STATUTORY INSTRUMENTS

1992 No. 3274

MEDICINES

The Medicines (Leaflets) 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 respectively concerned with health and with agriculture in Wales and in Scotland, 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 86(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 (Leaflets) Amendment Regulations 1992, and shall come into force on 1st January 1993.

(2) In these Regulations, "the principal Regulations" means the Medicines (Leaflets) Regulations 1977(**4**).

Amendment of regulation 2(1) of the principal Regulations

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

(**1**) 1968 c. 67. The expression "the Ministers" is defined in section 1(1) of that Act as amended. That section of the Act applies to radiopharmaceutical-associated products by virtue of regulation 2(1) of, and the Schedule to, the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605).

(**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) ofSchedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) *See* section 129(6) of the Medicines Act 1968 (c. 67).

(**4**) S.I. 1977/1055.

(2) After the definition of "medicinal product" there shall be inserted the following—

""generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

"kit" means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to its administration;

"precursor" means a radionuclide produced for the radio-labelling of another substance prior to administration, other than a radionuclide which is incorporated in, or produced from, a generator, or is included in a radiopharmaceutical;

"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;".

(3) For the definition of "proprietary medicinal product" shall be substituted the following—

""proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack, but does not include a homeopathic medicinal product or veterinary drug and references to a proprietary medicinal product shall be taken to include a reference to a radiopharmaceutical-associated product;".

(4) After that definition of "proprietary medicinal product" there shall be inserted the following—

""radiopharmaceutical" means any medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"radiopharmaceutical-associated product" means a generator, kit or precursor which is not itself a medicinal product;

"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;

"summary of product characteristics" means the information required to accompany any application for a product licence by virtue of article 4a of Council Directive 65/65/EEC which was inserted by article 1(2) of Council Directive 83/570/EEC(**10**) as amended by article 1(1) and (4) of Council Directive 89/341/EEC.".

Amendment of regulation 3 of the principal Regulations

3. For regulation 3 of the principal Regulations (standard requirements relating to leaflets) there shall be substituted the following regulation—

> "**3.**—(1) Subject to the following provisions of these regulations, all leaflets included in the package or container of any proprietary medicinal products other than relevant medicinal products shall contain the particulars set out in Schedule 1 to these regulations.
>
> (2) Subject to the following provisions of these regulations, all leaflets included in the package or container of any relevant medicinal products shall contain the particulars set out in Schedule 2 to these regulations in the order shown in that Schedule.".

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

Insertion of regulation 3A into the principal Regulations

4. After regulation 3 of the principal Regulations (standard requirements relating to leaflets), there shall be inserted the following regulation—

"**Standard requirements relating to leaflets for radiopharmaceuticals and radiopharmaceutical-associated products**

3A. Subject to the following provisions of these regulations, any leaflet which is enclosed with the packaging of a proprietary medicinal product which is a radiopharmaceutical or a radiopharmaceutical-associated product shall, in addition to containing any particulars required by any other provision of these regulations, contain—

(a) details of any precautions to be taken by the user and the patient during the preparation and administration of the product;

(b) details of any special precautions to be taken in respect of the disposal of the container and its unused contents.".

Amendment of regulation 4 of the principal Regulations

5.—(1) Regulation 4 of the principal Regulations (general provisions) shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1), for the words "such a leaflet" there shall be substituted "a leaflet relating to a proprietary medicinal product other than a relevant medicinal product".

(3) After paragraph (1) there shall be inserted the following—

"(1A) All particulars contained in such a leaflet as is described in regulation 3 above relating to a relevant medicinal product shall be drawn up in accordance—

(a) with the summary of product characteristics, if there is one;

(b) if there is no summary of product characteristics, with the data sheet, if there is one;

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

(4) In paragraph (2)—

(a) the word "such" shall be omitted;

(b) after the word "shall" shall be inserted the words "be written in clear and understandable terms for the patient, be clearly legible and"; and

(c) at the end of that paragraph, there shall be inserted the following:—

"but particulars contained in a leaflet relating to a relevant medicinal product may be given in English and in one or more other languages provided that the same particulars appear in all the languages used.".

(5) In paragraph (3) for the words "such leaflet" there shall be substituted "leaflet relating to a proprietary medicinal product other than a relevant medicinal product".

(6) Paragraph (5) shall be omitted.

(7) In paragraph (6)—

(a) for "the Schedule" there shall be substituted "Schedule 1"; and

(b) for "such a leaflet" there shall be substituted "a leaflet relating to a proprietary medicinal product other than a relevant medicinal product".

(8)

After paragraph (6) there shall be inserted the following paragraphs—

"(7) The particulars set out in paragraph 2 of Schedule 2 to these regulations shall not be required to be included in a leaflet relating to a relevant medicinal product where the product licence which relates to that product contains a provision directing that such particulars shall not be so included.

(8) A leaflet relating to a relevant medicinal product may include—

(a) a symbol or pictogram designed to clarify the particulars set out in Schedule 2 to these regulations;

(b) other information in accordance with paragraph (1A) of this regulation which is useful for health education,

to the exclusion of any element of a promotional nature.

(9) Where a leaflet—

(a) relates to a relevant medicinal product which is available in more than one pharmaceutical form or in more than one strength, and

(b) the name of that product does not include its pharmaceutical form or an indication of its strength,

there shall be added immediately after the name as required by paragraph 1 of Schedule 2 to these regulations, in the same style and size of letters as the name, a statement of the pharmaceutical form and an indication of the strength or both (as appropriate) of that product; and in this paragraph "strength" means the suitability of the product for a baby, child or adult.".

Amendment of regulation 5 of the principal Regulations

6.—(1) In paragraph (1) of regulation 5 of the principal Regulations (approval of contents of leaflets), after the words "a proprietary medicinal product" there shall be inserted the words "other than a relevant medicinal product".

(2) After paragraph (2) of regulation 5 of the principal Regulations (approval of contents of leaflets) there shall be inserted the following paragraph—

"(2A) Where the holder of a product licence for a relevant medicinal product proposes to alter the leaflet relating to it in any respect as to which regulation 4 of these regulations imposes a requirement (not being an alteration 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 leaflet, he may after the expiry of a period of 90 days from the date of the notification by him, supply that altered leaflet, or cause it to be supplied, with that product."

Amendment of the heading and numbering of the Schedule to the principal Regulations

7. For the heading of the Schedule to the principal Regulations (particulars required to be included in leaflets), there shall be substituted the following—

"SCHEDULE 1 Regulation 3(1)"

PARTICULARS REQUIRED TO BE INCLUDED IN LEAFLETS
RELATING TO PROPRIETARY MEDICINAL PRODUCTS
OTHER THAN RELEVANT MEDICINAL PRODUCTS

Insertion of Schedule 2 into the principal Regulations

8. After Schedule 1 there shall be inserted the following—

"SCHEDULE 2 Regulation 3(2)

PARTICULARS REQUIRED TO BE INCLUDED IN LEAFLETS RELATING TO RELEVANT MEDICINAL PRODUCTS

1. For identification of the medicinal product—

(a) the name of the medicinal product followed where the product contains only one active ingredient and its name is an invented name, by the common name;

(b) 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 medicinal product;

(c) 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;

(d) the pharmaco-therapeutic group, or type of activity in terms easily comprehensible for the patient;

(e) the name and address of the holder of the product licence and of the manufacturer.

2. The therapeutic indications.

3. A list of information which is necessary before taking the medicinal product, as follows—

(a) contra-indications;

(b) appropriate precautions for use;

(c) forms of interaction with other medicinal products, with alcohol, tobacco and food and any other form of interaction which may affect the action of the medicinal product;

(d) special warnings,

which

(i) take into account the particular condition of certain categories of users;

(ii) mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery;

(iii) give details of those excipients, knowledge of which is important for the safe and effective use of the medicinal product.

4. The necessary and usual instructions for proper use of the medicinal product which shall include:—

(a) the dosage;

(b) the method and, if necessary, route of administration;

(c) the frequency of administration, specifying if necessary the time at which the medicinal product may or must be administered;

and, where the nature of the product makes it appropriate, shall also include—

(d) the duration of treatment where it should be limited;

(e) the action to be taken in the case of an overdose;

(f) the course of action to take when one or more doses have not been taken;

(g) indication, if necessary, of the risk of withdrawal effects.

5. A description of the undesirable effects which can occur with normal use of the medicinal product and if necessary, the action to be taken in such a case, together with an express invitation to the patient to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or pharmacist.

6. A reference to the expiry date indicated on the label with:—

(a) a warning against using the product after this date;

(b) where appropriate, special storage precautions;

(c) if necessary, a warning against certain visible signs of deterioration.

7. The date upon which the leaflet was last revised.".

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 (Leaflets) Regulations 1977 ("the 1977 Regulations") by implementing in part Council Directive 92/27/EEC (OJNo.L113, 30.4.92, p.8) ("the Directive") which, inter alia, lays down the requirements for the form and content of leaflets supplied with certain medicinal products for human use for which a product licence is granted or renewed on or after 1st January 1994.

Regulations 3 and 8 (which derive from article 7(1) of the Directive) amend the 1977 Regulations to prescribe requirements for the content of such leaflets. In respect of proprietary medicinal products other than those defined in regulation 2(4) of these Regulations as relevant medicinal products, existing provisions of the 1977 Regulations remain in force (regulations 5(2), (5), (7) and 7).

The Regulations provide that leaflets for relevant medicinal products are to be drawn up in accordance with the summary of product characteristics or the data sheet or where neither of these documents exist with the information which would be in such a summary (new regulation 4(1A) as inserted by regulation 5(2)).

The Regulations also allow leaflets for relevant medicinal products to be printed in more than one language provided one is English and the same particulars appear in each language (regulation 5(4), article 8 of the Directive), allow the licensing authority to direct in the product licence that certain therapeutic indications shall not appear on leaflets (new regulation 4(7) as inserted by regulation 5(8), article 7(2) of the Directive) and allow symbols, pictograms or other information to appear on such leaflets if there is no promotional element (new regulation 4(8) as inserted by regulation 5(8)).

The Regulations provide for certain information to be shown where the name of a relevant medicinal product is given, where that information does not form part of that name (new regulation 4(9) as inserted by regulation 5(9), article 7.1(a) of the Directive).

In addition, a procedure is imposed for notifying the licensing authority of alterations to leaflets for relevant medicinal products (regulation 6, article 10(3) of the Directive).

There are amendments to the definitions in the 1977 Regulations in consequence of these amendments (regulation 2).

These Regulations also implement article 6 of Council Directive 89/343/EEC (OJNo.L142 25.5.1989 p.16) which imposes special requirements for the leaflets supplied with proprietary medicinal products which are radiopharmaceuticals and with radiopharmaceutical-associated products (regulation 4).