SCHEDULE 5

LABELS

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.

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