

1979 No. 1759

MEDICINES

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

Made - - - - 21st December 1979

Laid before Parliament 9th January 1980

Coming into Operation 1st February 1980

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 85(1), 86(1), 91(2) and (3) and 129(5) of the Medicines Act 1968(a) and now vested in them (b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations—

Citation and commencement

1. These regulations may be cited as the Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979 and shall come into operation on 1st February 1980.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

“administer” has the same meaning as in section 130(9) of the Act as modified by Article 2 of, and paragraph 9 of Part II of Schedule 2 to, the Medicines (Specified Articles and Substances) Order 1976(c);

“contact lens substance” means any substance or fluid described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976;

“description” has the same meaning as in section 130(8) of the Act;

“selling by retail” has the same meaning as in section 131(3) of the Act;

“selling by way of wholesale dealing” has the same meaning as in section 131(1) and (2) of the Act; and

“supplying in circumstances corresponding to retail sale” has the same meaning as in section 131(4) of the Act.

(a) 1968 c. 67, as applied by the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968).

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388) and in the case of the Department of Health and Social Services for Northern Ireland by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(c) S.I. 1976/968.

(2) In these regulations, a reference to a numbered regulation is a reference to the regulation of these regulations bearing that number and a reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation bearing that number.

Application

3. Subject to the provisions of regulation 7, 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.

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.

Additional particulars required for contact lens substances

6.—(1) Subject to the provisions of paragraph (3) and of regulation 7, in addition to the particulars specified in regulation 5, the particulars specified in paragraph (2) shall be shown either on a label on the container in which any contact lens substance is contained or 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 such substance.

(2) The particulars specified for the purposes of paragraph (1) in relation to any contact lens substance are—

- (a) the date after which it is recommended that the substance should no longer be used;
- (b) a recommended period within which the substance should be used after the container containing it has first been opened;
- (c) directions as to how the substance is to be used;
- (d) a warning in capital letters, "DO NOT MIX WITH OTHER FLUIDS EXCEPT AS DIRECTED"; and
- (e) a warning that the substance should not be administered to the eye concurrently with any eye medicament except on the advice of a doctor.

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

- (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 (2)(c) and (e) 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 (2)(d) that the warning relates to the substance in the liquid form in which it is to be administered.

Temporary and transitional provisions

7.—(1) The requirements imposed by these regulations shall not apply until 1st January 1982 to a contact lens substance when it is sold or supplied by, or so long as it is in the possession of, a person who, on 1st January 1980, is exempt—

- (a) by virtue of section 16(2) or (3) of the Act from the requirement to hold a product licence relating to that substance, or

- (b) by virtue of section 16(4) of the Act from the requirement to hold a manufacturer's licence relating to that substance.
- (2) Subject to paragraph (3), the requirements imposed by these regulations shall not apply to a contact lens substance—
- (a) until 1st July 1982, when it is sold or supplied by way of wholesale dealing or so long as it is in the possession of a person for the purpose of such sale or supply, and
- (b) until 1st January 1983, when it is sold by retail or supplied in circumstances corresponding to retail sale or so long as it is in the possession of a person for the purpose of such sale or supply.
- (3) The provisions of paragraph (2) shall not apply to a contact lens substance when it is sold or supplied by, or so long as it is in the possession of, a person who—
- (a) has manufactured or assembled it, or
- (b) in the case of an imported contact lens substance, has imported it or procured its importation, or
- (c) in the case of a contact lens substance which has not been imported, is responsible for its composition.
- (4) For the purposes of paragraph (3)(c) the responsibility of a person for the composition of a contact lens substance shall be determined by the application of section 7(6) of the Act to that substance as though it were a medicinal product the responsibility for the composition of which was being determined for the purposes of section 7(5) of the Act.

Offences

8. Any person who contravenes the provisions of these regulations or contravenes the provisions of sections 85(3) or 86(2) of the Act shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400 and shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

Patrick Jenkin,
Secretary of State for Social Services.

20th December 1979.

Nicholas Edwards,
Secretary of State for Wales.

21st December 1979.

George Younger,
Secretary of State for Scotland.

20th December 1979.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of December 1979.

(L.S.)

N. Dugdale,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations lay down special requirements as to the particulars to be furnished with certain substances and fluids for use with contact lenses or blanks which are for sale or supply, either on a label on the container or package or in an accompanying leaflet. They also contain transitional provisions. The substances and fluids concerned are those described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976.

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