

**MEDICINES ACT
(CHAPTER 176, SECTIONS 44 AND 46)**

**MEDICINES
(CONTACT LENS SUBSTANCES)
(LABELLING AND CONTAINERS)
REGULATIONS**

ARRANGEMENT OF REGULATIONS

Regulation

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[2nd January 1990]

Citation

1. These Regulations may be cited as the Medicines (Contact Lens Substances) (Labelling and Containers) Regulations.

Definitions

2. In these Regulations, unless the context otherwise requires —

“administration”, with its grammatical variations, has the same meaning as in section 2 (1) of the Act as modified by paragraph 1 of the First Schedule to the Medicines (Contact Lens Substances) (Specification and Prohibition) Order (O 9);

“blank” means a blank from which a contact lens is to be prepared;

“contact lens” means any thin curved shell of glass, plastic or other hard or soft material intended for use by being applied to the human eyeball;

“contact lens substance” has the same meaning as in the Medicines (Contact Lens Substances) (Specification and Prohibition) Order (O 9).

Application

3. The requirements imposed by these Regulations shall apply to any contact lens substance which, in the course of a business carried on by a person, is sold or supplied or is in his possession for the purpose of sale or supply.

Labels or leaflets

4.—(1) 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.

(3) Precedence shall be given to the particulars 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.

(4) 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.

Particulars required

5.—(1) Subject to paragraphs (2) and (3), the particulars specified for the purposes of regulation 4 in relation to any contact lens substance are —

- (a) the name of the substance or an appropriate description thereof;
- (b) 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;

- (c) directions as to how the substance is to be used;
- (d) the names of the ingredients of the substance including any antimicrobial agent displayed in descending order of concentration;
- (e) the date after which it is recommended that the substance should no longer be used;
- (f) a recommended period within which the substance should be used after the container containing it has first been opened;
- (g) where it is recommended that the substance should not be applied directly to the eye, a warning to that effect;
- (h) a warning in capital letters, “DO NOT MIX WITH OTHER FLUIDS EXCEPT AS DIRECTED”;
- (i) a warning that the substance should not be administered to the eye concurrently with any eye medicament except on medical advice;
- (j) the volume of the substance contained in the container;
- (k) the batch reference given by the person who manufactured the substance to the batch of which it forms a part;
- (l) the name and address of the manufacturer or person responsible for the assembly or composition of the substance; and
- (m) the name and address of the importer if the substance is imported.

(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) Where any contact lens substance is or is to be sold or supplied in solid form as a powder or tablet —

- (a) instructions as to how it is to be prepared for use, including a warning that only recommended fluids should be used for

dissolving the substance for administration, shall be included in the particulars;

- (b) the particulars specified in paragraph (1) (c) and (i) shall be so expressed as to relate to the substance in the liquid form in which it is to be administered; and
- (c) an explanation shall accompany the warning set out in paragraph (1) (h) that the warning relates to the substance in the liquid form in which it is to be administered.

Containers

6.—(1) The capacity of any container containing any contact lens substance shall not exceed the volumes specified in respect of the following purposes for which the substance is to be used:

- (a) Cleaning 50 ml
- (b) Disinfecting or soaking 500 ml
- (c) Irrigating or rinsing (where antimicrobial agents are added) 500 ml
- (d) Irrigating or rinsing (where no antimicrobial agent is added) 15 ml
- (e) Lubricating or wetting 25 ml.

(2) Paragraph (1) shall not apply to any container containing contact lens substance if the licensing authority is satisfied that the container is designed to dispense the substance in a manner which preserves the sterility of the substance remaining in the container.

Penalty

7. Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 2 years or to both.

[G.N. Nos. S 382/89; S 91/90; S 185/2001]
