STATUTORY INSTRUMENTS

1977 No. 1055

MEDICINES

The Medicines (Leaflets) Regulations 1977

Made - - - -	*21st June 1977*
Laid before Parliament	*24th June 1977*
Coming into Operation	*15th July 1977*

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture 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 by sections 86(1) and 91(2) of the Medicines Act 1968 and now vested in them(**1**) 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 the regulations, hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Medicines (Leaflets) Regulations 1977 and shall come into operation on 15th July 1977.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"medicinal product" has the same meaning as in section 130(1)(a) of the Act;

"proprietary medicinal product" means—

(a) a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack,

(b) for the purposes of paragraph (a) "medicinal product" does not include—

(i) vaccines, toxins or serums,

(**1**) 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(1969 I, p. 1070)), and 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).

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homoeopathic medicinal products, or

(iv) veterinary drugs;

and other expressions have the same meanings as in the Act or in the Medicines (Labelling) Regulations 1976(**2**) as amended(**3**)

(2) Except in so far as the context otherwise requires, any reference in these regulations to any enactment, order or regulations shall be construed as a reference to that enactment or order or those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(3) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889 shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Standard requirements relating to leaflets

3. Subject to the following provisions of these regulations, all leaflets relating to proprietary medicinal products which are supplied, or are intended to be supplied, with proprietary medicinal products shall contain the particulars set out in the Schedule to these regulations.

General provisions

4.—(1) All particulars contained in such a leaflet as is described in regulation 3 above, including the particulars required to be so contained by these regulations, shall be consistent with the provisions of any product licence granted under Part II of the Act in respect of the proprietary medicinal product which relates to such particulars.

(2) All particulars required by these regulations to be contained in such a leaflet shall, except with respect to numerals, be given in the English language.

(3) Except as provided in paragraph (4) below no such leaflet shall contain any reference to a medicinal product of any description other than the proprietary medicinal product with which that leaflet is supplied or is intended to be supplied.

(4) Notwithstanding the provisions of paragraph (3) above such a leaflet which—

(a) contains instructions solely in respect of the use of an apparatus or appliance for the purpose of administration of the proprietary medicinal product to which the leaflet relates, being instructions that are capable of having equal application to other medicinal products having the same pharmaceutical form, or

(b) contains the particulars set out in paragraphs 4 to 8 of the Schedule to these regulations, being particulars that would be the same in all respects in relation to other medicinal products of a different description, or

(c) contains any reference to a medicinal product other than the proprietary medicinal product to which the leaflet relates in so far as such reference is necessary to explain the contra-indications or precautions or the action to be taken in the event of overdosage of the proprietary medicinal product to which that leaflet relates,

may contain references to such other medicinal products.

(5) The particulars required by these regulations to be contained in such a leaflet shall be clearly separate from the remainder of the contents of the leaflet.

(**2**) (1976 III, p. 4570).
(**3**) S.I. 1977/996 (1977 II, p. 2813).

(6) The particulars set out in paragraphs 4 and 5 of the Schedule to these regulations shall not be required to be included in such a leaflet where—

(a) it is a provision of the product licence which relates to the proprietary medicinal product that the product is to be sold or supplied only by an appropriate practitioner or in accordance with a prescription given by a practitioner, or

(b) the proprietary medicinal product is a product which is of a description or falls within a class specified in an order made under section 58(1) of the Act (medicinal products on prescription only) and which is subject to the restrictions imposed by section 58(2) of the Act, or

(c) the product licence which relates to the proprietary medicinal product contains a provision directing that such particulars shall not be so included.

Approval of contents of leaflets

5.—(1) The holder of a product licence which relates to a proprietary medicinal product shall send or deliver to the licensing authority a copy of the particulars to be included in any leaflet as aforesaid not less than 42 days (or such shorter period as the authority may allow) before the first supply of the leaflet.

(2) Where the holder of a product licence has delivered a copy of the particulars to be included in such a leaflet to the licensing authority in accordance with paragraph (1) of this regulation and he has been informed in writing by the licensing authority, not later than 21 days after receipt of such particulars by the authority, that a leaflet containing such particulars ought not to be so supplied, or ought to be supplied only in a modified form, the holder of the licence shall not supply, or cause another person to supply, any such leaflet containing such particulars or, as the case may be, such particulars other than in a modified form, unless the consent of the licensing authority has been given in writing.

(3) Any person who contravenes this regulation shall be guilty of an offence and shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

Temporary and transitional provisions

6.—(1) These regulations shall not have effect—

(a) in relation to a proprietary medicinal product in respect of which a product licence was granted prior to the coming into operation of these regulations, until 1st October 1977;

(b) in relation to a leaflet which was printed before the date of the coming into operation of these regulations with a view to being enclosed in the container or package of a proprietary medicinal product by or on behalf of the holder of the product licence, the licence not being a licence granted after the date of the coming into operation of these regulations, until 1st April 1980;

(c) in relation to a leaflet which is printed after the date of the coming into operation of these regulations and is a copy of a leaflet printed before that date, in a period ending not later than 1st April 1980 during which an amended form of the leaflet which complies with the provisions of these regulations is in course of preparation, provided that the holder of the product licence has delivered a copy of the leaflet to the licensing authority and the authority have not within the period of 21 days after receipt of the leaflet by the authority notified the holder of the licence that the leaflet ought not to be supplied with the proprietary medicinal product.

(2) These regulations shall not have effect in relation to a leaflet which before the date of the coming into operation of these regulations has been enclosed in the container or package of a proprietary medicinal product by or on behalf of the holder of the product licence, the licence not being a licence granted after that date.

David Ennals
13th June 1977 — Secretary of State for Social Services

John Morris
14th June 1977 — Secretary of State for Wales

Bruce Millan
16th June 1977 — Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th June 1977.

L.S.

John Silkin
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of June 1977.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of June 1977.

L.S.

J. A. Young
Permanent Secretary

SCHEDULE

Regulation 3

PARTICULARS REQUIRED TO BE INCLUDED IN LEAFLETS

1. The appropriate non-proprietary name of the proprietary medicinal product (if any) and a proprietary designation.

2. A statement of the appropriate quantitative particulars of the proprietary medicinal product and, where ingredients other than active ingredients are stated, distinguishing between such ingredients as are and such ingredients as are not active ingredients and, where the quantities stated are those from which the product has been prepared, such quantities being preceded by a statement to that effect, except that where any medicinal product or ingredient is identified by reference to a name, or abbreviation of a name, at the head of a monograph in a specified publication and the quantity of that product or ingredient is stated, the requirements of this paragraph shall be regarded as having been complied with.

3. Where any ingredient has an international non-proprietary name, that name, except that particulars of the international non-proprietary name shall not be required to be given where there is an insignificant difference between the spelling of that international non-proprietary name and such name at the head of a monograph or approved synonym or approved name.

4. Directions for use of the proprietary medicinal product.

5. Therapeutic indications for the proprietary medicinal product.

6. Contra-indications, warnings and precautions including any contra-indications, warnings and precautions required to be given by the provisions of any product licence relating to the proprietary medicinal product and thereby required to be addressed to the person to or by whom the product is to be administered.

7. Any special requirements for the handling and storage of the proprietary medicinal product.

(a) (a) The name and address of the holder of the product licence which relates to the proprietary medicinal product or the business name and address of the part of his business that is responsible for its sale or supply, or

(b) where the provisions of the product licence which relates to the proprietary medicinal product or a manufacturer's licence authorising the assembly of the product permit, or where the proprietary medicinal product is assembled by or under the supervision of a pharmacist in accordance with the provisions of section 10(1)(b) or 10(6) of the Act, the name and address of a person who sells the proprietary medicinal product by retail or supplies it in circumstances corresponding to retail sale.

9. The name and address of the person who has manufactured the proprietary medicinal product and, if different therefrom, the name and address of the person in the course of whose business the proprietary medicinal product was enclosed in its container, except that such requirement shall be treated as having been complied with if—

(a) one person only has manufactured the proprietary medicinal product, or

(b) more than one person has manufactured medicinal products of the same description as the proprietary medicinal product and the licensing authority have been notified of the names of the persons who have manufactured medicinal products of the same description and have directed that the name and address of any such person may be omitted.

EXPLANATORY NOTE

These Regulations made under the Medicines Act 1968 implement certain Community obligations under Council Directive 75/319/EEC which relates to proprietary medicinal products. The regulations prescribe particulars to be contained in leaflets supplied with proprietary medicinal products.