

SCHEDULE 5

Regulation 12

LABELS

Interpretation

1. In this Schedule—

“dispensed traditional herbal medicinal product” means a traditional herbal medicinal product prepared or dispensed in accordance with a prescription given by a practitioner; and

“requirements” includes restrictions.

Introductory

2. The requirements of this Schedule supplement those of Title V of the 2001 Directive relating to—

- (a) special warnings necessary for particular medicinal products;
- (b) the legal status for supply to the patient, in accordance with Title VI of the 2001 Directive;
- (c) identification and authenticity.

Dispensed traditional herbal medicinal products

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

- (a) where the traditional herbal medicinal product is for use by being administered to a particular human being, the name of the person to whom the traditional herbal medicinal product is to be administered;
- (b) the name and address of the person who sells or supplies the traditional herbal medicinal product;
- (c) the date on which the traditional herbal medicinal product is dispensed; and
- (d) where the traditional herbal medicinal product has been prescribed by a practitioner, such of the following particulars as he may request—
 - (i) the name of the traditional herbal medicinal product or its common name,
 - (ii) directions for use of the traditional herbal medicinal product, and
 - (iii) precautions relating to the use of the traditional herbal 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 traditional herbal 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 traditional herbal 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

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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.

Traditional herbal medicinal products not on a general sale list

4. Subject to the following provisions of this Schedule, where a traditional herbal 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 shall unless the product is a dispensed traditional herbal medicinal product, be labelled to show the capital letter “P” within a rectangle within which there shall be no other matter of any kind.

Exemptions

5.—(1) 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 traditional herbal 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 traditional herbal medicinal product labelled in accordance with the provisions of this Schedule is placed when such traditional herbal medicinal product is sold by retail or supplied in circumstances corresponding to retail sale;
- (c) any container or package immediately enclosing the container of a traditional herbal medicinal product which is for export; or
- (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 paragraph 4, or
 - (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 traditional herbal medicinal product and such container is immediately enclosed in a package which is labelled in accordance with paragraph 4.

(2) Where any package immediately enclosing a container as is described in paragraph (1)(d) (ii) is—

- (a) itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph;
- (b) part of a continuous series comprising a sheet or strip of like packages; and
- (c) required to be labelled to show the letter referred to in paragraph 4,

the requirement shall be deemed to have been complied with if the said letter is displayed at frequent intervals on the said sheet or strip of such packages.