CRUELLAS

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

At its meetings of 26-28 June, 25 and 27 September and 15-16 October 1990, the committee considered the draft opinion. It adopted its conclusions by 20 votes to none, with one abstention.

The following took part in the vote: Beumer, chairman; Fuchs, vice-chairman; Siso Cruellas, draftsman; Cassidy, Cox, Ernst de la Graete, Herman, Lulling, Merz, Metten, Pinxten, Rogalla, Speciale, Amaral (for de 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).

I. Proposal for a directive concerning the legal status for the supply of medicinal products for human use

1. Contents of the proposal

(a) The present situation

The conditions of supply of medicinal products for human use vary considerably between Member States. Certain medicinal products which are freely on sale in some Member States can only be obtained on prescription in others.

However, persons circulating in the Community have the right to carry a reasonable quantity of medicinal products for their personal use. It is also permitted to import by post a reasonable quantity of medicinal products for personal use². To facilitate the exercise of these rights while preventing their abuse, it is therefore desirable to harmonize the criteria for the classification of medicinal products.

(b) The proposed measures

The directive therefore lays down the criteria applicable to the legal status for the supply of medicinal products in the Community or the Member State concerned. It also categorizes medicinal products on the basis of type of prescription (Article 2), specifies the arrangements for publication and revision of the lists of medicinal products subject to prescription (Article 3) and the conditions of supply of medicinal products without prescription (Article 4). These criteria are based on principles which have already been established in this area by the Council of Europe and the UN.

2. Comments

In view of its subject-matter, this directive has a number of aspects. It will certainly make it easier for the Community citizen to use the medicinal products that he needs wherever he happens to be in the Community. In this context, the directive should clarify the arrangements and conditions of sale of medicinal products which are not subject to prescription. It also deals with the regulation of the advertising of pharmaceuticals, which will be the subject of a forthcoming Commission proposal.

It would, however, be exaggerated to suppose that this proposal will lead to rapid harmonization of the different statuses for the supply of medicinal products, since these reflect the different medical cultures and traditions rooted in the societies of the Member States.

This directive, however, represents a first step towards a more harmonious conception of medicinal products in professional circles.

² European Court reports: Schumacher case, 215/87, 7 March 1989

It requires, nonetheless, a number of modifications or further specifications, with regard, in particular to the list of categories of prescription (Article 2) and to the arrangements for the revision of the list of medicinal products subject to prescription (under which insufficient protection is granted to manufacturers' rights) (Article 3; no provision is made for justification of decisions of the authorities or for appeal procedures). In addition, the criteria for the supply of medicinal products should be determined on the basis of the different categories of prescription (Article 4).

DRAFT AMENDMENTS

Proposal for a directive concerning the legal status for the supply of medicinal products for human use

Amendment No. 8
Article 2 (former Article 3) to read:

- | | |
|--|---|
| 1. When a marketing authorization is granted, the competent authority shall specify the legal status for the supply of the medicinal product: | 1.Unchanged except for second indent: |
| - medicinal product not subject to medical prescription, | |
| - medicinal product subject to medical prescription, mentioning one of the categories referred to in Article 2. | - medicinal product subject to medical prescription, mentioning one of the categories referred to in Article 3. |
| <p>To this end, the criteria laid down in Article 4 shall apply.</p> | |
| 2. All medical products containing a new chemical entity shall be subject to medical prescription, and classed in one of the categories referred to in Article 2. | 2.All medical products containing a new chemical <u>or biological</u> entity shall be subject to medical prescription, and classed in one of the categories referred to in Article 3. |
| 3. The competent authority shall publish at least annually the list of medicinal products subject to medical prescription specifying the category of classification. | 3.Unchanged. |

4. On the occasion of the 5-yearly renewal of the marketing authorization or when new scientific elements are communicated to them, the competent authorities shall examine and, as appropriate, may amend the legal status for the supply of a medicinal product, by applying the criteria listed in Article 4.

4. Unchanged

5. (new)

Where the specification or alteration of the legal status for the supply of a medicinal product takes place independently of the marketing authorization or its five-yearly renewal, the competent authorities in the Member States shall decide on the basis of Article 3 and the present article and shall publish the decisions. Appeal procedures in respect of these decisions shall be established and brought to the notice of the holders of marketing authorizations.

Amendment No. 9

Article 3 (former Article 2) to read:

Medicinal products which may only be available on medical prescription shall be classified, at the time of granting the authorization for marketing, in one of the following categories:

Unchanged.

- (a) medicinal products on prescription, which may be renewed during a period of six months from the date of the prescription, unless otherwise specified;
- (b) medicinal products on prescription, which may not be renewed without the prescriber's express consent;

- (a) medicinal products on prescription, which may be renewed during a period of three months from the date of the prescription, unless otherwise specified;
- (b) Unchanged.

(c) medicinal products on special prescription, containing a substance classified as a psychotropic or a narcotic substance within the meaning of the international conventions in force (conventions of the United Nations of 1961 and 1971);

(d) medicinal products on restricted prescription, reserved
- for use in hospitals,
- to certain specialists.

(c) medicinal products containing non-exempted dosages of a substance classified as a psychotropic or a narcotic substance within the meaning of the international conventions in force (conventions of the United Nations of 1961 and 1971);

(d) medicinal products on restricted prescription, reserved
- for use in hospitals,
- for diagnosis in hospitals,
- for prescription by specialists.

Amendment No. 10
Article 4(1)

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:

1. Unchanged.

1.1. Criteria determining whether a medicinal product shall be supplied only on prescription:

- | | |
|--|---|
| (a) potential risks appearing during the preclinical and clinical tests and trials; | (a) Unchanged |
| (b) novelty of the active principle, as stated in Article 3, paragraph 2; | (b) novelty of the active principle, as stated in Article <u>2</u> , paragraph 2; |
| (c) possibility of serious side effects in normal conditions of use; | (c) Unchanged. |
| (d) serious risks associated with contra-indications and precautions for use; | (d) Unchanged. |
| (e) indications requiring a medical diagnosis or special medical supervision; | (e) Unchanged. |
| (f) harmfulness of constituents under normal conditions of use, taking into account posology, pack size or possible excessively extended treatment; | (f) Unchanged. |
| (g) parenteral administration, except when very long term illness requires an active participation by the patient in the treatment (for example diabetes); | (g) Unchanged. |

1.2. Criteria determining whether a medicinal product shall be supplied only on prescription within the terms of Article 3(a):

(h) treatment of chronic disorders where administration does not require the prescriber's supervision during the period of validity of the prescription, which shall be longer than the period corresponding to the contents of one pack.

1.3. Criteria determining whether a medicinal product shall be supplied only on prescription within the terms of Article 3(c):

(h) important risk of abuse, addiction or misuse for criminal purposes

(i) important risk of abuse, addiction or misuse for criminal purposes because the product contains substances classified as psychotropic or narcotic substances or substances which, in view of their novelty or properties, could be included in that category as a precautionary measure.

1.4. Criteria determining whether a medicinal product shall be supplied only on prescription within the terms of Article 3(d):

(j) Use in hospitals:

Medicinal products which, by reason of their pharmacological characteristics or their novelty, or in the interests of public health, are reserved for use in treatments which can only be carried out in hospitals;

(k) Diagnosis in hospitals:

Medicinal products employed in the treatment of illnesses which require diagnosis in a hospital or other institution with adequate facilities for diagnosis, even where the administration and follow-up can be carried out on an out-patient basis;

(l) Prescription by specialists:

Medicinal products for use by out-patients which could produce severe adverse effects, and which therefore call for supervised treatment.

1.5 Criteria determining whether a medicinal product shall be supplied only on prescription within the terms of Article 2(b):

(m) where the provisions of subparagraphs (k) and (l) above do not apply for the medicinal product to be supplied on prescription in accordance with paragraph 1.1 of the present article.

Amendment No. 11
Article 4(2)

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.

2. (first word deleted) 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.

CONCLUSION

The three proposals for directives are aimed at rationalizing the distribution of medicinal products for human use in order to facilitate their circulation in conditions offering the highest possible security to the patient.

They are consequently in line with the objective of creating a large unified market in a sector which has hitherto been relatively compartmentalized.

- Proposal concerning the legal status for the supply of medicinal products for human use

The conditions of supply of medicinal products for human use vary considerably between Member States, according to whether or not the products concerned are subject to prescription. This situation is an obstacle to the harmonization of the use of medicinal products in the Community. It is therefore to be welcomed that the directive lays down, in particular the criteria applicable to the legal status for the supply of medicinal products for human use (categories of medicinal product according to type of prescription; arrangements for the publication and revision of lists of medicinal products).

However, some of the provisions seem to be unnecessarily complicated (as in the case of the prescription categories). In addition, there is insufficient protection of manufacturers' rights in the event of revision of the list; provision should be introduced for the justification of decisions and for appeal procedures.

O P I N I O N

of the Committee on Budgets

Letter from the Chairman of the committee to the Chairman of the Committee on the Environment, Public Health and Consumer Protection

Subject: Proposal for a Council directive concerning the legal status for the supply of medicinal products for human use
(COM(89) 607 final)

Dear Mr Chairman,

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

After considering the nature of the proposal and its financial consequences, the Committee on Budgets decided to deliver a favourable opinion thereon.

Yours faithfully,

(sgd) Thomas von der VRING

The following were present for the vote: von der Vring, chairman; Arias Cañete, Böge, Colajanni, Colom I Naval, Elles, Kellet-Bowman, Langes, Lo Giudice, McCartin (for Forte), Miranda da Silva, Pasty, Theato, Tomlinson and Wynn.

