STATUTORY INSTRUMENTS

1979 No. 1759

The Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979

Particulars required on labels or in leaflets

4.—(1) Subject to the provisions of paragraphs (2) and (3) and of regulation 7, the particulars specified in regulation 5 shall be shown on a label on the container containing any contact lens substance.

(2) Where the container containing any contact lens substance is too small for it to be reasonably practicable to show all the particulars specified in regulation 5 on the label thereon, such of those particulars as there is space for shall be shown on that label, precedence being given to them in accordance with the order in which they appear in regulation 5, and the other particulars so specified shall be shown on a label on the package in which the container is immediately enclosed or in a leaflet which is supplied or intended to be supplied with the contact lens substance.

(3) Where the size or nature of the container containing any contact lens substance is such that it is not reasonably practicable to show any of the particulars specified in regulation 5 on a label thereon, those particulars shall be shown on a label on the package in which the container is immediately enclosed or in a leaflet which is supplied or intended to be supplied with the contact lens substance.

5.—(1) Subject to the provisions of paragraph (2), the particulars specified for the purposes of regulation 4 in relation to any contact lens substance are—

(a) the number of any product licence which relates to such substance;

(b) the batch reference given by the person who manufactured such substance to the batch of which it forms a part;

(c) the name of such substance or an appropriate description thereof;

(d) the purpose or purposes for which such substance is to be used and in particular, if it is to be used for cleaning, disinfecting, irrigating, lubricating, wetting, soaking or rinsing a contact lens or blank or as a barrier between such lens or blank and the human eyeball, for which of those purposes it is to be used;

(e) the name and address of the holder of any product licence which relates to such substance;

(f) where it is recommended that the substance should not be applied directly to the eye, a warning to that effect; and

(g) the name of any antimicrobial agent which is an ingredient of such substance and the percentage of that substance which that agent comprises, calculated in terms of weight in weight (w/w), weight in volume (w/v), or volume in volume (v/v) as appropriate.

(2) The particulars specified in paragraph (1)(f) shall be shown in capital letters and where the substance is or is to be sold or supplied in solid form as a powder or tablet those particulars shall be so expressed as to relate to the substance in the liquid form in which it is to be administered.

(3) In this regulation, the expression "contact lens" refers only to a contact lens which consists of a thin curved shell of glass, plastic or other hard or soft material intended for use by being applied

to the human eyeball and the word “blank” refers only to a blank from which a contact lens is to be prepared.