SCHEDULE 5

Regulation 11

LABELS

Interpretation

1. In this Schedule, unless the context otherwise requires—

"dispensed relevant medicinal product" means a relevant medicinal product prepared or dispensed in accordance with a prescription given by a practitioner;

"relevant medicinal product on a general sale list" means a relevant medicinal product of a description, or falling within a class, specified in an order under section 51 of the Act which is for the time being in force;

"requirements" includes restrictions;

"retail sale" has the same meaning as in section 131 of the Act; and

"supply in circumstances corresponding to retail sale" has the same meaning as in section 131 of the Act.

Introductory

2. The requirements of this Schedule supplement those of Council Directive 92/27/EEC relating to:

(a) special warnings necessary for particular medicinal products;

(b) the legal status for supply to the patient, in accordance with Council Directive 92/26/EEC;

(c) identification and authenticity.

Dispensed relevant medicinal products

3.—(1) Subject to the following provisions of this Schedule, where a relevant medicinal product is a dispensed relevant medicinal product the container of that product shall be labelled to show the following particulars—

(a) the name of the person to whom the product is to be administered;

(b) the name and address of the person who sells or supplies the product;

(c) the date on which the product is dispensed;

(d) where the relevant medicinal product has been prescribed by a practitioner, such of the following particulars as he may request—

(i) the name of the relevant medicinal product or its common name;

(ii) directions for use of the relevant medicinal product; and

(iii) precautions relating to the use of the relevant medicinal product,

or where a pharmacist, in the exercise of his professional skill and judgement, is of the 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 relevant medicinal product is enclosed in a package immediately enclosing that container the particulars set out in sub-paragraph (1) may be omitted from the container if that package is labelled to show such particulars.

(3) Where a number of containers or packages, or of containers and packages, of dispensed relevant medicinal products all of the same description are enclosed in a package, sub-paragraph (1) (d) shall be deemed to have been complied with if such of the particulars referred to in that sub-paragraph as would, apart from this sub-paragraph, be required to be shown on each container or package, or on each container and package so enclosed, are shown on either one or more such containers or packages or such containers and packages as the case may be.

Delivery and storage

4.—(1) Subject to the following provisions of this Schedule, where for the purposes of transport, delivery or storage a number of packages of relevant medicinal products all of the same description, not being relevant medicinal products to which paragraph 1 of Schedule 1 applies, are enclosed in a package, such package shall be labelled to show the following particulars—

(a) any special requirements for the storage and handling of the product;

(b) the expiry date of the product; and

(c) the manufacturer's batch number.

(2) Sub-paragraph (1) does not apply to any package in the form of a packing case, crate or other covering used solely for the purposes of transport or delivery (but not storage) of containers and packages of relevant medicinal products each of which is labelled in accordance with the provisions of this Schedule.

Relevant medicinal products on a general sale list

5.—(1) Subject to the following provisions of this Schedule, where a relevant medicinal product on a general sale list, not being a dispensed relevant medicinal product, is sold by retail, or supplied in circumstances corresponding to retail sale or by means of an automatic machine or is in the possession of any person for the purpose of such sale or supply, every container and every package immediately enclosing a container of such product, being a product described in any of the following sub-paragraphs, shall be labelled to show the words and particulars set out in such sub-paragraph or sub-paragraphs—

(a) if the product contains aloxiprin, aspirin or paracetamol, the words "If symptoms persist consult your doctor" and, except where the product is for external use only, the recommended dosage;

(b) if the product contains aloxiprin, the words "Contains an aspirin derivative";

(c) if the product contains aspirin, except where the product is for external use only or where the name of the product includes the word "aspirin" and appears on the container or package, the words "Contains aspirin";

(d) if the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the container or package, the words "Contains paracetamol";

(e) if the product contains paracetamol, the words "Do not exceed the stated dose";

(2) Where a container or package is required by this paragraph to show—

(a) words set out in more than one of sub-paragraphs (b), (c) and (d) of sub-paragraph (1), there may be substituted for those words other words showing that the product contains more than one of the substances aloxiprin, aspirin and paracetamol and naming the substances so contained, except that in the case of aloxiprin the words "aspirin derivative" shall appear and the word "aloxiprin" need not appear;

(b) words set out in one or more of those sub-paragraphs, such words shall appear in a prominent position and shall be within a rectangle within which there shall be no other

matter of any kind, except that where words set out in more than one of the said sub-paragraphs appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

(3) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall appear adjacent to either the directions for use, where such directions appear on the container or package, or the recommended dosage, where such recommendation appears on the container or package.

(4) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall not be required to be shown if, by virtue of paragraph 6, the words set out in head (a) of sub-paragraph (2) of that paragraph are required to be, and are, shown.

(5) Without prejudice to the operation of sub-paragraph (1), where a relevant medicinal product, not being a dispensed medicinal product, is—

(a) sold by retail; or

(b) supplied in circumstances corresponding to retail sale; or

(c) in the possession of a person for the purpose of such sale or supply; or

(d) sold by way of wholesale dealing,

then, if the product is a product referred to in regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**1**) which is not presented for sale in the manner described in relation to that product in that regulation, every container and every package immediately enclosing a container of that relevant medicinal product shall be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

Relevant medicinal products not on a general sale list

6.—(1) Subject to the following provisions of this Schedule, where a relevant medicinal product to which any of the restrictions imposed by section 52 of the Act (sale or supply of medicinal products not on general sale list) apply is sold by retail, or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such a product—

(a) shall be labelled in accordance with the provisions of paragraph 5 as if such provisions applied to such containers and packages as they apply to containers and packages of relevant medicinal products on a general sale list;

(b) shall, if the product is described in any head of sub-paragraph (2), be labelled to show the words and particulars set out in that head, except that where words set out in more than one of heads (a), (b) and (c) of that sub-paragraph appear on the container or package then the word "Warning" need not appear more than once, and where the product is a dispensed relevant medicinal product then the words set out in those heads need not appear;

(c) shall, unless any of the provisions of paragraph 7 apply to such container or package or the product is a dispensed relevant medicinal product, be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

(2) The descriptions and words referred to in sub-paragraph (1) are—

(a) if the product would be subject to restrictions imposed under section 58 of the Act but for an exemption from any such restrictions conferred by an order made under that section by reason of the proportion or level in such product of any substance, except where the product is for external use only or contains any of the substances described in head (c) of this sub-paragraph the words "Warning. Do not exceed the stated dose";

(**1**) S.I. 1980/1923. The relevant amending instruments are S.I. 1982/28, 1990/1124 and 1994/2411.

(b) if the product is for the treatment of asthma or other conditions associated with bronchial spasm or contains ephedrine or any of its salts, except where the product is for external use only, the words "Warning. Asthmatics should consult their doctor before using this product";

(c) if the product contains an antihistamine or any of its salts or molecular compounds, except where the product is for external use only or where the marketing authorization contains no warning relating to the sedating effect of the product in use, the words "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink";

(d) if the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, the words "For external use only";

(e) if the product contains hexachlorophane, either the words "Not to be used for babies" or a warning that the product is not to be administered, except on medical advice, to a child under two years.

(3) The requirement of sub-paragraph (1)(c) shall apply to every container and every package immediately enclosing a container of a relevant medicinal product which is sold by way of wholesale dealing and which is not a relevant medicinal product on a general sale list.

(4) Where a container or package is required by this paragraph to be labelled to show any of the words or particulars specified in heads (a) to (e) of sub-paragraph (2), such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in more than one head of that sub-paragraph appear on the container or package then any of them may be together within a rectangle within which there shall be no other matter of any kind.

Prescription only relevant medicinal products

7. Subject to the following provisions of this Schedule, every container and every package immediately enclosing a container of a relevant medicinal product which is subject to restrictions imposed under section 58(1) of the Act (relevant medicinal products on prescription only) shall, if the product is described in heads (d) or (e) of sub-paragraph (2) of paragraph 6, be labelled to show the words and particulars set out in that head and shall, except where the product is sold by retail or supplied in circumstances corresponding to retail sale or is the subject of an exemption, by virtue of the provisions of section 58(4)(a), from any of the restrictions imposed by section 58(2) of the Act, be labelled to show the letters "POM" in capital letters within a rectangle within which there shall be no other matter of any kind.

Exemptions

8. Nothing in this Schedule shall require the labelling of—

(a) any package in the form of a transparent wrapping or cover to a container and package of a relevant 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;

(b) any package in the form of a wrapping paper, paper bag or similar covering in which the container and package of a relevant medicinal product labelled in accordance with the provisions of this Schedule is placed when such relevant medicinal product is sold by retail or supplied in circumstances corresponding to retail sale; or

(c) any container or package immediately enclosing the container of a relevant medicinal product which is for export;

(d) any container which is—

(i) an ampoule or other container of not more than 10 millilitres nominal capacity which is immediately enclosed in a package which is labelled in accordance with those provisions of paragraphs 5 to 7 which apply to such package;

(ii) 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 relevant medicinal product and such container is immediately enclosed in a package which is labelled in accordance with those provisions of paragraphs 5 to 7 which apply to such package;

(iii) where the package immediately enclosing such a container as is described in head (ii) above is itself in the form of a bubble, blister or other sealed unit as is mentioned in that head and is part of a continuous series comprising a sheet or strip of like packages and is required to be labelled to show any of the words, particulars or letters referred to in paragraphs 5 to 7, such requirements shall be deemed to have been complied with if the said words, particulars or letters, as the case may be, are displayed at frequent intervals on the said sheet or strip of such packages.