STATUTORY INSTRUMENTS

1992 No. 3273

MEDICINES

The Medicines (Labelling) Amendment Regulations 1992

Made - - - -	*22nd December 1992*
Laid before Parliament	*23rd December 1992*
Coming into force - -	*1st January 1993*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred upon them by sections 85(1) and 91(3) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said provisions and now vested in them(**2**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**3**), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Labelling) Amendment Regulations 1992, and shall come into force on 1st January 1993.

(2) In these Regulations "the principal Regulations" means the Medicines (Labelling) Regulations 1976(**4**).

Amendment of regulation 3(1) of the principal Regulations

2.—(1) Regulation 3(1) of the principal Regulations (interpretation) shall be amended in accordance with the following paragraphs of this regulation.

(2) After the definition of "business name" there shall be inserted the following—

(**1**) 1968 c. 67. The expression "the Ministers" is defined in section 1(1) of that Act as amended.
(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I.1969/388); in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales)(No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).
(**3**) See section 129(6) of the Medicines Act 1968 (c. 67).
(**4**) S.I. 1976/1726; the relevant amending instruments are S.I. 1977/996, 1977/2168, 1978/41, 1978/1140, 1983/1729, 1985/1558, 1988/1009.

""common name" in relation to a relevant medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name;".

(3) After the definition of "medicinal products of the same description" there shall be inserted the following—

""name" in relation to a relevant medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product;".

(4) After the definition of "person responsible for the composition of a medicinal product" there shall be inserted the following—

""product to which Chapters II to V of the 1965 Directive applies" means a medicinal product to which, in accordance with Article 2 of Council Directive 65/65/EEC as amended(**5**), Article 34 of Council Directive 75/319/EEC(**6**), Article 1 of Council Directive 89/342/EEC(**7**), Article 1 of Council Directive 89/343/EEC(**8**) and Article 1 of Council Directive 89/381/EEC(**9**), Chapters II to V of Council Directive 65/65/EEC apply;".

(5) After the definition of "quantity" there shall be inserted the following—

""relevant medicinal product" means a product to which Chapters II to V of the 1965 Directive applies in respect of which a product licence is granted or renewed on or after 1st January 1994;".

(6) After the definition of "specified publication" there shall be inserted the following—

""strength" in relation to a relevant medicinal product means the content of active ingredient in that product expressed quantitatively per dosage unit, per unit volume or by weight, according to the dosage form;".

Insertion of regulations 4A, 4B, 4C, 4D and 4E into the principal Regulations

3. After regulation 4 of the principal Regulations there shall be inserted the following regulations—

"**Standard labelling requirements for containers and packages for medicinal products for human use**

4A.—(1) Except where paragraph (2) or (3) of this regulation applies, containers and packages of relevant medicinal products shall be labelled to show the particulars set out in Schedule 7 to these regulations.

(2) Where the container of a relevant medicinal product is not a blister pack and is too small to be labelled to show all of the particulars set out in Schedule 7 to these regulations, it shall nevertheless be labelled to show the particulars set out in paragraphs 1, 4, 6, 9 and 15 of that Schedule.

(3) Where the container of a relevant medicinal product is a blister pack and is enclosed within a package which complies with paragraph (1) of this regulation, that container shall be labelled to show the particulars set out in paragraphs 1, 9, 12 and 15 of Schedule 7 to these regulations.

(4) Containers and packages of relevant medicinal products may be labelled to show—

(**5**) OJ No. 22, 9.2.1965, p.369/65; the relevant amending Directive is Article 1(3) of 89/341/EEC (OJ No. L142, 25.5.1989, p.11).
(**6**) OJ No. L147, 9.6.1975, p.13.
(**7**) OJ No. L142, 25.5.1989, p.14.
(**8**) OJ No. L142, 25.5.1989, p.16.
(**9**) OJ No. L181, 28.6.1989, p.44.

(a) a symbol or pictogram designed to clarify the particulars set out in Schedule 7 to these regulations;

(b) other information compatible with the summary of product characteristics which is useful for health education,

to the exclusion of any element of a promotional nature.

(5) In sub-paragraph (b) of paragraph (4) of this regulation, "summary of product characteristics" means the information required to accompany any application for a product licence by virtue of Article 4a of Directive 65/65/EEC which was inserted by Article 1(2) of Directive 83/570/EEC(**10**) and amended by Article 1(1) and (4) of Directive 89/341/EEC, which expression shall include, where there no such information accompanied the application—

(a) the data sheet, if there is one; or

(b) if there is no data sheet, the information which would be required to accompany an application for a product licence by virtue of Article 4a of Directive 65/65/EEC.

Standard labelling requirements for containers and packages of radiopharmaceuticals for human use

4B. Containers and packages of products to which Chapters II to V of the 1965 Directive applies which are radiopharmaceuticals shall be labelled to show the particulars set out in Schedule 8 to these regulations in addition to any particulars required by any other provision of these regulations.

General provisions relating to labelling of medicinal products for human use

4C.—(1) All labelling of containers and packages of relevant medicinal products shall be—

(a) legible and indelible;

(b) comprehensible; and

(b) either in the English language only or in English and in one or more other languages provided that the same particulars appear in all the languages used.

(2) Where the holder of a product licence for a relevant medicinal product proposes to alter the labelling relating to it in any respect as to which regulation 4A of these regulations imposes a requirement (not being an application made in connection with the grant or variation of a product licence), he shall notify the licensing authority in writing of such proposed alteration and, unless the licensing authority has earlier notified him that it does not approve the altered labelling, he may, after the expiry of 90 days from the date of notification by him, supply the product, or cause the product to be supplied, with the altered labelling.

Special requirements for the labelling of the name of medicinal products for human use

4D.—(1) In any case where—

(a) a relevant medicinal product is available in more than one pharmaceutical form or in more than one strength; and

(b) the name of that product does not include the pharmaceutical form and the strength of the product,

(**10**) OJ No. L332, 28.11.1983, p.1.

in a place where the label prominently shows the name of the product there shall be added immediately after the name, in the same style and size of letters as the name, a statement of the pharmaceutical form or strength of that product; and in this paragraph "strength" means the suitability of the product for a baby, child or adult.

(2) The requirement for a container or package of a relevant medicinal product to be labelled to show its name is not met by the container or package being labelled to show an invented name which is liable to be confused with the common name.

Application of particular regulations

4E. Regulations 5 to 8, 11, 12, 14D and E, 15 to 17, 18(2) and 19 of these regulations shall not apply in relation to relevant medicinal products.".

Insertion of Schedules 7 and 8 into the principal Regulations

4. After Schedule 6 to the principal Regulations, there shall be inserted the following Schedules—

"SCHEDULE 7 Regulation 4A(1)

STANDARD LABELLING REQUIREMENTS FOR CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS FOR HUMAN USE

1. The name of the product followed, where the product contains one active ingredient and its name is an invented name, by the common name.

2. A statement of the active ingredients of the product expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names of the ingredients.

3. The pharmaceutical form of the product.

4. The contents of the product by weight, by volume or by number of doses of the product.

5. A list of excipients known to have a recognised action or effect. In relation to products which are injectable or are topical or eye preparations, all excipients.

6. The method and, if necessary, the route of administration of the product.

7. A special warning that the product must be stored out of reach of children.

8. Any special warning required by the product licence for the product concerned.

9. The expiry date of the product (stating the month and year) in clear terms.

10. Any special storage precautions for the product.

11. Any special precautions for the disposal of any unused products or waste materials derived from such products.

12. The name of the holder of the product licence of the product.

13. The address of the holder of the product licence of the product.

14. Any product licence number as allocated by the licensing authority which relates to the product preceded by the letters "PL" in capital letters or other abbreviation of the expression "product licence".

15. The manufacturer's batch reference.

16. Where a product is intended for self-medication, any instruction on the use of the product.

SCHEDULE 8

Regulation 4B

STANDARD LABELLING REQUIREMENTS FOR CONTAINERS AND PACKAGES OF RADIOPHARMACEUTICALS FOR HUMAN USE

1. The container and the package shall be labelled in accordance with the 1985 Edition (as amended in 1990) of the Regulations for the Safe Transport of Radioactive Materials recommended by the International Atomic Energy Agency.

2. The labelling on the shielding shall explain in full the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or for liquids, the number of millilitres in the container.

3. The vial shall be labelled to show—

(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;

(b) the international symbol for radioactivity;

(c) the name of the manufacturer; and

(d) the amount of radioactivity as specified in paragraph 2 above.".

Virginia Bottomley
21st December 1992 Secretary of State for Health

David Hunt
21st December 1992 Secretary of State for Wales

Fraser of Carmyllie
21st December 1992 Minister of State, Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd December 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 18th December 1992.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th December 1992.

L.S.

W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Labelling) Regulations 1976 "the 1976 Regulations") implementing in part Council Directive 92/27/EEC (OJNo. L113, 30.4.1992, p.8) ("the Directive") which, inter alia, lays down the requirements for labelling of containers and packages of medicinal products for human use for which a product licence is granted or renewed on or after 1st January 1994.

Regulations 3 and 4 (which insert the new regulations 4A(1) and the new Schedule 7 and which derive from article 2(1) of the Directive) make new provision for the labelling of packages and containers of certain medicinal products for human use (see the definitions of "product to which Chapters II to V of the 1965 Directive applies" inserted by regulation 2(4) and of "relevant medicinal product" inserted by regulation 2(5)). In respect of other medicinal products, existing provisions of the 1976 Regulations remain in force.

Different requirements apply for the labelling of small containers of medicinal products and containers which are blister packs (see the new regulation 4A(2) and (3) inserted by regulation 3, deriving from article 3(2) and (3) of the Directive). The Regulations also allow symbols, pictograms or other information to appear on such labels provided there is no promotional element (new regulation 4A(4)).

Requirements are also imposed to the effect that the particulars on the label must be legible, comprehensible and in the English language. Particulars may appear in more than one language if one language is English, and the same particulars must appear in all the languages used (see the new regulation 4C(1) inserted by regulation 3, deriving from article 4(2) of the Directive). In addition, a procedure is imposed for notifying the licensing authority of alteration to labels of relevant medicinal products (new regulation 4C(2)).

The Regulations also provide for certain information to be shown on a label where the name of a relevant medicinal product is given, where that information does not form part of that name (see the new regulation 4D inserted by regulation 3).

These Regulations also implement article 5 of Council Directive 89/343/EEC (OJ No. L142, 25.5.1989, p.16) which imposes special requirements for the labelling of radiopharmaceuticals (see the new regulation 4B and the new Schedule 8 inserted by regulations 3 and 4).

Copies of the Regulations for the Safe Transport of Radioactive Materials recommended by the International Atomic Energy Agency (referred to in the new Schedule 8) may be obtained from Government bookshops quoting ISBN 92 0 12390 8, price £19.00 net.