

1976 No. 1726

MEDICINES

The Medicines (Labelling) Regulations 1976

Made - - - 14th October 1976

Laid before Parliament 28th October 1976

Coming into Operation 22nd November 1976

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 85(1), 85(4), 86(1), and 91(2) and (3) of the Medicines Act 1968(a) and now vested in them(b) 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 following regulations, hereby make the following regulations:—

Citation

1. These regulations may be cited as the Medicines (Labelling) Regulations 1976.

Commencement

2. These regulations shall come into operation on 22nd November 1976 and, subject to the provisions of regulation 19 of these regulations, shall have effect—

- (a) in relation to a dispensed medicinal product, on 22nd November 1976;
- (b) in relation to a medicinal product to which—
 - (i) a product licence, clinical trial certificate or animal test certificate relates which is granted or issued on or after 22nd November 1976, or
 - (ii) a product licence which has been granted before 22nd November 1976 relates, any of the provisions of which relating to the composition of the medicinal product, or particulars as to the uses and effect of, or warnings concerning, the product, are varied on or after 22nd November 1976, except where the provisions of the product licence, as so varied, include a provision

(a) 1968 c. 67.

(b) 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 paragraph 2(1)(b) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

that labelling on containers and packages of the product may continue to be used after the date on which the provisions of the licence are so varied,

on the date on which such licence or certificate is granted or issued or the provisions of such licence are varied, as the case may be;

- (c) in relation to a medicinal product, not being a medicinal product to which the provisions of paragraph (a), (b), (d) or (e) of this regulation apply, on 1st July 1977;
- (d) in relation to a medicinal product to which a product licence which is a licence of right relates, or a medicinal product in such a container as is mentioned in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units), not, in either case, being a medicinal product to which the provisions of paragraph (a) or (b) of this regulation apply—
 - (i) where such medicinal product is assembled in the same labelled container in which the product is to be sold by retail or supplied in circumstances corresponding to retail sale, on 1st January 1979, or
 - (ii) where such medicinal product is not such a product as is mentioned in the preceding sub-paragraph, on 1st January 1980;
- (e) in relation to such a medicinal product as is mentioned in regulation 14 of these regulations (medicinal products for incorporation in animal feeding stuffs), on 1st July 1977.

Interpretation

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

“the Act” means the Medicines Act 1968;

“animal feeding stuff” includes a complete feeding stuff, a feed supplement and a protein concentrate;

“appropriate non-proprietary name” in relation to a medicinal product or ingredient means—

- (i) where the medicinal product or ingredient is described in a monograph in a specified publication any name, or abbreviation of such name, at the head of that monograph or, in the case of the European Pharmacopoeia, an approved synonym or, where such name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that specified publication, or
- (ii) where the medicinal product or ingredient is not described in a monograph in a specified publication but has an approved name, such approved name, or
- (iii) where the medicinal product or ingredient is not described in a monograph in a specified publication and does not have an approved name, but has an international non-proprietary name, such international non-proprietary name, or
- (iv) where the medicinal product is not described in a monograph in a specified publication and does not have an approved name or an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of the medicinal product or ingredient;

“appropriate quantitative particulars” means—

- (i) the quantity of each active ingredient, or that part of the active molecule responsible for the therapeutic or pharmacological activity, identified by its appropriate non-proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity, or units of activity, or, where the medicinal product consists of confectionery in the form of a pastille or lozenge, expressed as aforesaid or in terms of a percentage by weight or volume of such pastille or lozenge, or, where the medicinal product is a homoeopathic product, expressed in terms of the dilution of the unit preparation of that active ingredient, or
- (ii) where there is no dosage unit, the quantity of each active ingredient or that part of the active molecule responsible for the therapeutic or pharmacological activity, identified by its appropriate non-proprietary name, in the container of the medicinal product expressed in terms of weight, volume, capacity, or units of activity, or percentage by weight or volume of the total quantity, or, where the medicinal product is a homoeopathic product, expressed in terms of the dilution of the unit preparation of that active ingredient, or
- (iii) where the medicinal product contains any active ingredient that cannot be definitively characterised, the quantity of each ingredient or that part of the active molecule responsible for the therapeutic or pharmacological activity, identified by its appropriate non-proprietary name, expressed in terms of weight, volume, capacity, or units of activity or percentage by weight or volume, from which each dosage unit of the medicinal product, or, where there is no dosage unit, the quantity of the medicinal product in the container, has been prepared, or, where the medicinal product is a herbal remedy in solution in liquid form, the total quantity of the active ingredient which is in solid form in the container, or, where the medicinal product is a homoeopathic product, expressed in terms of the dilution of the unit preparation of that active ingredient or
- (iv) where there are no active ingredients in the medicinal product, the quantity of the ingredient which is present in the highest proportion whether in weight, volume or capacity, identified by its appropriate non-proprietary name, expressed in terms of weight, volume, capacity, or percentage by weight or volume of the total quantity from which the medicinal product in the container has been prepared, except where such ingredient is a diluent, excipient, preservative, stabiliser or bulking agent or, where the medicinal product is a homoeopathic product, expressed in terms of the dilution of the unit preparation of that active ingredient, or
- (v) where the medicinal product includes a biological substance to which an antimicrobial preservative has been added in addition to an active ingredient, the quantity of such antimicrobial preservative in the container of the medicinal product, expressed in terms of weight, volume, capacity or percentage by weight or volume of the total quantity;

“approved name” means the name which appears in the current edition (as defined in section 103(5) of the Act) of the list prepared and published under section 100 of the Act as in force at the time of sale or supply of the medicinal product by the person who has labelled the container of the medicinal product;

“approved synonym” has the same meaning as in section 65(8) of the Act;

“biological substance” includes an antigen, toxin, antitoxin, serum, antiserum or vaccine;

“business name” means a name or style under which any business is being carried on, being a name or style required to be registered under the Registration of Business Names Act 1916(a);

“complete feeding stuff” means a substance or a mixture of substances designed for feeding to animals without further mixing with other feeding stuffs;

“data sheet” has the same meaning as in section 96(6) of the Act;

“dispensed medicinal product” means—

- (i) a medicinal product prepared or dispensed by a practitioner or prepared or dispensed in accordance with a prescription given by a practitioner, or
- (ii) a medicinal product for use by being administered to human beings where that medicinal product has been sold or supplied by a doctor or dentist for administration to a particular patient of his and that doctor or dentist sells or supplies that medicinal product to that patient or to a person under whose care that patient is, or
- (iii) a medicinal product for use by being administered to animals where that medicinal product has been sold or supplied by a veterinary surgeon or veterinary practitioner for administration to a particular animal or herd which is under the care of that veterinary surgeon or veterinary practitioner, to a person having the possession or control of that animal or herd, or
- (iv) a medicinal product prepared or dispensed in a registered pharmacy by or under the supervision of a pharmacist in the circumstances set out in sections 10(3) or 10(4)(a) of the Act, or
- (v) a medicinal product where the person selling or supplying the medicinal product sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person’s presence to use his own judgment as to the treatment required;

“dosage unit” means, where the medicinal product is in the form of a tablet, capsule or other discrete article, that tablet, capsule or discrete article, or, where the medicinal product is not in such form as afore-said, that quantity of the medicinal product which is used as the unit by reference to which the dose of the medicinal product is measured;

- “expiry date” means the date after which, or the month and year after the end of which, or the month and year before the beginning of which, the medicinal product should not be used;
- “feed supplement” means a substance or a mixture of substances designed for further mixing before feeding to animals at an inclusion rate of less than 5 per cent. with other animal feeding stuffs;
- “homoeopathic product” means a medicinal product prepared in accordance with the methods of homoeopathic medicine or similar system which is sold or supplied as a homoeopathic product and is so described by the person who sells or supplies that medicinal product;
- “foreign or international compendium of standards” means the national pharmacopoeia or similar compendium of a foreign country or the Specifications for the Quality Control of Pharmaceutical Preparations published by the World Health Organisation;
- “international non-proprietary name” means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the WHO Chronicle;
- “medicated” when used in relation to an animal feeding stuff, feed supplement or protein concentrate, means having a medicinal product incorporated therein;
- “medicinal product” includes articles or substances specified in the Medicines (Control of Substances for Manufacture) Order 1971(a) and in the Medicines (Surgical Materials) Order 1971(b) but shall not include any herbal remedy to which the provisions of section 12(2) of the Act are applicable;
- “medicinal products of the same description” has the same meaning as in section 130(8) of the Act;
- “person responsible for the composition of a medicinal product” has the same meaning as in section 7(6) of the Act;
- “proprietary designation” means a word or words used in connection with the sale or supply of medicinal products for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale or supply;
- “protein concentrate” means a substance or a mixture of substances designed for further mixing before feeding to animals at an inclusion rate of 5 per cent. or more with other animal feeding stuffs;
- “quantity” means, where the quantity is not the exact quantity, the quantity which is as near to the exact quantity as is reasonably practicable or which differs from the exact quantity only to such extent as is reasonably necessary in the circumstances having regard to the nature of the medicinal product in question;
- “requirements” includes restrictions;

(a) S.I. 1971/1200 (1971 II, p. 3506).

(b) S.I. 1971/1267 (1971 II, p. 3632).

“retail sale” has the same meaning as in section 131 of the Act;

“sale by way of wholesale dealing” has the same meaning as in section 131 of the Act;

“supply in circumstances corresponding to retail sale” has the same meaning as in section 131 of the Act;

“specified publication” has the same meaning as in section 103 of the Act;

“unit preparation” means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being further diluted tenfold, or serially in multiple powers of ten, in an inert liquid diluent, and then used either in liquid form or by impregnating tablets, granules, powders or other inert substances for the purposes of being administered to human beings;

and other expressions have the same meanings as in the Act.

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

(3) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) 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.

Application

4. Subject to the following provisions of these regulations, the requirements imposed by these regulations shall apply to medicinal products which, in the course of a business carried on by a person, are sold, supplied or are in his possession for the purpose of sale or supply in the United Kingdom.

Standard labelling requirements for containers and packages

5.—(1) Subject to the following provisions of these regulations, containers and packages of medicinal products shall be labelled so as to comply with the requirements specified in the following paragraphs of this regulation.

(2) Subject to paragraphs (3) to (5) of this regulation, every container of a medicinal product shall be labelled to show the particulars set out in Schedule 1 to these regulations, except that where the container is enclosed in a package, the particulars set out in paragraph 1(b) of that Schedule may be omitted, and, where the particulars set out in paragraph 3 of that Schedule are set out in a leaflet supplied with a medicinal product which is included in the package immediately enclosing the container of that medicinal product, such particulars may be omitted if both the container of the medicinal product and the package immediately enclosing the container are labelled to show that such particulars are included in the leaflet.

(3) Where the container of a medicinal product is an ampoule or other container of not more than 10 millilitres nominal capacity which is enclosed in a package, the provisions of paragraph (2) of this regulation shall not apply to such container which shall be labelled to show the particulars set out in

(a) 1889 c. 63.

paragraphs 1(a), (c), (d) and (e), 2, 7, 10 and 12 of Schedule 1 to these regulations and to include a statement specifying the route of administration of the medicinal product, except that such statement may be omitted from a container other than an ampoule where the route of administration is readily apparent.

(4) Where the container is in the form of a wrapper consisting of paper, film, plastic material, metal foil or other sheet or strip material or in the form of a bubble, blister or other sealed unit consisting of such sheet or strip material, enclosing one or more dosage units of a medicinal product and such container is enclosed in a package, the provisions of paragraph (2) of this regulation shall not apply to such container which shall be labelled to show the particulars set out in paragraphs 1(a), (d) and (e) and 12 of Schedule 1 to these regulations, except that where the container is of so small a size that it is not reasonably practicable to show the particulars set out in paragraph 12 of that Schedule, those particulars may be omitted and, where any such container is in the form of a capsule or similar article containing a medicinal product designed to be released for administration by manually or mechanically breaking the capsule or similar article and it is not reasonably practicable to show the particulars set out in paragraphs 1(a), (d) and (e) of that Schedule, those particulars may be omitted.

(5) For the purposes of paragraph (4) of this regulation, where a container which is in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph is part of a continuous series comprising a sheet or strip of like containers, that paragraph shall be deemed to have been complied with if the particulars referred to in that paragraph are displayed at frequent intervals on the said sheet or strip of such containers.

(6) Where the package immediately enclosing the container to which the provisions of paragraph (4) of this regulation apply is itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph such package shall be labelled to show the particulars referred to in that paragraph and, if such package is part of a continuous series comprising a sheet or strip of like packages, such particulars shall be displayed at frequent intervals on the said sheet or strip of such packages.

(7) Except in the case of a package to which the provisions of paragraph (6) of this regulation apply, every package immediately enclosing a container of a medicinal product shall be labelled to show the particulars set out in Schedule 1 to these regulations.

(8) Every package immediately enclosing a package to which the provisions of paragraph (6) of this regulation apply shall be labelled to show the particulars set out in Schedule 1 to these regulations.

Clinical trials

6. Subject to the following provisions of these regulations, where a medicinal product is for administration in a clinical trial—

- (a) every container of such medicinal product shall be labelled to show the particulars set out in Schedule 2 to these regulations and, except where the container is an ampoule or is enclosed in a package, particulars of any special requirements for the storage or handling of the medicinal product, and
- (b) every package immediately enclosing a container of such medicinal product shall be labelled to show the particulars set out in that Schedule and particulars of any special requirements for the storage or handling of the medicinal product.

Medicinal tests on animals

7. Subject to the following provisions of these regulations, where a medicinal product is for administration in a medicinal test on animals—

- (a) every container and every package immediately enclosing the container of such medicinal product shall be labelled with the words “For Animal Test Use Only” and to show the particulars set out in Schedule 3 to these regulations except that, where the container is an ampoule and it is enclosed in a package which is labelled to show all the particulars set out in that Schedule, it shall be labelled to show the particulars set out in paragraphs 1, 2, 7 and 8 of that Schedule and except that, where a product licence has been granted in respect of such medicinal product and the medicinal product is to be administered in the same pharmaceutical form as that described in the application for the grant of that product licence and in all respects in accordance with the provisions of that product licence, the words “For Animal Test Use Only” may be omitted, and
- (b) where any container which is required to be labelled in accordance with the provisions of paragraph (a) of this regulation is enclosed in more than one package, every package immediately enclosing the package immediately enclosing such container shall be labelled to show the particulars set out in paragraphs 1, 2 and 6 to 8 of that Schedule.

Ingredient medicinal products

8.—(1) Subject to the following provisions of these regulations, where a medicinal product is an ingredient to which the provisions of section 130(1)(b) of the Act apply, or an ingredient to which the provisions of the Medicines (Control of Substances for Manufacture) Order 1971 apply, every container and every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a) to (e), 2, 6, 7, 10, 11 and 12 of Schedule 1 to these regulations and the particulars set out in paragraph 9 of that Schedule or the name and address of the holder of the product licence which relates to the medicinal product or the business name and address of the part of his business that is responsible for its sale or supply.

(2) This regulation shall not apply to such a container of a medicinal product as is described in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units).

Dispensed medicinal products

9.—(1) Subject to the following provisions of these regulations, where a medicinal product is a dispensed medicinal product the container of such medicinal product shall be labelled to show the following particulars—

- (a) where the medicinal product is for use by being administered to a particular human being, the name of the person to whom the medicinal product is to be administered,
- (b) where the medicinal product is for use by being administered to animals, the name of the person who has the possession or control of the animal or herd to which the medicinal product is to be administered and the address of the premises at which the animal or herd is kept, or, where animals or herds are kept at a number of premises, the address of one of such premises,

- (c) where the medicinal product is not prescribed by a practitioner, directions for use of the medicinal product, except that where the product is prepared or dispensed in a registered pharmacy by or under the supervision of a pharmacist in accordance with a specification furnished by the person to whom the product is or is to be sold or supplied in circumstances to which section 10(3)(a) of the Act applies the directions for use of the product may be omitted,
- (d) the name and address of the person who sells or supplies the medicinal product,
- (e) the date upon which the medicinal product is dispensed, and
- (f) where the medicinal product has been prescribed by a practitioner, such of the following particulars as he may request, namely:—
 - (i) the particulars set out in paragraph 1(a) of Schedule 1 to these regulations,
 - (ii) directions for use of the medicinal product, and
 - (iii) precautions relating to the use of the medicinal product,
 or where a pharmacist, in the exercise of his professional skill and judgment, is of opinion that any of such particulars are inappropriate and has taken such steps as in all the circumstances are reasonably practicable to consult with the practitioner but has been unable to do so, particulars of the same kind as those requested by the practitioner as appear to the pharmacist to be appropriate.

(2) Where the container of a dispensed medicinal product is enclosed in a package immediately enclosing that container the particulars set out in paragraph (1) of this regulation may be omitted from the container if that package is labelled to show such particulars.

Surgical materials

10. Subject to the following provisions of these regulations, where a medicinal product is a product to which the provisions of the Medicines (Surgical Materials) Order 1971 apply, every container and every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), (b), (d) and (e), 3, 4 and 6 to 12 of Schedule 1 to these regulations and a statement of the nature and origin of the article or substance and the quantity of the medicinal product in the container, expressed in terms of weight or volume or length, except that where such medicinal product is for administration in a clinical trial, every container and every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in Schedule 2 to these regulations.

Medicinal products exempt from product licences

11.—(1) Subject to the following provisions of these regulations, where a medicinal product is a product to which the restrictions imposed by section 7 of the Act (product licence) do not apply by virtue of—

- (a) the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971(a) as amended(b) (in this regulation referred to as “the Foods and Cosmetics Order”)—
 - (i) every container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), (c), (d) and (e), 2, 6 and 7 of Schedule 1 to these regulations, and the name and

(a) S.I. 1971/1410 (1971 II, p.3945).

(b) S.I. 1973/2079 (1973 III, p. 7182).

address of the person who has manufactured the medicinal product or of the person responsible for its composition or of the person who first sells or supplies it as a medicinal product, and

- (ii) every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), (b), (d) and (e), 2 and 6 of that Schedule and the name and address of the person who has manufactured the medicinal product or of the person responsible for its composition or of the person who first sells or supplies it as a medicinal product,

except that, where such medicinal product is a product for external use as a cosmetic as defined by Article 1(2) of the Foods and Cosmetics Order or where the container of such medicinal product is required to be labelled in accordance with the requirements of the Labelling of Food Regulations 1970(a) as amended(b), the Labelling of Food (Scotland) Regulations 1970(c) as amended(d) or the Labelling of Food Regulations (Northern Ireland) 1970(e) as amended(f), or any regulations amending or replacing any of those regulations, and, where required to be so labelled, the container of the product is labelled in compliance with such of those regulations as are appropriate, the particulars required by this paragraph of this regulation may be omitted from the container and package of such medicinal product;

- (b) the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(g) or the Medicines (Exception from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(h) as amended(i)—

- (i) every container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), (c), (d) and (e), 2, 6, 7, 10 and 11 of Schedule 1 to these regulations, and

- (ii) every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a) to (e), 2, 6, 7, 10 and 11 of that Schedule and the name and address of the person who has manufactured the medicinal product or of the person responsible for its composition or of the person who first sells or supplies it as a medicinal product;

- (c) any provisions of the Act or any orders made under the Act other than the orders referred to in the preceding sub-paragraphs of this paragraph—

- (i) the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), (c), (d) and (e), 2, 3, 6

(a) S.I. 1970/400 (1970 I, p. 1383).

(b) S.I. 1972/1510, 1976/859 (1972 III, p. 4441; 1976 II, p. 2211).

(c) S.I. 1970/1127 (1970 II, p. 3559).

(d) S.I. 1972/1790 (1972 III, p. 5163).

(e) S.R. & O. of N.I. 1970/80 (1970, p. 339).

(f) S.R. & O. of N.I. 1972/318 (1972, p. 1516); S.R. & O. of N.I. 1976/212.

(g) S.I. 1971/1450 (1971 III, p. 4118).

(h) S.I. 1972/1200 (1972 II, p. 3553).

(i) S.I. 1974/498 (1974 I, p. 1768).

and 7 of Schedule 1 to these regulations, and the name and address of the person who sells or supplies the medicinal product, and

- (ii) every package immediately enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraphs 1(a) to (e), 2, 3, 6 and 7 of that Schedule and the name and address of the person who sells or supplies the medicinal product.

(2) Subject to the following paragraph this regulation shall not apply to a medicinal product that is a dispensed medicinal product, or to the container of a medicinal product that is contained in such container as is described in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units) or to such package of a medicinal product as is described in paragraph (6) of that regulation.

(3) The exemption conferred by paragraph (1)(a) of this regulation shall, in the circumstances specified in that paragraph, apply to such container or package as is referred to in paragraph (2) of this regulation, other than the container or package of a dispensed medicinal product.

(4) The requirements of paragraph (1)(c) of this regulation shall apply only when, in the course of a business carried on by a person, such medicinal product is sold by retail, supplied in circumstances corresponding to retail sale or is in his possession for the purposes of such sale or supply.

Importation and Exportation

12.—(1) Subject to the following provisions of these regulations, the provisions of paragraph (2) of this regulation shall have effect in relation to—

- (a) a medicinal product being a biological substance which is sold or supplied for use by being administered to animals, or
- (b) any medicinal product, not being a biological substance, if—
 - (i) the particulars specified in paragraph (2) of this regulation are not shown on the container in which that medicinal product is enclosed or on the package immediately enclosing the container, and
 - (ii) there are included in the package enclosing the package immediately enclosing such container medicinal products of one description only;

where, in the course of a business carried on by a person such a medicinal product is imported or is for export.

(2) The package enclosing the package immediately enclosing the container of such a medicinal product as is mentioned in paragraph (1) of this regulation shall be labelled to show the particulars set out in paragraphs 6 and 10 of Schedule 1 to these regulations and—

- (a) the particulars set out in paragraph 9 of that Schedule, or
- (b) the name and address of the person who is the holder of the product licence which relates to the medicinal product, or
- (c) the number of the manufacturer's licence which relates to the medicinal product preceded by the letters "ML" in capital letters, or

- (d) the name and address of the person who has manufactured the medicinal product, or
- (e) the name and address of the person responsible for the composition of the medicinal product.

Delivery and storage

13. Subject to the following provisions of these regulations, where for the purposes of transit, transport, delivery or storage a number of packages of medicinal products of the same description, not being medicinal products to which regulation 6 of these regulations is applicable, are enclosed in a package such package shall be labelled to show the particulars set out in paragraphs 6, 7 and 10 of Schedule 1 to these regulations.

Medicinal products for incorporation in animal feeding stuffs or which are medicated animal feeding stuffs in respect of which a product licence or animal test certificate has been granted

14.—(1) Subject to the following provisions of these regulations, every container and package of a medicinal product to which a product licence relates which contains provisions relating to the incorporation of that product in animal feeding stuffs or of a medicinal product which is a medicated animal feeding stuff in respect of which a product licence has been granted, shall be labelled to show the particulars set out in Schedule 4 to these regulations.

(2) Where the container or any package enclosing the container of such medicinal product as is mentioned in paragraph (1) of this regulation is of such a size as to make it impracticable for such container or package to be labelled to show all the particulars set out in Schedule 4 to these regulations, such container or package, as the case may be, shall be labelled to show the particulars set out in paragraphs 1 to 4, 6, 7(a), 8 to 10, 14, 15 and 19 of that Schedule if a leaflet containing all the particulars set out in that Schedule (other than those set out in paragraph 19 of that Schedule) is supplied with such container or package and is delivered to the purchaser or consignee thereof.

(3) Where such medicinal product as is mentioned in paragraph (1) of this regulation is a dispensed medicinal product, every container and any package enclosing the container of such medicinal product shall be labelled to show the particulars set out in paragraph 1(b) to (f) of regulation 9 of these regulations and in paragraphs 1 to 5, 8, 10 and 17 of Schedule 4 to these regulations.

(4) Where a medicinal product is for incorporation in animal feeding stuffs in accordance with a product licence which authorises a medicinal test on animals or in accordance with an animal test certificate, or where a medicinal product which is a medicated animal feeding stuff is for administration in such test in accordance with such licence or certificate, every container and package of such medicinal product shall be labelled with the words "For Animal Test Use Only" and to show the particulars set out in Schedule 3 to these regulations and in paragraphs 12 and 17 to 19 of Schedule 4 to these regulations, except that where a product licence has been granted in respect of such medicinal product and the medicinal product is to be administered in the same pharmaceutical form as that described in the application for the grant of that product licence and in all respects in accordance with the provisions of that product licence, the words "For Animal Test Use Only" may be omitted.

(5) The provisions of regulations 12 and 13 of these regulations shall have effect in relation to such a medicinal product as is mentioned in paragraph (1) of this regulation subject to the following modifications:—

- (a) in regulation 12 of these regulations the particulars to be shown shall be the particulars set out in paragraphs 10, 14 and 15 of Schedule 4 to these regulations;
- (b) in regulation 13 of these regulations the particulars to be shown shall be the particulars set out in paragraphs 10, 11 and 15 of that Schedule.

(6) For the purposes of section 85(4) of the Act (sale or supply of medicinal products not enclosed in a container) a person who, in the course of a business carried on by him, sells or supplies such a medicinal product as is mentioned in paragraph (1) of this regulation without its being enclosed in a container, shall not be taken to contravene this regulation if a leaflet containing the particulars set out in Schedule 4 to these regulations (other than those set out in paragraph 19 of that Schedule) is supplied with such medicinal product and such leaflet is delivered to the purchaser or consignee thereof together with such medicinal product.

Contract manufacture or assembly

15.—(1) Subject to the following provisions of these regulations, where the supply of a medicinal product is between any of the persons concerned in the manufacture or assembly of that medicinal product and such supply is solely for the purpose of or in connection with such assembly, or where the medicinal product is in the possession of any such person for such supply, the package immediately enclosing the container of such medicinal product shall be labelled to show the name of the medicinal product, the name and address of the person who supplied the medicinal product, the product licence number (if any) relating to the medicinal product and the particulars set out in paragraph 10 of Schedule 1 to these regulations.

(2) For the purpose of paragraph (1) of this regulation, a person shall be taken to be concerned in the manufacture or assembly of a medicinal product if he is—

- (a) the holder of the product licence which relates to that medicinal product or, if by virtue of an exemption conferred by the Act or by an order under the Act no product licence has been granted in relation to that medicinal product, he is the person responsible for the composition of that medicinal product, or a person whose activities but for such exemption would require to be authorised by a product licence, or
- (b) the person who manufactures that medicinal product to the order of the person described in sub-paragraph (a) of this paragraph or to the order of the Crown, or
- (c) the person who assembles that medicinal product to the order of the person described in sub-paragraph (a) of this paragraph or to the order of the Crown.

Provisions in licences, clinical trial certificates and animal test certificates

16.—(1) The requirements imposed by these regulations are subject to any provision in a licence granted under Part II of the Act or in a clinical trial certificate or animal test certificate issued thereunder relating to the labelling of the containers or packages of the medicinal product or the particulars to be

contained in leaflets supplied with the medicinal product to which such licence or certificate relates and, where such provision is inconsistent with any requirement imposed by these regulations, then, only in so far as and to the extent that it is so inconsistent, such requirement shall be deemed to have been complied with if the said provision in the licence or, as the case may be, certificate is complied with.

(2) All particulars required by these regulations to be shown by the labelling of any container or package of a medicinal product or to be contained in a leaflet supplied with the medicinal product shall be consistent with the provisions of any such licence, clinical trial certificate or animal test certificate as is mentioned in the preceding paragraph of this regulation which relates to the medicinal product.

(3) Where a person, in the course of a business carried on by him, sells by way of wholesale dealing or has in his possession for sale by way of wholesale dealing, or sells by retail, or supplies in circumstances corresponding to retail sale, or has in his possession for the purposes of such sale or supply a medicinal product, in such circumstances that the particulars shown by the labelling on the container or package of that medicinal product or a leaflet supplied with that medicinal product are inconsistent with the provisions of the product licence which relates to that product, those provisions having been varied by the licensing authority under or by virtue of any provisions of the Act after the latest date on which that medicinal product was in the possession of the person who is the holder of such product licence, and on that date such particulars were consistent with the provisions of that product licence relating to that medicinal product, he shall be deemed to have complied with the requirements of paragraph (2) of this regulation in relation to that medicinal product.

General provisions

17.—(1) All labelling of containers of medicinal products shall be carried out in an indelible manner on the body of the container except that, where the container is a transparent container, such labelling may be carried out inside the body of the container, and where the medicinal product consists of confectionery in the form of a pastille or lozenge, any requirement of these regulations that containers of a medicinal product shall be labelled to show the particulars set out in paragraph 10 of Schedule 1 to these regulations shall be regarded as having been complied with if those particulars are shown on a separate label included in the container of such medicinal product.

(2) All labelling of packages of medicinal products shall be carried out in an indelible manner.

(3) Where a medicinal product contains a single active ingredient and particulars of the appropriate non-proprietary name of such ingredient are required by these regulations to be shown on the container of the medicinal product or, where the container is a container to which regulation 5(4) of these regulations applies, on the package in which such a container is enclosed, such appropriate non-proprietary name shall be shown in prominent lettering on the container or the package, as the case may be.

(4) All particulars required by these regulations to be shown on any labelling of any container or package of a medicinal product or contained in any leaflet accompanying such medicinal product shall, except with respect to numerals, be given in the English language, except that where the name of a herbal remedy

or ingredient of a herbal remedy at the head of a specified publication is a botanical name, that botanical name may be given or where the name of a medicinal product is in a language other than English but is the name which by that medicinal product is usually known in the United Kingdom that name may be given, but nothing in this regulation shall prohibit such particulars being given in two or more languages provided that one of such languages is English.

(5) All such particulars shall be clear, legible and readily discernible so as to be easily read by an intending purchaser or user of the medicinal product under normal conditions of purchase or use.

(6) No labelling of any container or package of a medicinal product or particulars contained in any leaflet accompanying such medicinal product shall include any reference, direct, or indirect, to the Act or any regulations (including these regulations) or orders made under the Act or to the Medicines Commission or to any committee established under section 4 of the Act or to any licence or certificate granted or issued under the Act unless such reference is required by or made pursuant to the provisions of the Act or such regulations, orders, licence or certificate.

(7) Every container and package of a medicinal product for use by being administered to animals, not being a container or package of a medicinal product for use by being administered to either human beings or animals or for administration in a medicinal test on animals, shall be labelled to show the words "For Animal Treatment Only" except that where such container or package is of so small a size that it is not reasonably practicable to show such words, they may be omitted.

(8) Every leaflet supplied with a medicinal product for use by being administered to animals, not being a leaflet supplied with a medicinal product for use by being administered to either human beings or animals or for administration in a medicinal test on animals, or a leaflet which is a data sheet, shall contain the words "For Animal Treatment Only".

Miscellaneous provisions

18.—(1) Every statement of appropriate quantitative particulars made in accordance with these regulations in which a reference is made to the substances aspirin or paracetamol shall refer to those substances by those names.

(2) Nothing in these regulations shall require the labelling of—

- (i) any package in the form of a transparent wrapping or cover to a container or package of a medicinal product or any package the whole or part of which is transparent or open if the particulars shown on the labelled container enclosed in that package are clearly visible, or
- (ii) any package in the form of a packing case, crate or other covering (not being a package to which the provisions of regulation 13 of these regulations are applicable) used solely for the purposes of transit, transport or delivery of containers or packages of medicinal products labelled in accordance with the provisions of these regulations, or
- (iii) any package in the form of a wrapping paper, paper bag or similar covering in which the container or package of a medicinal product labelled in accordance with the provisions of these regulations is placed when such medicinal product is sold by retail or supplied in circumstances corresponding to retail sale, or

- (iv) any package of a medicinal product that is a dispensed medicinal product, not being a dispensed medicinal product to which the provisions of regulation 14(3) of these regulations are applicable, or
- (v) any container or package immediately enclosing the container of a medicinal product which is for export.

Temporary provisions

19.—(1) In relation to such a medicinal product as is mentioned in paragraph (c) of regulation 2 of these regulations—

- (a) during the period until and including 30th June 1978, the container and package of such medicinal product shall be labelled to show the particulars set out in paragraph 9 of Schedule 1 to these regulations and the particulars shown on the labelled container shall be consistent with the provisions of the product licence which relates to the medicinal product;
- (b) where a person who has manufactured such a medicinal product in the course of a business carried on by him sells such a medicinal product or has in his possession such product for sale in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation, but not with the requirements of these regulations, and—
 - (i) the container of such a medicinal product is labelled by means of a label affixed to the container and that label was printed before 22nd November 1976 or the package of such medicinal product was printed before that date, or
 - (ii) the container of such medicinal product is labelled by means of fired on, embossed or similar labelling applied to the body of the container before 1st July 1977,

and the container or the package is labelled to comply with the requirements set out in the preceding sub-paragraph, during the period until and including 30th June 1978, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with;

- (c) where a person, in the course of a business carried on by him, sells by way of wholesale dealing or has in his possession for sale by way of wholesale dealing such a medicinal product in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation, but not with the requirements of these regulations, and—
 - (i) the medicinal product is in a container to which the provisions of sub-paragraph (b) of this paragraph do not apply, during the period until and including 31st December 1977, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with, or
 - (ii) the medicinal product is in a container to which the provisions of sub-paragraph (b) of this paragraph apply, and the container is labelled to comply with the requirements set out in sub-paragraph (a) of this paragraph, during the period until and including

31st December 1978, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with;

(d) where a person, in the course of a business carried on by him, sells by retail, supplies in circumstances corresponding to retail sale, or has in his possession for the purposes of such sale or supply such a medicinal product in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation, but not with the requirements of these regulations, and—

(i) the medicinal product is in a container to which the provisions of sub-paragraph (b) of this paragraph do not apply, during the period until and including 31st December 1978, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with, or

(ii) the medicinal product is in a container to which the provisions of sub-paragraph (b) of this paragraph apply, and the container is labelled to comply with the requirements set out in sub-paragraph (a) of this paragraph, during the period until and including 31st December 1979, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with.

(2) In relation to such a medicinal product as is mentioned in paragraph (d) of regulation 2 of these regulations—

(a) where the medicinal product is assembled on or after 1st July 1977, the container of such a medicinal product shall be labelled to show the particulars set out in paragraphs 1(a), 9 and 10 of Schedule 1 to these regulations and, where the medicinal product is such a product as is mentioned in paragraph (d)(i) of regulation 2 of these regulations, the appropriate quantitative particulars and the quantity of the medicinal product in the container, except that where the medicinal product is in such a container as is mentioned in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units) which is enclosed in a package, such particulars may be omitted from the label on the container if the package is labelled to show such particulars;

(b) where a person, in the course of a business carried on by him, sells by way of wholesale dealing or has in his possession for sale by way of wholesale dealing such a medicinal product in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation and, so far as they relate to the product, the provisions of sub-paragraph (a) of this paragraph, but not otherwise in accordance with the requirements of these regulations, and—

(i) the medicinal product is such a product as is mentioned in paragraph (d)(i) of regulation 2 of these regulations, during the period until and including 30th June 1979, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with, or

- (ii) where the medicinal product is such a product as is mentioned in paragraph (d)(ii) of regulation 2, during the period until and including 30th June 1980, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with;
- (c) where a person, in the course of a business carried on by him, sells by retail, supplies in circumstances corresponding to retail sale, or has in his possession for the purposes of such sale or supply such a medicinal product as is mentioned in paragraph (d)(i) or paragraph (d)(ii) of regulation 2 of these regulations in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation and, so far as they relate to the product, the provisions of sub-paragraph (a) of this paragraph, but not otherwise in accordance with the requirements of these regulations, during the period until and including 30th June 1980, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with.
- (3) Containers and packages of a medicinal product to which paragraph (4) of this regulation applies shall during such a period as is mentioned in that paragraph be labelled either—
- (a) in accordance with the requirements relating to labelling imposed by Part I of the Therapeutic Substances Act 1956(a) or by Part II of the Diseases of Animals Act 1950(b) or by Part II of the Diseases of Animals Act (Northern Ireland) 1958(c), and the provisions of any regulations made under Part I of the Therapeutic Substances Act 1956 or (as the case may be) of any order made under Part II of the Diseases of Animals Act 1950 or Part II of the Diseases of Animals Act (Northern Ireland) 1958 in relation to the labelling of medicinal products which were deemed by virtue of section 26(5) of the Act to be incorporated in product licences which are licences of right, or
- (b) in accordance with the provisions of these regulations (other than paragraph (1) or (2) of this regulation) as if these regulations had effect in relation to such a medicinal product during such a period.
- (4) Paragraph (3) of this regulation shall have effect in relation to a medicinal product which is a biological substance in the circumstances in which by virtue of any provision of regulation 2 of these regulations and paragraph (1) or (2) of this regulation the provisions of these regulations (other than the said paragraph (1) or (2)) do not have effect in relation to such a medicinal product during any period until regulation 2 takes effect and any period specified in the said paragraph (1) or (2).
- (5) Subject to paragraphs (6) and (7) of this regulation the containers and packages of a medicinal product to which the said paragraph (6) applies shall during such a period as is mentioned in that paragraph be labelled either—
- (a) in accordance with the requirements relating to labelling imposed by the enactments, rules and regulations referred to in the said paragraph (6) as if those enactments, rules and regulations had continued in force, or

(a) 1956 c. 25.

(b) 1950 c. 36.

(c) 1958 c. 13 (N.I.).

(b) in accordance with the provisions of these regulations (other than paragraph (1) or (2) of this regulation) as if these regulations had effect in relation to such a medicinal product during such a period.

(6) Paragraph (5) of this regulation shall have effect in relation to a medicinal product of a description to which any of the requirements relating to labelling imposed by the enactments, rules and regulations referred to in paragraph (7) of this regulation applied immediately before these regulations came into operation, in the circumstances in which, by virtue of any provision of regulation 2 of these regulations and paragraph (1) or (2) of this regulation the provisions of these regulations (other than the said paragraph (1) or (2)) do not have effect in relation to such a medicinal product during any period until regulation 2 takes effect and any period specified in the said paragraph (1) or (2).

(7) Paragraph (5) of this regulation shall have effect in the circumstances specified in paragraph (6) of this regulation on the day on which the following enactments, rules and regulations cease to have effect, namely:

the Pharmacy and Poisons Act 1933(a),
the Pharmacy and Medicines Act 1941(b),
the Poisons Rules 1972(c), as amended(d),
the Pharmacy and Poisons Act (Northern Ireland) 1925(e),
the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945(f), and
the Poisons Regulations (Northern Ireland) 1974(g).

Offences

20. Any person who contravenes the provisions of these regulations or contravenes the provisions of section 85(3) or 86(2) of the Act shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400 and shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

David Ennals

Secretary of State for Social Services.

28th September 1976.

John Morris

Secretary of State for Wales.

1st October 1976.

Bruce Millan

Secretary of State for Scotland.

7th October 1976.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th October 1976.

(a) 1933 c. 25. (b) 1941 c. 42. (c) S.I. 1972/1939 (1972 III, p. 5750).
(d) S.I. 1974/81, 595, 1557, 1975/1073, 1976/978 (1974 I, pp. 254, 2359, III, p. 5894; 1975 II, p. 3758; 1976 II, p. 2571).
(e) 1925 c. 8 (N.I.). (f) 1945 c. 9 (N.I.). (g) S.R. of N.I. 1974/246 (1974 II, p. 1120).

(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 13th day of October 1976.

(L.S.)

N. Dugdale
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 14th day of October 1976.

(L.S.)

J. A. Young
Permanent Secretary.

SCHEDULE 1

Regulations 5, 8, 10, 11, 12 and 13

STANDARD PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES

1.—(a) The name of the medicinal product being either the appropriate non-proprietary name or a proprietary designation.

(b) A description of the pharmaceutical form of the medicinal product.

(c) A statement, in a conspicuous position, of the appropriate quantitative particulars of the 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 medicinal product has been prepared, such quantities being preceded by a statement to that effect, except that where any 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 ingredient is stated, the requirements of this paragraph shall be regarded as having been complied with.

(d) Where under sub-paragraph (a) or (c) of this paragraph a medicinal product or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym, words or letters identifying the specified publication or compendium except where such specified publication is the current edition of the British Pharmacopoeia or the British Pharmaceutical Codex, and, except where the specified publication or compendium is the current edition, figures giving the edition.

(e) Where under sub-paragraph (a) or (c) of this paragraph a medicinal product or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym, or is identified by an approved name, and the international non-proprietary name (if any) of such medicinal product or ingredient is not the same as such name at the head of a monograph or approved synonym or approved name, as the case may be, that international non-proprietary name followed by the letters "INN" in capital letters, 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.

2. The quantity of the medicinal product in the container or, where the container is a container to which regulation 5(4) of these regulations applies, in the package of the medicinal product, expressed in terms of weight, volume or capacity or number of dosage units, except that where the medicinal product is a freeze-dried vaccine the number of doses in the container shall be stated.

3. Directions for use and, where the medicinal product is for use by being administered to animals, the purposes for which the medicinal product is to be used, except that where—

(a) it is a provision of the product licence which relates to the medicinal product that the product may not be sold or supplied except by an appropriate practitioner or in accordance with a prescription given by a practitioner, or

(b) the medicinal product is a product which is specified in an order made under section 58(1) of the Act (medicinal products on prescription only) and which is for use by being administered to human beings such directions for use may be shown by a statement that the medicinal product is to be used in accordance with the directions of an appropriate practitioner.

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

5. Where the medicinal product is for use by being administered to animals, any restrictions on the purposes for which the medicinal product may be used in the provisions of any product licence relating to the medicinal product.

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

7. Where a medicinal product should be used within three years of the date upon which the manufacturing batch of which it formed part was approved for sale or supply by the person responsible for the control of its quality, the expiry date of the medicinal product.

8.—(a) The name and address of the holder of the product licence which relates to the 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 medicinal product or a manufacturer's licence authorising the assembly of the product permit, or where the 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 medicinal product by retail or supplies it in circumstances corresponding to retail sale, or

(c) Where the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 have directed that the provisions of that Article may apply to the assembly of the medicinal product and that the names and addresses of a specified person or persons may be given in the labelling of containers or, as the case may be, packages, of the medicinal product, the name and address of any person or persons so specified.

9. Any product licence number as allocated by the licensing authority which relates to the medicinal product preceded by the letters "PL" in capital letters or other abbreviation of the expression "product licence" which has been in general use for that purpose in connection with the labelling of containers and packages of medicinal products before the coming into operation of these regulations, or, where the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 have directed as referred to in the preceding paragraph of this Schedule, such product licence number preceded by the letters "PL" in capital letters or other abbreviation as aforesaid or the number of the relevant direction.

10. The batch reference, which shall consist of figures or letters or a combination thereof, of the person who has manufactured the medicinal product for the batch of which the medicinal product forms part, preceded by the letters "BN" or "LOT" or other letters indicating a batch reference, except that where the container of the medicinal product is of so small a size that it is not reasonably practicable to show both the batch reference and such letters preceding it, or where the container of the medicinal product is a collapsible tube and the batch reference is shown on the crimp of such container, such letters may be omitted.

11. The number of the manufacturer's licence preceded by the letters "ML" in capital letters, or the name and address of the holder of such manufacturer's licence or, if there is no such licence, the name and address of the person who has manufactured the medicinal product and, if different therefrom, the name and address of the person in the course of whose business the medicinal product was enclosed in its container, except that such requirement shall be treated as having been complied with if—

- (a) the holder of the product licence is the person who has manufactured the medicinal product, or
- (b) one person only has manufactured the medicinal product, or
- (c) the person who has manufactured the medicinal product was manufacturing medicinal products of the same description as the medicinal product before these regulations came into operation, or
- (d) more than one person has manufactured medicinal products of the same description as the medicinal product and the licensing authority have been notified of the change of persons who have manufactured medicinal products of the same description and have consented to the batch reference system.

12. Any other statements or particulars required to be stated on the labels of the containers or, as the case may be, packages of the medicinal product by the provisions of any product licence which relates to the medicinal product or by a direction given by the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971.

SCHEDULE 2

Regulation 6

PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS FOR CLINICAL TRIALS

1. Where the clinical trial is being carried out on the premises of a body or institution, the name and address of that body or institution, or where the clinical trial is not being carried out on such premises, the name and address of the place where the clinical trial is being carried out, or in either case, the name and address of the person who is the holder of the product licence which authorises the clinical trial in question or of the clinical trial certificate which relates to the clinical trial.

2. Such designation as will sufficiently identify the clinical trial.

3. Such designation as will sufficiently identify the person to whom the medicinal product is being administered in the course of the clinical trial.

4. Where more than one medicinal product is supplied in the course of the clinical trial such designation on the container of each medicinal product as will sufficiently identify each such medicinal product.

5. Any other statement or particulars required to be stated on the labels of the containers or, as the case may be, packages of the medicinal product by the provisions of any clinical trial certificate or product licence which relates to the medicinal product.

SCHEDULE 3

Regulations 7 and 14

PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS FOR MEDICINAL TESTS ON ANIMALS

1. Such designation as will sufficiently identify the animal test.
2. Where more than one medicinal product is supplied in the course of the animal test such designation on the container of each medicinal product as will sufficiently identify each such medicinal product.
3. The quantity of the medicinal product in the container expressed in terms of weight, volume or capacity or number of dosage units, except that where the medicinal product is a freeze-dried vaccine the number of doses in the container shall be stated.
4. The purposes for which the medicinal product is to be used including any restrictions on such use in the provisions of the animal test certificate or product licence which relates to the medicinal product, the directions for use including dosage and methods and routes of administration, contra-indications, warnings and precautions.
5. Where the medicinal product is to be incorporated in any animal feeding stuff, the directions for such incorporation, the species and categories within species of animals to which the medicinal product is to be administered, and a statement that such incorporation must be in accordance with the terms of such animal test certificate or product licence.
6. Any special requirements for the handling and storage of the medicinal product.
7. The expiry date of the medicinal product.
8. Any other statement or particulars required to be stated on the labels of the containers or, as the case may be, packages of the medicinal product by the provisions of the animal test certificate or product licence which relates to the medicinal product.

SCHEDULE 4

Regulation 14

PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS FOR INCORPORATION IN ANIMAL FEEDING STUFFS OR WHICH ARE MEDICATED ANIMAL FEEDING STUFFS

1. If the medicinal product has a proprietary designation, that proprietary designation.
2. A statement, in a conspicuous position, of the quantity of each active ingredient in the medicinal product, identified by its appropriate non-proprietary name.
3. Where under paragraph 1 or 2 of this Schedule a medicinal product or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym,

words or letters identifying the specified publication or compendium, except where such specified publication is the current edition of the British Pharmacopoeia or the British Pharmaceutical Codex, and, except where the specified publication or compendium is the current edition, figures giving the edition.

4. Where under paragraph 1 or 2 of this Schedule a medicinal product or ingredient is identified by reference to a name, or abbreviation of such name, at the head of a monograph in a specified publication or in a foreign or international compendium of standards or, in the case of the European Pharmacopoeia, an approved synonym, and the international non-proprietary name (if any) of such medicinal product or ingredient is not the same as such name or approved synonym, that international non-proprietary name followed by the letters "INN" in capital letters, 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 or approved synonym.

5. The quantity of the medicinal product in the container of the medicinal product expressed in terms of weight, volume or capacity or number of dosage units.

6. The purposes for which the medicinal product is to be used and the directions for use, including—

- (a) the permissible daily level of active ingredient to be administered where this is specified in the product licence which relates to the product, and
- (b) the species, and categories within species, of animals to which the medicinal product is to be administered.

7. In the case of a medicinal product in respect of which there is a product licence relating to the incorporation of that product in an animal feeding stuff—

- (a) directions for such incorporation including the quantity of active ingredient to be present in the complete feeding stuff, and
- (b) a statement that incorporation must be in accordance with the terms of the product licence or in accordance with the terms of a prescription given by a veterinary surgeon or veterinary practitioner.

8. Contra-indications, warnings and precautions required to be given by the provisions of any product licence which relates to the medicinal product and thereby required to be addressed to the user of the medicinal product.

9. Any restrictions on the purposes for which the medicinal product may be used in the provisions of any product licence which relates to the medicinal product.

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

11. The expiry date of the medicinal product.

12. In the case of a medicinal product in respect of which there is a product licence containing provisions relating to the incorporation of that product in an animal feeding stuff, the period during which that product remains effective when incorporated in such feeding stuff.

13.—(a) The name and address of the holder of the product licence which relates to the 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 medicinal product or a manufacturer's licence authorising assembly of the product permit, or where the 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 medicinal product by retail or supplies it in circumstances corresponding to retail sale, or

(c) Where the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 have directed that the provisions of that Article may apply to the assembly of the medicinal product

and that the names and addresses of a specified person or persons may be given in the labelling of containers or, as the case may be, packages of the medicinal product, the name and address of any person or persons so specified.

14. Any product licence number as allocated by the licensing authority which relates to the medicinal product preceded by the letters "PL" in capital letters or other abbreviation of the expression "product licence" which has been in general use for that purpose in connection with the labelling of containers and packages of medicinal products to which this Schedule applies before the coming into force of these regulations, or, where the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 have directed as referred to in the preceding paragraph of this Schedule, such product licence number preceded by the letters "PL" in capital letters, or other abbreviation as aforesaid, or the number of the relevant direction.

15. The batch reference, which shall consist of figures or letters or a combination thereof, of the person who has manufactured the medicinal product for the batch of which the medicinal product forms part, preceded by the letters "BN" or "LOT" or other letters indicating a batch reference.

16. The number of the manufacturer's licence preceded by the letters "ML" in capital letters, or the name and address of the holder of such manufacturer's licence or, if there is no such licence, the name and address of the person who has manufactured the medicinal product and, if different therefrom, the name and address of the person in the course of whose business the medicinal product was enclosed in its container, except that such requirement shall be treated as having been complied with if—

- (a) the holder of the product licence is the person who has manufactured the medicinal product, or
- (b) one person only has manufactured the medicinal product, or
- (c) the person who has manufactured the medicinal product was manufacturing medicinal products of the same description as the medicinal product before these regulations came into operation, or
- (d) more than one person has manufactured medicinal products of the same description as the medicinal product and the licensing authority have been notified of the change of persons who have manufactured medicinal products of the same description and have consented to the batch reference system.

17. Any other statements or particulars required to be stated on the labels of the containers or, as the case may be, packages of the medicinal product, or to be contained in leaflets supplied with the medicinal product, by the provisions of any product licence which relates to the medicinal product or by a direction given by the licensing authority acting under Article 3(1) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971.

18. In the case of a medicinal product which is a medicated animal feeding stuff, being either a medicated feed supplement or a medicated protein concentrate, sold or supplied otherwise than to a manufacturer of medicated animal feeding stuffs or to a person supplying such manufacturer, a statement that the medicinal product is a medicated feed supplement or a medicated protein concentrate, as the case may be.

19. In any case where particulars from this Schedule are omitted from a label in accordance with the provisions as to small-sized labels contained in regulation 14(2) of these regulations, a statement that a leaflet of instructions is supplied with the medicinal product.

EXPLANATORY NOTE

(This Note does not form part of the Regulations.)

These Regulations made under the Medicines Act 1968 impose requirements relating to the labelling of containers and packages of medicinal products. They prescribe standard labelling requirements for containers and packages. They prescribe special labelling requirements for containers and packages of medicinal products for administration in clinical trials and in medicinal tests on animals; for containers and packages of ingredients for medicinal products; for containers and packages of surgical materials; and for containers and packages of medicinal products for incorporation in animal feeding stuffs and certain medicated animal feeding stuffs. They contain certain exemptions for dispensed medicinal products, for medicinal products exempted from licensing to which the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971, the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 or the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 apply, and for certain other categories of medicinal products and impose requirements in relation to containers and packages of those medicinal products. They prescribe the particulars to be shown on packages of certain medicinal products for import or export. They also contain transitional provisions.

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