SCHEDULE 5

LABELS

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";

(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.