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Contents

I *Acts whose publication is obligatory*

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II *Acts whose publication is not obligatory*

Council

- ★ Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use 1
- ★ Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use 5
- ★ Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets 8
- ★ Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use 13
- ★ Council Directive 92/29/EEC of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels 19

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/25/EEC

of 31 March 1992

on the wholesale distribution of medicinal products for human use

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

in cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the wholesale distribution of medicinal products is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products for human use may cover several Member States simultaneously;

Whereas it is necessary to exercise control over the entire chain of distribution of medicinal products, from their

manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions; whereas the requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products;

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 however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to supply medicinal products to the public keep records showing transactions in products received;

Whereas authorization must be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State must recognize authorizations granted by other Member States;

Whereas certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorized to supply medicinal products to the public certain public service obligations; whereas those Member States must be able to continue to impose those obligations on wholesalers established within their territory; whereas they must also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those which they impose on their own wholesalers and provided that such obligations may be regarded as

⁽¹⁾ OJ No C 58, 8. 3. 1990, p. 16 and
OJ No C 207, 8. 8. 1991, p. 11.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 139,
and OJ No C 67, 16. 3. 1992.

⁽³⁾ OJ No C 269, 14. 10. 1991, p. 84.

warranted on grounds of public health protection and are proportionate in relation to the objective of such protection,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive covers the wholesale distribution in the Community of medicinal products for human use to which Chapters II to V of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽¹⁾ apply.

2. For the purposes of this Directive:

- *wholesale distribution of medicinal products* shall mean all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned,
- *public service obligation* shall mean the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

Article 2

Without prejudice to Article 3 of Directive 65/65/EEC, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory.

Article 3

1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products, stating the place for which it is valid.

2. Where persons authorized or entitled to supply medicinal products to the public may also, under national

law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1.

3. Possession of an authorization, as mentioned in Article 16 of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products ⁽²⁾, shall include authorization to distribute by wholesale the medicinal products covered by that authorization. Possession of an authorization to engage in activity as a wholesaler in medicinal products shall not give dispensation from the obligation to possess a manufacturing authorization and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.

4. At the request of the Commission or any Member State, Member States shall supply all appropriate information concerning the individual authorizations which they have granted under paragraph 1.

5. Checks on the persons and establishments authorized to engage in the activity of wholesaler in medicinal products and the inspection of their premises shall be carried out under the responsibility of the Member State which granted the authorization.

6. The Member State which granted the authorization referred to in paragraph 1 shall suspend or revoke that authorization if the conditions of authorization cease to be met. It shall forthwith inform the other Member States and the Commission thereof.

7. Should a Member State consider that, in respect of a person holding an authorization granted by another Member State under the terms of paragraph 1, the conditions of authorization are not, or are no longer, met, it shall forthwith inform the Commission and the other Member State involved. The latter shall take the measures necessary and shall inform the Commission and the first Member State of the decisions taken and the reasons for those decisions.

Article 4

1. Member States shall ensure that the time taken for the procedure for examining the application for the authorization referred to in Article 3 (1) does not exceed 90 days from the day on which the competent authority of the Member State concerned receives the application.

The competent authority may, if need be, require the applicant to supply all necessary information concerning the conditions of authorization. Where the authority exercises this option, the period laid down in this

⁽¹⁾ OJ No 22, 9. 2. 1965, p. 369/65. Directive last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

⁽²⁾ OJ No L 147, 9. 6. 1975, p. 13. Directive last amended by Directive 89/381/EEC (OJ No L 181, 28. 6. 1989, p. 44).

paragraph shall be suspended until the requisite additional data have been supplied.

2. All decisions to refuse, suspend or revoke the authorization referred to in Article 3 (1) shall state in detail the reasons on which they are based. A decision shall be notified to the party concerned, who shall at the same time be informed of the redress available to him under the laws in force and of the time limit allowed for access to such redress.

Article 5

In order to obtain the authorization referred to in Article 3 (1), applicants must fulfil the following minimum requirements:

- (a) they must have suitable and adequate premises, installations and equipment so as to ensure proper conservation and distribution of the medicinal products;
- (b) they must have staff, and in particular a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;
- (c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 6.

Article 6

Holders of the authorization referred to in Article 3 (1) must fulfil the following minimum requirements:

- (a) they must make the premises, installations and equipment referred to in Article 5 (a) accessible at all times to the persons responsible for inspecting them;
- (b) they must obtain their supplies of 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 such authorization under the terms of Article 3 (3);
- (c) they must supply medicinal products only to persons who are themselves in possession of the authorization referred to in Article 3 (1) or who are authorized or entitled to supply medicinal products to the public in the Member State concerned;
- (d) they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or holder of the marketing authorization for the product concerned;
- (e) they must keep records either in the form of purchase/sales invoices, or on computer, or in any other form giving for any transaction in medicinal products received or dispatched at least the following information:
 - date,
 - name of the medicinal product,

- quantity received or supplied,
 - name and address of the supplier or consignee, as appropriate;
- (f) they must keep the records referred to under (e) available to the competent authorities, for inspection purposes, for a period of five years;
 - (g) they must comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Article 10.

Article 7

With regard to the supply of medicinal products to pharmacists and persons authorized or entitled 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, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorized to engage in equivalent activities.

The said obligations should, moreover, be justified, in keeping with the Treaty, on grounds of public health protection and be proportionate in relation to the objective of such protection.

Article 8

For all supplies of medicinal products to a person authorized or entitled to supply medicinal products to the public in the Member State concerned, the authorized wholesaler must enclose a document that makes it possible to ascertain:

- the date,
- the name and pharmaceutical form of the medicinal product,
- the quantity supplied,
- the name and address of the supplier and consignor.

Member States shall take all appropriate measures to ensure that persons authorized or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.

Article 9

The provisions of this Directive shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:

- narcotic or psychotropic substances within their territory,

- medicinal products derived from blood governed by Directive 89/381/EEC ⁽¹⁾,
- immunological medicinal products governed by Directive 89/342/EEC ⁽²⁾,
- radiopharmaceuticals governed by Directive 89/343/EEC ⁽³⁾.

Article 10

The Commission shall publish guidelines on good distribution practice. To this end it shall consult the Committee for Proprietary Medicinal Products and the Pharmaceutical Committee.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1993.

They shall forthwith inform the Commission thereof.

2. When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

⁽¹⁾ OJ No L 181, 28. 6. 1989, p. 44.

⁽²⁾ OJ No L 142, 25. 5. 1989, p. 14.

⁽³⁾ OJ No L 142, 25. 5. 1989, p. 16.

COUNCIL DIRECTIVE 92/26/EEC

of 31 March 1992

concerning the classification for the supply of medicinal products for human use

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas measures aimed at progressively establishing the internal market over a period expiring on 31 December 1992 need to be taken; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the conditions for the supply of medicinal products for human use to the public vary appreciably from one Member State to another; whereas medicinal products sold without prescriptions in certain Member States can be obtained only on medical prescription in other Member States;

Whereas Directive 91/28/EEC ⁽⁴⁾ specifies what medicinal products may be advertized to the public; whereas, in view of the development of means of communication, the conditions governing the supply of medicinal products to the public should be harmonized.

Whereas, moreover, persons moving around within the Community have the right to carry a reasonable quantity of medicinal products lawfully 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 governing the supply of medicinal products to the public;

Whereas, in addition, under the new system of registration of medicinal products in the Community, certain medicinal

products will be the subject of a Community marketing authorization; whereas, in this context, the classification for the supply of medicinal products covered by a Community marketing authorization needs to be established; whereas it is therefore important to set the criteria on the basis of which Community decisions will be taken;

Whereas it is therefore appropriate, as an initial step, to harmonize the basic principles applicable to the classification 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 narcotic and psychotropic substances;

Whereas this Directive is without prejudice to the national social security arrangements for reimbursement or payment for medicinal products on prescription,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns the classification for the supply of medicinal products for human use in the Community into:

- medicinal products subject to medical prescription,
- medicinal products not subject to medical prescription.

2. For the purposes of this Directive, the definition of 'medicinal product' in Article 1 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽⁵⁾ as last amended by Directive 89/343/EEC ⁽⁶⁾, shall apply. In addition, 'medicinal prescription' shall mean any prescription issued by a professional person qualified to prescribe medicinal products.

Article 2

1. When a marketing authorization is granted, the competent authorities shall specify the classification of the medicinal product into:

- a medicinal product subject to medical prescription,
- a medicinal product not subject to medical prescription.

⁽¹⁾ OJ No C 58, 8. 3. 1990, p. 18.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 178 and
OJ No C 67, 16. 3. 1992.

⁽³⁾ OJ No C 225, 10. 9. 1990, p. 21.

⁽⁴⁾ See page 13 of this Official Journal.

⁽⁵⁾ OJ No 22, 9. 6. 1965, p. 369/65.

⁽⁶⁾ OJ No L 142, 25. 5. 1989, p. 14.

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

2. The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. In that case, they shall refer to the following classification:

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

Article 3

1. Medicinal products shall be subject to medical prescription where they:

- are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or
- are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or
- contain substances or preparations thereof the activity and/or side effects of which require further investigation, or
- are normally prescribed by a doctor to be administered parenterally.

2. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

- the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force (United Nations Conventions of 1961 and 1971), or
- the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, or
- the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to that group as a precautionary measure.

3. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

- the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment,

- the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere, or

- the medicinal product is intended for outpatients but its use may produce very serious side-effects requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

4. A competent authority may waive application of paragraphs 1, 2 and 3 having regard to:

- (a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; and/or
- (b) other circumstances of use which it has specified.

5. If a competent authority does not designate medicinal products into sub-categories referred to in Article 2 (2), it shall nevertheless take into account the criteria referred to in paragraphs 2 and 3 of this Article in determining whether any medicinal product shall be classified as a prescription-only medicine.

Article 4

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

Article 5

1. The competent authorities shall draw up a list of the medicinal products subject on their territory to medical prescription, specifying, if necessary, the category of classification. They shall update this list annually.

2. On the occasion of the five-yearly renewal of the marketing authorization or when new facts are brought to their notice, the competent authorities shall examine and, as appropriate, amend the classification of a medicinal product, by applying the criteria listed in Article 3.

Article 6

1. Within two years of adoption of this Directive, the Member States shall communicate the list referred to in Article 5 (1) to the Commission and to the other Member States, when requested by the latter.

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.

3. Within four years of the 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.

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be

accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

COUNCIL DIRECTIVE 92/27/EEC

of 31 March 1992

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

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas measures aimed at progressively establishing the internal market over a period expiring on 31 December 1992 need to be taken; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulations or administrative action relating to medicinal products ⁽⁴⁾, as last amended by Directive 89/343/EEC ⁽⁵⁾, establishes a list of particulars to be given on the immediate packaging and the outer packaging of medicinal products for human use; whereas this list should be supplemented and details given of how labelling is to be presented;

Whereas Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products ⁽⁶⁾, as last amended by Directive 89/381/EEC ⁽⁷⁾, establishes a non-exhaustive list of particulars to be included in package leaflets; whereas this list should be supplemented and details given of how such leaflets are to be presented;

Whereas the provisions on labelling and on package leaflets should be brought together in a single text;

Whereas the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information;

Whereas the marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet,

HAS ADOPTED THIS DIRECTIVE:

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, to which Chapters II, III, IV and V of Directive 65/65/EEC apply.

2. For the purposes of this Directive:

- *name of the medicinal product* means the name given to a medicinal product, which may be either an invented name or a common or scientific name, together with a trade mark or the name of the manufacturer; the invented name shall not be liable to confusion with the common name,
- *common name* means the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name,
- *strength of the medicinal product* means the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form,
- *immediate packaging* means the container or other form of packaging immediately in contact with the medicinal product,
- *outer packaging* means the packaging into which is placed the immediate packaging,

(1) OJ No C 58, 8. 3. 1990, p. 21.

(2) OJ No C 183, 15. 7. 1991, p. 213.

(3) OJ No C 225, 10. 9. 1990, p. 24.

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

(5) OJ No L 142, 25. 5. 1989, p. 14.

(6) OJ No L 147, 9. 6. 1975, p. 13.

(7) OJ No L 81, 28. 6. 1989, p. 44.

- *labelling* means information on the immediate or outer packaging,
- *package leaflet* means a leaflet containing information for the user which accompanies the medicinal product,
- *manufacturer* means the holder of the authorization referred to in Article 16 of Directive 75/319/EEC on behalf of whom the qualified person has performed the specific obligations laid down in Article 22 of that Directive.

CHAPTER II

Labelling of medicinal products

Article 2

1. 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 followed by the common name where the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (baby, child or adult as appropriate) must be included in the name of the medicinal product;
- (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 by number of doses of the product;
- (d) a list of those excipients known to have a recognized action or effect and included in the guidelines published pursuant to Article 12. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;
- (e) the method and, if necessary, the route of administration;
- (f) a special warning that the medicinal product must be stored out of reach of children;
- (g) a special warning, if this is necessary for the medicinal product concerned;
- (h) the expiry date in clear terms (month/year);
- (i) special storage precautions, if any;
- (j) special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;

- (k) the name and address of the holder of the authorization for placing the medicinal product on the market;
- (l) the number of the authorization for placing the medicinal product on the market;
- (m) the manufacturer's batch number;
- (n) in the case of self-medication, instructions on the use of the medicinal products.

2. The outer packaging may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.

Article 3

1. The particulars laid down in Article 2 shall appear on immediate packagings other than those referred to in paragraphs 2 and 3.

2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Article 2:

- the name of the medicinal product as laid down in Article 2 (a),
- the name of the holder of the authorization for placing the product on the market,
- the expiry date,
- the batch number.

3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Article 2 cannot be displayed:

- the name of the medicinal product and, if necessary, the strength and the route of administration,
- the method of administration,
- the expiry date,
- the batch number,
- the contents by weight, by volume or by unit.

Article 4

1. The particulars referred to in Articles 2 and 3 shall be easily legible, clearly comprehensible and indelible.

2. The particulars listed in Article 2 shall appear in the official language or languages of the Member State where the product is placed on the market. This provision shall not prevent these particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.

Article 5

1. Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling where such labelling complies with the requirements of this Chapter.

2. Notwithstanding paragraph 1, Member States may require the use of certain forms of labelling making it possible to indicate:

- the price of the medicinal product,
- the reimbursement conditions of social security organizations,
- the legal status for supply to the patient, in accordance with Directive 92/26/EEC ⁽¹⁾,
- identification and authenticity.

CHAPTER III

User package leaflet

Article 6

The inclusion in the packaging of all medicinal products of a package leaflet for the information of users shall be obligatory unless all the information required by Article 7 is directly conveyed on the outer packaging or on the immediate packaging.

Article 7

1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

(a) for the identification of the medicinal product:

- the name of the medicinal product, followed by the common name if the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (for example, baby, child, adult) must be included in the name of the medicinal product,
- a full statement of the active ingredients and excipients expressed qualitatively and a statement of the active ingredients expressed quantitatively, using their common names, in the case of each presentation of the product,
- the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product,

- the pharmaco-therapeutic group, or type of activity in terms easily comprehensible for the patient,
- the name and address of the holder of the authorization for placing the medicinal product on the market and of the manufacturer;

(b) the therapeutic indications;

(c) a list of information which is necessary before taking the medicinal product:

- contra-indications,
- appropriate precautions for use,
- forms of interaction with other medicinal products and other forms of interaction (for example, alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product,
- special warnings.

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),
- mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
- detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in the guidelines published pursuant to Article 12;

(d) the necessary and usual instructions for proper use, in particular:

- the dosage,
- the method and, if necessary, route of administration,
- the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered,

and, as appropriate, depending on the nature of the product:

- the duration of treatment, where it should be limited,
- the action to be taken in the case of an overdose (for example, symptoms, emergency procedures),
- the course of action to take when one or more doses have not been taken,
- indication, if necessary, of the risk of withdrawal effects;

(e) a description of the undesirable effects which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the

⁽¹⁾ See page 5 of this Official Journal.

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 certain visible signs of deterioration;
- (g) the date on which the package leaflet was last revised.

2. Notwithstanding paragraph 1 (b), the competent authorities may decide that certain therapeutic indications shall not be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient.

3. The package leaflet may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.

Article 8

The package leaflet must be written in clear and understandable terms for the patient and be clearly legible in the official language or languages of the Member State where the medicinal product is placed on the market. This provision does not prevent the package leaflet being printed in several languages, provided that the same information is given in all the languages used.

Article 9

Member States shall not prohibit or impede the marketing of medicinal products within their territory on grounds relating to the package leaflet if the latter complies with the requirements of this Chapter.

CHAPTER IV

General and final provisions

Article 10

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 authorities competent for authorizing marketing when the authorization for placing the medicinal product on the market is requested.

2. The competent authorities shall refuse the authorization for placing the medicinal product on the market if the labelling or the package leaflet do not comply with the provisions of this Directive or if they are not in accordance with the particulars listed in the summary of product characteristics referred to in Article 4b of Directive 65/65/EEC.

3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Directive and not connected with the summary of characteristics shall be submitted to the authorities competent for authorizing marketing. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.

4. The fact that the competent authorities do not refuse an authorization to place the medicinal product on the market pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer or as appropriate the holder of the authorization to place the medicinal product on the market.

5. The competent authorities may exempt labels and package leaflets for specific medicinal products from the obligation that certain particulars shall appear and that the leaflet must be in the official language or languages of the Member State where the product is placed on the market, when the product is not intended to be delivered to the patient for self-administration.

Article 11

1. Where the provisions of this Directive are not complied with, and a notice served on the person concerned has remained without effect, the competent authorities of the Member States may suspend the authorization to place the medicinal product on the market, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Directive.

2. All decisions taken pursuant to paragraph 1 shall state in detail the reasons on which they are based. They shall be notified to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force and of the time limit allowed for the exercise of such remedies.

Article 12

1. As necessary, the Commission shall publish guidelines concerning in particular:

- the formulation of certain special warnings for certain categories of medicinal products,
- the particular information needs relating to self-medication,

- the legibility of particulars on the labelling and package leaflet,
- methods for the identification and authentication of medicinal products,
- the list of excipients which must feature on the labelling of medicinal products and the way these excipients must be indicated.

2. These guidelines shall be adopted in the form of a Directive addressed to the Member States, in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC.

Article 13

Articles 13 to 20 of Directive 65/65/EEC and Articles 6 and 7 of Directive 75/319/EEC are hereby repealed.

Article 14

Member States shall take the measures necessary to comply with this Directive before 1 January 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

From 1 January 1994, Member States shall refuse an application for authorization to place a medicinal product on the market or for the renewal of an existing authorization, where the labelling and the package leaflet do not comply with the requirements of this Directive.

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

COUNCIL DIRECTIVE 92/28/EEC

of 31 March 1992

on the advertising of medicinal products for human use

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Directive 84/450/EEC ⁽⁴⁾ harmonized the laws, regulations and administrative provisions of the Member States concerning misleading advertising; whereas this Directive is without prejudice to the application of measures adopted pursuant to that Directive;

Whereas all Member States have adopted further specific measures concerning the advertising of medicinal products; whereas there are disparities between these measures; whereas these disparities are likely to have an impact on the establishment and functioning of the internal market, since advertising disseminated in one Member State is likely to have effects in other Member States;

Whereas Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities ⁽⁵⁾ prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located; whereas this principle should be made of general application by extending it to other media;

Whereas advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered; whereas advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined;

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

Whereas the advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons; whereas, nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe;

Whereas medical sales representatives have an important role in the promotion of medicinal products; whereas, therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics;

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

Whereas it should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them;

Whereas persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market; whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation;

Whereas advertising of medicinal products should be subject to effective, adequate monitoring; whereas reference in this regard should be made to the monitoring mechanisms set up by Directive 84/450/EEC;

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,

⁽¹⁾ OJ No C 163, 4. 7. 1990, p. 10 and
OJ No C 207, 8. 8. 1991, p. 25.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 227 and
OJ No C 67, 16. 3. 1992.

⁽³⁾ OJ No C 60, 8. 3. 1991, p. 40.

⁽⁴⁾ OJ No L 250, 19. 9. 1984, p. 17.

⁽⁵⁾ OJ No L 298, 17. 10. 1989, p. 23.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, definitions and general principles

Article 1

1. This Directive concerns the advertising in the Community of medicinal products for human use covered by Chapters II to V of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽¹⁾.

2. For the purposes of this Directive:

- the definitions of the name of the medicinal product and of the common name shall be those laid down in Article 1 of Directive 92/27/EEC ⁽²⁾;
- the summary of product characteristics shall be the summary approved by the competent authority which granted the marketing authorization in accordance with Article 4b of Directive 65/65/EEC.

3. For the purposes of this Directive, advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

- the advertising of medicinal products to the general public,
- advertising of medicinal products to persons qualified to prescribe or supply them,
- visits by medical sales representatives to persons qualified to prescribe medicinal products,
- the supply of samples,
- the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and

in particular payment of their travelling and accommodation expenses in connection therewith.

4. The following are not covered by this Directive:

- the labelling of medicinal products and the accompanying package leaflets, which are subject to the provisions of Directive 92/27/EEC;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;
- statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

Article 2

1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.

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

3. The advertising of a medicinal product:

- shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,
- shall not be misleading.

CHAPTER II

Advertising to the general public

Article 3

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

- are available on medical prescription only, in accordance with Directive 92/26/EEC ⁽³⁾,
- contain psychotropic or narcotic substances, within the meaning of the international conventions,

⁽¹⁾ OJ No 22, 9. 2. 1965, p. 369/65. Directive last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

⁽²⁾ See page 8 of this Official Journal.

⁽³⁾ See page 5 of this Official Journal.

— may not be advertised to the general public in accordance with paragraph 2.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Member States shall prohibit the mentioning in advertising to the general public of therapeutic indications such as:

- tuberculosis,
- sexually transmitted diseases,
- other serious infectious diseases,
- cancer and other tumoral diseases,
- chronic insomnia,
- diabetes and other metabolic illnesses.

3. Member States shall also be able to ban on their territory advertising to the general public of medicinal products the cost of which may be reimbursed.

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

5. The prohibition referred to in paragraph 1 shall apply without prejudice to Articles 2, 3 and 14 of Directive 89/552/EEC.

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes; they may, however, authorize such distribution in special cases for other purposes.

Article 4

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

- (a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;
- (b) include the following minimum information:
 - the name of the medicinal product, as well as the common name if the medicinal product contains only one active ingredient,
 - the information necessary for correct use of the medicinal product,
 - an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, according to the case.

2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product if it is intended solely as a reminder.

Article 5

The advertising of a medicinal product to the general public shall not contain any material which:

- (a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- (b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another treatment or medicinal product;
- (c) suggests that the health of the subject can be enhanced by taking the medicine;
- (d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 3 (4);
- (e) is directed exclusively or principally at children;
- (f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
- (g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- (h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- (i) could, by a description or detailed representation of a case history, lead to erroneous self diagnosis;
- (j) refers, in improper, alarming or misleading terms, to claims of recovery;
- (k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof;
- (l) mentions that the medicinal product has been granted a marketing authorization.

CHAPTER III

Advertising to health professionals

Article 6

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

- essential information compatible with the summary of product characteristics;
- the supply classification of the medicinal product.

Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

2. Member States may decide that 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 it is intended solely as a reminder.

Article 7

1. Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include as a minimum the particulars listed in Article 6 (1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.

Article 8

1. Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote.

2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 6 (1).

3. Medical sales representatives shall transmit to the scientific service referred to in Article 13 (1) any information about the use of the medicinal products they advertise, with particular reference to any adverse reactions reported to them by the persons they visit.

Article 9

1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion must always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health professionals.

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

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by this Article.

Article 10

The provisions of Article 9 (1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality must always be reasonable in level and remain subordinate to the main scientific objective of the meeting; it must not be extended to persons other than health professionals.

Article 11

1. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

- (a) a limited number of samples for each medicinal product each year on prescription;

- (b) any supply of samples must be in response to a written request, signed and dated, from the recipient;
- (c) those supplying samples must maintain an adequate system of control and accountability;
- (d) each sample shall be identical with the smallest presentation on the market;
- (e) each sample shall be marked free medical sample — not for resale or bear another legend of analogous meaning;
- (f) each sample shall be accompanied by a copy of the summary of product characteristics;
- (g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions may be supplied.

2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.

CHAPTER IV

Monitoring of advertising

Article 12

1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, shall in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Directive may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings.

2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or administrative authorities powers enabling them, in cases where they deem such measures to be necessary taking into account all the interests involved and in particular the public interest:

- to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising,
- or
- if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication,

even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.

Member States shall also make provision for the measures referred to in the first subparagraph to be taken under an accelerated procedure:

- either with interim effect, or
- with definitive effect,

on the understanding that it is for each Member State to decide which of the two options to select.

Furthermore, Member States may confer upon the courts or administrative authorities powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:

- to require publication of that decision in full or in part and in such form as they deem adequate,
- to require in addition the publication of a corrective statement.

3. Under the legal provisions referred to in paragraph 1, Member States shall ensure that any decision taken in accordance with paragraph 2 shall state in detail the reasons on which it is based and shall be communicated in writing to the person concerned, mentioning the redress available at law and the time limit allowed for access to such redress.

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

Article 13

1. The marketing authorization holder shall establish within his undertaking a scientific service in charge of information about the medicinal products which he places on the market.

2. The person responsible for placing the product on the market shall:

- keep available for, or communicate to, the authorities or bodies responsible for monitoring advertising of medicinal products a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination,
- ensure that advertising of medicinal products by his undertaking conforms to the requirements of this Directive,

- verify that medical sales representatives employed by his undertaking have been adequately trained and fulfill the obligations imposed upon them by Article 8 (2) and (3),
- supply the authorities or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities,
- ensure that the decisions taken by the authorities or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.

Article 14

Member States shall take the appropriate measures to ensure that all the provisions of this Directive are applied in full and shall determine in particular what penalties shall be imposed should the provisions adopted in the execution of this Directive be infringed.

Article 15

1. Member States shall take the measures necessary in order to comply with this Directive with effect from 1 January 1993. They shall forthwith inform the Commission thereof.

2. When Member States adopt the said measures, such measures shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

COUNCIL DIRECTIVE 92/29/EEC

of 31 March 1992

on the minimum safety and health requirements for improved medical treatment on board vessels

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission ⁽¹⁾, drawn up after consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the Opinion of the Economic and Social Committee ⁽³⁾,

Whereas the Commission communication on its programme concerning safety, hygiene and health at work ⁽⁴⁾ envisages measures to ensure medical treatment at sea;

Whereas the safety and health of workers on board a vessel, which constitutes a workplace involving a wide range of risks, bearing in mind, inter alia, its geographical isolation, where appropriate, require special attention;

Whereas vessels should have adequate medical supplies, kept in good order and checked at regular intervals, so that workers can obtain the necessary medical treatment at sea;

Whereas, in order to ensure appropriate medical treatment at sea, training and information of seafarers should be encouraged as regards the use of medical supplies;

Whereas the use of long-distance medical-consultation methods constitutes an efficient way of contributing to the protection of the safety and health of workers,

Article 1

Definitions

For the purposes of this Directive, the following terms shall have the following meanings:

(a) *vessel*: any vessel flying the flag of a Member State or registered under the plenary jurisdiction of a Member State, seagoing or estuary-fishing, publicly or privately owned, excluding:

- inland navigation vessels,
- warships,
- pleasure boats used for non-commercial purposes and not manned by professional crews,
- tugs operating in harbour areas.

Vessels shall be classed in three categories in accordance with Annex I;

(b) *worker*: any person carrying out an occupation on board a vessel, including trainees and apprentices, but excluding port pilots and shore personnel carrying out work on board a vessel at the quayside;

(c) *Owner*: the registered owner of a vessel unless that vessel has been chartered by demise or is managed, either wholly or in part, by a natural or legal person other than the registered owner under the terms of a management agreement; in that case the owner shall be construed as the demise charterer or natural or legal person managing the vessel as appropriate;

(d) *medical supplies*: medicines, medical equipment and antidotes, a non-exhaustive list of which is given in Annex II;

(e) *antidote*: a substance used to prevent or treat a harmful effect or effects, direct or indirect, of one or more substances included on the list of dangerous substances in Annex III.

Article 2

Medicines and medical equipment — Sick-bay — Doctor

Each Member State shall take the measures necessary to ensure that:

1. (a) every vessel flying its flag or registered under its plenary jurisdiction always carries on board medical

⁽¹⁾ OJ No C 183, 24. 7. 1990, p. 6 and OJ No C 74, 20. 3. 1991, p. 11.

⁽²⁾ OJ No C 48, 25. 2. 1991, p. 154 and OJ No C 326, 16. 12. 1991, p. 72.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 165.

⁽⁴⁾ OJ No C 28, 3. 2. 1988, p. 3.

supplies which meet at least, in terms of quality, the specifications of Annex II sections I and II for the category of vessel to which it belongs;

- (b) the quantities of medicinal products and medical equipment to be carried depend on the nature of the voyage — in particular ports of call, destination, duration — the type or types of work to be carried out during the voyage, the nature of the cargo and the number of workers;
 - (c) the content of the medicines and medical equipment included in the medical supplies shall be detailed on a checklist corresponding at least to the general framework laid down in Annex IV, sections A, B and C II 1 and II 2;
2. (a) for each of its life-rafts and life-boats, every vessel flying its flag or registered under its plenary jurisdiction carries a watertight medicine chest at least containing the medical supplies specified in Annex II, sections I and II, for category C vessels;
 - (b) the content of these chests is also detailed on the checklist referred to in paragraph 1 (c);
 3. every vessel flying its flag or registered under its plenary jurisdiction, of more than 500 gross registered tonnes, with a crew of 15 or more workers and engaged on a voyage of more than three days, has a sick-bay in which medical treatment can be administered under satisfactory material and hygienic conditions;
 4. every vessel flying its flag or registered under its plenary jurisdiction, with a crew of 100 or more workers and engaged on an international voyage of more than three days, has a doctor responsible for the medical care of the workers on board.

Article 3

Antidotes

Each Member State shall take the measures necessary to ensure that:

1. any vessel flying its flag or registered under its plenary jurisdiction and carrying any of the dangerous substances listed in Annex III carries on board medical supplies including at least the antidotes listed in Section III of Annex II;
2. any ferry-type vessels flying its flag or registered under its plenary jurisdiction, whose conditions of operation do not always allow it to know well enough in advance the nature of the dangerous substances being transported, has on board medical supplies including at least the antidotes listed in section III of Annex II.

However, on a regular where the crossing is due to last less than two hours, the antidotes may be limited to those which have to be administered in cases of extreme emergency within a period of time not exceeding the normal duration of the crossing;

3. the contents of the medical supplies, as regards antidotes, shall be detailed on a check list corresponding at least to the general framework laid down in Annex IV, sections A, B and C, II 3.

Article 4

Allocation of responsibilities

Each Member State shall take the measures necessary to ensure that:

1. (a) the provision and replenishment of the medical supplies of any vessel flying its flag or registered under its plenary jurisdiction are undertaken on the exclusive responsibility of the owner, without any expense to the workers;
- (b) the management of the medical supplies is placed under the responsibility of the captain of the vessel; he may, without prejudice to this responsibility, delegate the use and maintenance of the medical supplies to one or more workers specially designated by reason of their competence;
2. the medical supplies are maintained in good condition and replenished and/or replaced as soon as possible, and in every case as a priority part of normal revictualling procedures;
3. in an emergency established by the captain as far as possible after having obtained a medical opinion, the required medicines, medical equipment and antidotes which are not available on board are made available as soon as possible.

Article 5

Information and training

Each Member State shall take the measures necessary to ensure that:

1. medical supplies are accompanied by one or more guides to their use, including instructions for use of at least the antidotes required in Annex II section III;
2. all persons receiving professional maritime training and intending to work on board ship have been given basic training in the medical and emergency measures to be taken immediately in the event of an accident or serious medical emergency;
3. the captain and any worker or workers to whom he delegates the use of the medical supplies pursuant to

Article 4 (1) (b) have received special training updated periodically, at least every five years, taking into account the specific risks and needs connected with the different categories of vessel and in accordance with the general guidelines set out in Annex V.

Article 6

Medical consultations by radio

1. To ensure better emergency treatment for workers, each Member State shall take the measures necessary to ensure that:

- (a) one or more centres are designated to provide workers with free medical advice by radio;
- (b) some of the doctors providing their services for the radio consultation centres have been trained in the special conditions prevailing on board ship.

2. In order to optimize the advice given, the radio consultation centres may keep personal medical records, with the agreement of the workers concerned.

Such records shall remain confidential.

Article 7

Inspection

1. Each Member State shall take the measures necessary to ensure that a competent person or a competent authority carries out an annual inspection to check that on board all vessels flying its flag:

- the medical supplies meet the minimum requirements of this Directive;
- the checklist provided for in Article 2 (1) (c) confirms that the medical supplies comply with those minimum requirements;
- the medical supplies are correctly stored;
- any expiry dates have been respected.

2. Inspections of the medical supplies stored on life-rafts shall be carried out in the course of those life-rafts' annual maintenance.

Those inspections may exceptionally be postponed for up to five months.

Article 8

Committee

1. With a view to the strictly technical adaption of the Annexes to this Directive in the light of technical progress or changes in international regulations or specifications and new findings in this field, the Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 9

Final provisions

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1994. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, such measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they have already adopted or which they adopt in the field governed by this Directive.

3. Member States shall report to the Commission every five years on the implementation of this Directive, giving the views of the two sides of industry.

The Commission shall inform the European Parliament, the Council, the Economic and Social Committee and the Advisory Committee for Safety, Hygiene and Health at Work thereof.

4. The Commission shall report at least every five years to the European Parliament, the Council and the Economic

and Social Committee on the implementation of this Directive, taking into account paragraphs 1, 2 and 3.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

ANNEX I

CATEGORIES OF VESSELS

(Article 1 (a))

- A. Sea-going or sea-fishing vessels, with no limitation on length of trips.
- B. Sea-going or sea-fishing vessels making trips of less than 150 nautical miles from the nearest port with adequate medical equipment ⁽¹⁾.
- C. Harbour vessels, boats and craft staying very close to shore or with no cabin accommodation other than a wheelhouse.

⁽¹⁾ Category B shall be extended to sea-going or sea-fishing vessels which make trips of less than 175 nautical miles from the nearest port with adequate medical equipment and which remain continuously within range of helicopter rescue services. To this end, each Member State shall forward up-to-date information on the areas in which routine helicopter rescue services are provided, and the circumstances in which they operate:

- (a) to the other Member States and the Commission; and
- (b) to the captains of vessels flying its flag or registered under its plenary jurisdiction who are, or are likely to be, concerned by application of the first subparagraph of this footnote; the information shall be forwarded in the most appropriate way, for example through radio-consultation centres, rescue coordination centres or coastal radio stations.

ANNEX II

MEDICAL SUPPLIES (NON-EXHAUSTIVE LIST)

(Article 1 (d))

I. MEDICINES

	Categories of vessels		
	A	B	C
1. Cardiovascular			
(a) Cardio-circulatory analeptics — Sympathomimetics	x	x	
(b) Anti-angina preparations	x	x	x
(c) Diuretics	x	x	
(d) Anti-haemorrhagics including uterotonics if there are women on board	x	x	x
(e) Anti-hypertensive	x		
2. Gastro-intestinal system			
(a) Medicines for gastric and duodenal disorders			
— Histamine H ₂ receptor anti-ulcer antagonists	x		
— Anti-acid mucous dressings	x	x	
(b) Anti-emetics	x	x	x
(c) Lubricant laxatives	x		
(d) Anti-diarrhoeals	x	x	x
(e) Intestinal antiseptics	x	x	
(f) Haemorrhoid preparations	x	x	
3. Analgesics and anti-spasmodics			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	x	x	x
(b) Powerful analgesics	x	x	
(c) Spasmolytics	x	x	
4. Nervous system			
(a) Anxiolytics	x	x	
(b) Neuroleptics	x	x	
(c) Seasickness remedies	x	x	x
(d) Anti-epileptics	x		
5. Anti-allergics and anti-anaphylactics			
(a) H ₁ Anti-histaminics	x	x	
(b) Injectable glucocorticoids	x	x	
6. Respiratory system			
(a) Bronchospasm preparations	x	x	
(b) Anti-tussives	x	x	
(c) Medicines used for colds and sinusitis	x	x	

		Categories of vessels		
		A	B	C
7. Anti-infection				
(a) Antibiotics (at least two families)		x	x	
(b) Anti-bacterial sulphamide		x	x	
(c) Urinary antiseptics		x		
(d) Anti-parasitics		x	x	
(e) Intestinal anti-infectives		x	x	
(f) Anti-tetanus vaccines and immunoglobulins		x	x	
8. Compounds promoting rehydration, caloric intake and plasma expansion		x	x	
9. Medicines for external use				
(a) <i>Skin medicines</i>				
— Antiseptic solutions		x	x	x
— Antibiotic ointments		x	x	
— Anti-inflammatory and analgesic ointments		x	x	
— Anti-mycotic skin creams		x		
— Burn preparations		x	x	x
(b) <i>Eye medicines</i>				
— Antibiotic drops		x	x	
— Antibiotic and anti-inflammatory drops		x	x	
— Anaesthetic drops		x	x	
— Hypotonic myotic drops		x	x	
(c) <i>Ear medicines</i>				
— Antibiotic solutions		x	x	
— Anaesthetic and anti-inflammatory solutions		x	x	
(d) <i>Medicines for oral and throat infections</i>				
— Antibiotic or antiseptic mouthwashes		x	x	
(e) <i>Local anaesthetics</i>				
— Local anaesthetics using freezing		x		
— Local anaesthetics given by subcutaneous injection		x	x	
— Dental anaesthetic and antiseptic mixtures		x	x	

II. MEDICAL EQUIPMENT

	<i>Categories of vessels</i>		
	A	B	C
1. Resuscitation equipment			
— Manual resuscitation appliance	x	x	
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container	x	x ⁽¹⁾	
— Mechanical aspirator to clear upper respiratory passages	x	x	
— Cannula for mouth-to-mouth resuscitation	x	x	x
2. Dressing and suturing equipment			
— Disposable suture stapler or suture kit with needles	x	x	
— Adhesive elastic bandage	x	x	x
— Gauze strips	x		
— Tubular gauze for finger bandages	x		
— Sterile gauze compresses	x	x	x
— Cotton wool	x	x	
— Sterile sheet for burns victims	x	x	
— Triangular sling	x	x	
— Disposable polyethylene gloves	x	x	x
— Adhesive dressings	x	x	x
— Sterile compression bandages	x	x	x
— Adhesive sutures or zinc oxide bandages	x	x	x
— Non-absorbable sutures with needles	x		
— Vaseline gauze	x	x	
3. Instruments			
— Disposable scalpels	x		
— Stainless-steel instrument box	x	x	
— Scissors	x	x	
— Dissecting forceps	x	x	
— Haemostatic clamps	x	x	
— Needle forceps	x		
— Disposable razors	x		
4. Examination and monitoring equipment			
— Disposable tongue depressors	x	x	
— Reactive strips for urine analysis	x		
— Temperature charts	x		
— Medical evacuation sheets	x	x	
— Stethoscope	x	x	
— Aneroid sphygmomanometer	x	x	
— Standard medical thermometer	x	x	
— Hypothermic thermometer	x	x	

(1) Under the conditions of use prescribed by national laws and/or practices.

Categories of vessels			
	A	B	C
5. Equipment for injection, perfusion, puncture and catheterization			
— Bladder drainage instruments	x		
— Rectal drip set	x		
— Disposable filter infusor	x		
— Urine drainage bag	x		
— Disposable syringes and needles	x	x	
— Catheter	x		
6. General medical equipment			
— Bedpan	x		
— Hot-water bottle	x		
— Urine bottle	x		
— Ice bag	x		
7. Immobilization and setting equipment			
— Malleable finger splint	x	x	
— Malleable forearm and hand splint	x	x	
— Inflatable splint	x	x	
— Thigh splint	x	x	
— Collar for neck immobilization	x	x	
— Thomas splint or dimple mattress	x		
8. Disinfection, disinsectization and prophylaxis			
— Water-disinfection compound	x		
— Liquid insecticide	x		
— Powder insecticide	x		

III. ANTIDOTES

1. Medicines
- General

— Cardio-vascular

— Gastro-intestinal system

— Nervous system

— Respiratory system

— Anti-infective

— For external use
2. Medical equipment
- Necessary for the administration of oxygen (including maintenance requisites)

Note

For the detailed implementation of Section III, Member States may refer to the IMO Medical First Aid Guide for use in accidents involving dangerous goods (MFAG) contained in the 1990 consolidated edition of the IMO International Maritime Dangerous Goods Code.

Any adaptation of Section III in implementation of Article 8 may take account, *inter alia*, of any updating of the MFAG.

ANNEX III

DANGEROUS SUBSTANCES

(Article 1 (e) and Article 3 (1))

The substances listed in this Annex are to be taken into account in whatever form they are carried on board, including the form of waste or cargo residues.

- Explosive substances and objects,
- Gases: compressed, liquified or dissolved under pressure,
- Inflammable liquids,
- Inflammable solids,
- Substances liable to spontaneous combustion,
- Substances which, on contact with water, give off inflammable gases,
- Combustible substances,
- Organic peroxides,
- Toxic substances,
- Infectious substances,
- Radioactive substances,
- Corrosive substances,
- Various dangerous substances, i.e. any other substances which experience has shown, or may show, to be dangerous, so that the provisions of Article 3 need to be applied.

Note

For the detailed implementation of this Annex, Member States may refer to the 1990 consolidated edition of the IMO International Maritime Dangerous Goods Code.

Any adaptation of this Annex in implementation of Article 8 may take account, *inter alia*, of any updating of the IMO International Maritime Dangerous Goods Code.

ANNEX IV

GENERAL FRAMEWORK FOR THE INSPECTION OF VESSELS' MEDICAL SUPPLIES

(Article 2 (1) (c), Article 3 (3))

SECTION A. CATEGORY A VESSELS

I. Details of the vessel

Name:
Flag:
Home port:

II. Medical supplies

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. MEDICINE			
1.1. Cardiovascular			
(a) Cardio-circulatory analeptics — Sympathomimetics	0	0	0
(b) Anti-angina preparations	0	0	0
(c) Diuretics	0	0	0
(d) Anti-haemorrhagics including uterotonics if there are women on board	0	0	0
(e) Anti-hypertensive	0	0	0
1.2. Gastro-intestinal system			
(a) Medicines for gastric and duodenal disorders			
— Histamine H ₂ receptor anti-ulcer antagonists	0	0	0
— Anti-acid mucous dressings	0	0	0
(b) Anti-emetics	0	0	0
(c) Lubricant laxatives	0	0	0
(d) Anti-diarrhoeals	0	0	0
(e) Intestinal antiseptics	0	0	0
(f) Haemorrhoid preparations	0	0	0
1.3. Analgesics and anti-spasmodics			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
(b) Powerful analgesics	0	0	0
(c) Spasmolytics	0	0	0
1.4. Nervous system			
(a) Anxiolytics	0	0	0
(b) Neuroleptics	0	0	0
(c) Seasickness remedies	0	0	0
(d) Anti-epileptics	0	0	0
1.5. Anti-allergics and anti-anaphylactics			
(a) H ₁ Anti-histaminics	0	0	0
(b) Injectable glucocorticoids	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1.6. Respiratory system			
(a) Bronchospasm preparations	0	0	0
(b) Anti-tussives	0	0	0
(c) Medicines used for colds and sinusitis	0	0	0
1.7. Anti-infection			
(a) Antibiotics (at least two families)	0	0	0
(b) Anti-bacterial sulphamide	0	0	0
(c) Urinary antiseptics	0	0	0
(d) Anti-parasitics	0	0	0
(e) Intestinal anti-infectives	0	0	0
(f) Anti-tetanus vaccines and immunoglobulins	0	0	0
1.8. Compounds promoting rehydration, caloric intake and plasma expansion	0	0	0
1.9. Medicines for external use			
(a) <i>Skin medicines</i>			
— Antiseptic solutions	0	0	0
— Antibiotic ointments	0	0	0
— Anti-inflammatory and analgesic ointments	0	0	0
— Anti-mycotic skin creams	0	0	0
— Burn preparations	0	0	0
(b) <i>Eye medicines</i>			
— Antibiotic drops	0	0	0
— Antibiotic and anti-inflammatory drops	0	0	0
— Anaesthetic drops	0	0	0
— Hypotonic myotic drops	0	0	0
(c) <i>Ear medicines</i>			
— Antibiotic solutions	0	0	0
— Anaesthetic and anti-inflammatory solutions	0	0	0
(d) <i>Medicines for oral and throat infections</i>			
— Antibiotic or antiseptic mouthwashes	0	0	0
(e) <i>Local anaesthetics</i>			
— Local anaesthetics using freezing	0	0	0
— Local anaesthetics given by subcutaneous injection	0	0	0
— Dental anaesthetic and antiseptic mixtures	0	0	0
2. MEDICAL EQUIPMENT			
2.1. Resuscitation equipment			
— Manual resuscitation appliance	0	0	0
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container	0	0	0
— Mechanical aspirator to clear upper respiratory passages	0	0	0
— Cannula for mouth-to-mouth resuscitation	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
2.2. Dressing and suturing equipment			
— Disposable suture stapler or suture kit with needles	0	0	0
— Adhesive elastic bandage	0	0	0
— Gauze strips	0	0	0
— Tubular gauze for finger bandages	0	0	0
— Sterile gauze compresses	0	0	0
— Cotton wool	0	0	0
— Sterile sheet for burns victims	0	0	0
— Triangular sling	0	0	0
— Disposable polyethylene gloves	0	0	0
— Adhesive dressings	0	0	0
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
— Non-absorbable sutures with needles	0	0	0
— Vaseline gauze	0	0	0
2.3. Instruments			
— Disposable scalpels	0	0	0
— Stainless-steel instrument box	0	0	0
— Scissors	0	0	0
— Dissecting forceps	0	0	0
— Haemostatic clamps	0	0	0
— Needle forceps	0	0	0
— Disposable razors	0	0	0
2.4. Examination and monitoring equipment			
— Disposable tongue depressors	0	0	0
— Reactive strips for urine analysis	0	0	0
— Temperature charts	0	0	0
— Medical evacuation sheets	0	0	0
— Stethoscope	0	0	0
— Aneroid sphygmomanometer	0	0	0
— Standard medical thermometer	0	0	0
— Hypothermic thermometer	0	0	0
2.5. Equipment for injection, perfusion, puncture and catheterization			
— Bladder drainage instruments	0	0	0
— Rectal drip set	0	0	0
— Disposable filter infusor	0	0	0
— Urine drainage bag	0	0	0
— Disposable syringes and needles	0	0	0
— Catheter	0	0	0
2.6. General medical equipment			
— Bedpan	0	0	0
— Hot-water bottle	0	0	0
— Urine bottle	0	0	0
— Ice bag	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
2.7. Immobilization and setting equipment			
— Malleable finger splint	0	0	0
— Malleable forearm and hand splint	0	0	0
— Inflatable splint	0	0	0
— Thigh splint	0	0	0
— Collar for neck immobilization	0	0	0
— Thomas splint or diple mattress	0	0	0
2.8. Disinfection, disinsectization and prophylaxis			
— Water-disinfection compound	0	0	0
— Liquid insecticide	0	0	0
— Powder insecticide	0	0	0
3. ANTIDOTES			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0
3.4. Nervous system	0	0	0
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen	0	0	0

Venue and date:

Captain's signature:

Approval of the competent person or authority:

SECTION B. CATEGORY B VESSELS

I. Details of the vessel

Name:

Flag:

Home port:

II. Medical supplies

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. MEDICINE			
1.1. Cardiovascular			
(a) Cardio-circulatory analeptics — Sympathomimetics	0	0	0
(b) Anti-angina preparations	0	0	0
(c) Diuretics	0	0	0
(d) Anti-haemorrhagics including uterotonics if there are women on board	0	0	0
1.2. Gastro-intestinal system			
(a) Medicines for gastric and duodenal disorders — Anti-acid mucous dressings	0	0	0
(b) Anti-emetics	0	0	0
(c) Anti-diarrhoeals	0	0	0
(d) Intestinal antiseptics	0	0	0
(e) Haemorrhoid preparations	0	0	0
1.3. Analgesics and anti-spasmodics			
(a) Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
(b) Powerful analgesics	0	0	0
(c) Spasmolytics	0	0	0
1.4. Nervous system			
(a) Anxiolytics	0	0	0
(b) Neuroleptics	0	0	0
(c) Seasickness remedies	0	0	0
1.5. Anti-allergics and anti-anaphylactics			
(a) H ₁ Anti-histaminics	0	0	0
(b) Injectable glucocorticoids	0	0	0
1.6. Respiratory system			
(a) Bronchospasm preparations	0	0	0
(b) Anti-tussives	0	0	0
(c) Medicines used for colds and sinusitis	0	0	0
1.7. Anti-infection			
(a) Antibiotics (at least two families)	0	0	0
(b) Anti-bacterial sulphamide	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
(c) Anti-parasitics	0	0	0
(d) Intestinal anti-infectives	0	0	0
(e) Anti-tetanus vaccines and immunoglobulins	0	0	0
1.8. Compounds promoting rehydration, caloric intake and plasma expansion	0	0	0
1.9. Medicines for external use			
(a) <i>Skin medicines</i>			
— Antiseptic solutions	0	0	0
— Antibiotic ointments	0	0	0
— Anti-inflammatory and analgesic ointments	0	0	0
— Burn preparations	0	0	0
(b) <i>Eye medicines</i>			
— Antibiotic drops	0	0	0
— Antibiotic and anti-inflammatory drops	0	0	0
— Anaesthetic drops	0	0	0
— Hypotonic myotic drops	0	0	0
(c) <i>Ear medicines</i>			
— Antibiotic solutions	0	0	0
— Anaesthetic and anti-inflammatory solutions	0	0	0
(d) <i>Medicines for oral and throat infections</i>			
— Antibiotic or antiseptic mouthwashes	0	0	0
(e) <i>Local anaesthetics</i>			
— Local anaesthetics given by subcutaneous injection	0	0	0
— Dental anaesthetic and antiseptic mixtures	0	0	0
2. MEDICAL EQUIPMENT			
2.1. Resuscitation equipment			
— Manual resuscitation appliance	0	0	0
— Appliance for the administration of oxygen with pressure-reducing valve such that ship's industrial oxygen can be used, or oxygen container	0	0	0
— Mechanical aspirator to clear upper respiratory passages	0	0	0
— Cannula for mouth-to-mouth resuscitation	0	0	0
2.2. Dressing and suturing equipment			
— Disposable suture stapler or suture kit with needles	0	0	0
— Adhesive elastic bandage	0	0	0
— Sterile gauze compresses	0	0	0
— Cotton wool	0	0	0
— Sterile sheet for burns victims	0	0	0
— Triangular sling	0	0	0
— Disposable polyethylene gloves	0	0	0
— Adhesive dressings	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
— Vaseline gauze	0	0	0
2.3. Instruments			
— Stainless-steel instrument box	0	0	0
— Scissors	0	0	0
— Dissecting forceps	0	0	0
— Haemostatic clamps	0	0	0
2.4. Examination and monitoring equipment			
— Disposable tongue depressors	0	0	0
— Medical evacuation sheets	0	0	0
— Stethoscope	0	0	0
— Aneroid sphygmomanometer	0	0	0
— Standard medical thermometer	0	0	0
— Hypothermic thermometer	0	0	0
2.5. Equipment for injection, perfusion, puncture and catheterization			
— Disposable syringes and needles	0	0	0
2.6. Immobilization and setting equipment			
— Malleable finger splint	0	0	0
— Malleable forearm and hand splint	0	0	0
— Inflatable splint	0	0	0
— Thigh splint	0	0	0
— Collar for neck immobilization	0	0	0
3. ANTIDOTES			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0
3.4. Nervous system	0	0	0
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen	0	0	0

Venue and date:

Captain's signature:

Authorization by competent person or authority:

SECTION C. CATEGORY C VESSELS

I. Details of the vessel

Name:
Flag:
Home port:

II. Medical supplies

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
1. MEDICINE			
1.1. Cardiovascular			
(a) Anti-angina preparations	0	0	0
(b) Anti-haemorrhagics including uterotonics if there are women on board	0	0	0
1.2. Gastro-intestinal system			
(a) anti-emetics	0	0	0
(b) anti-diarrhoeals	0	0	0
1.3. Analgesics and anti-spasmodics			
— Analgesics, anti-pyretics and anti-inflammatory preparations	0	0	0
1.4. Nervous system			
— Seasickness remedies	0	0	0
1.5. Medicines for external use			
— Skin medicines			
— Antiseptic solutions	0	0	0
— Burn preparations	0	0	0
2. MEDICAL EQUIPMENT			
2.1. Resuscitation equipment			
— Cannula for mouth-to-mouth resuscitation	0	0	0
2.2. Dressing and suturing equipment			
— Adhesive elastic bandage	0	0	0
— Sterile gauze compresses	0	0	0
— Disposable polyethylene gloves	0	0	0
— Adhesive dressings	0	0	0
— Sterile compression bandages	0	0	0
— Adhesive sutures or zinc oxide bandages	0	0	0
3. ANTIDOTES			
3.1. General	0	0	0
3.2. Cardio-vascular	0	0	0
3.3. Gastro-intestinal system	0	0	0

	Quantities required	Quantities actually carried on board	Remarks (in particular, any expiry date)
3.4. Nervous system	0	0	0
3.5. Respiratory system	0	0	0
3.6. Anti-infective	0	0	0
3.7. For external use	0	0	0
3.8. Other	0	0	0
3.9. Necessary for the administration of oxygen	0	0	0

Venue and date:
Captain's signature:
Authorization of the competent person or authority:

ANNEX V

MEDICAL TRAINING OF THE CAPTAIN AND DESIGNATED WORKERS

(Article 5 (3))

- I. 1. Basic understanding of physiology, symptomatology and therapeutics.
 - 2. Elements of preventive medicine, notably individual and collective hygiene, and elements of possible prophylactic measures.
 - 3. Ability to perform basic types of treatment and supervise emergency disembarkation at sea.
Person responsible for treatment aboard category A vessels should if possible receive their practical training in hospitals.
 - 4. Detailed knowledge of how to use the various remote medical consultation facilities.
- II. This training should take account of the programmes of instruction detailed in relevant recent international documents.