STATUTORY INSTRUMENTS

1979 No. 1760

MEDICINES

The Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979

Made - - - -	*28th December* 1979
Laid before Parliament	*9th January* 1980
Coming into Operation	*1st February* 1980

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 18, 36, 95, 96(6) and 129(1) and (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) (Advertising and Miscellaneous Amendments) Regulations 1979 and shall come into operation on 1st February 1980.

Interpretation

2.—(1) In these regulations—

"the Act" means the Medicines Act 1968;

"contact lens substance" means any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens or blank or any fluid in which such lens or blank is soaked or rinsed or any fluid used as a barrier between such lens or blank and the human eyeball or any other substance used in connection with the use of such lens or blank;

(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), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments, 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).

"data sheet" has the same meaning as in section 96(6) of the Act;

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

"information sheet" means an advertisement, other than a data sheet, in the form of a leaflet relating to a contact lens substance;

"optician" means a person who is registered in any register established and maintained under section 2 of the Opticians Act 1958**(a)** either as an ophthalmic optician or as a dispensing optician; and

"the Schedule" means the Schedule to these regulations.

(2) In these regulations, unless the context otherwise requires, a reference to a numbered regulation is a reference to the regulation of these regulations bearing that number.

(3) In this regulation and in the Schedule, 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.

Particulars required in information sheets

3. Subject to the provisions of regulation 8, any information sheet which is sent or delivered to a pharmacist or optician must contain the particulars set out in paragraphs 1 to 13 of the Schedule and, where such substance is for use by being directly administered to the human eyeball, the particulars set out in paragraph 14 of the Schedule.

Particulars required in data sheets

4. Subject to the provisions of regulation 8, the particulars prescribed for the purposes of section 96(6) of the Act as the particulars required to be contained in a data sheet which relates to a contact lens substance of any description and is sent or delivered to a doctor shall be the particulars set out in paragraphs 1 to 13 of the Schedule and in addition, where such substance is for use by being directly administered to the human eyeball, the particulars set out in paragraph 14 of the Schedule.

Amendment to the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971

5. In regulation 2(1) of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971**(b)** immediately after the definition of "clinical trial certificate" there shall be inserted the following definition—

" "medicinal product" includes the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976;**(c)**".

(a) 1958 c. 32.
(b) S.I. 1971/973, amended by S.I. 1972/1201, 1975/681, 1977/1051.
(c) S.I. 1976/968.

Amendment to the Medicines (Data Sheet) Regulations 1972

6. In regulation 1(2) of the Medicines (Data Sheet) Regulations 1972**(a)** in the definition of "medicinal product" there shall be inserted between the word "includes" and the word "articles", where that word first appears, the following words—

", except for the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976,".

Amendment to the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975

7. In regulation 1(2) of the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975**(b)** in the definition of "medicinal product" there shall be inserted between the word "article" and the word "specified" the words ", except for the substances and fluids described in paragraph 2 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976, which is".

Temporary and transitional provisions

8. The requirements of regulation 3 shall not apply to an information sheet and the requirements of regulation 4 shall not apply to a data sheet where such information sheet or data sheet—

(*a*) relates to a contact lens substance in respect of which the restrictions imposed by section 7(2) of the Act (product licences) do not apply on 1st January 1980**(c)** by reason of section 16(2) of the Act (transitional exemption for products then on the market), and

(*b*) is sent or delivered, to a pharmacist or optician if it is an information sheet or to a doctor if it is a data sheet, within 6 months after such day as may be appointed by an order made under section 17 of the Act which provides that section 16(2) of the Act shall cease to have effect on or after that day in relation to contact lens substances of the description to which the information sheet of data sheet relates.

Offences

9. Any person who contravenes the provisions of regulation 3 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £400.

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.

(a) S.I. 1972/2076. **(b)** S.I. 1975/1326.

(c) The day appointed under section 16, as applied, by the Medicines (Contact Lens Fluids and Other Substances) (Appointed Day) Order 1979, S.I. 1979/1539.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 28th December 1979.

(L.S.) *Peter Walker*,
Minister of Agriculture, Fisheries and Food.

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.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of December 1979.

(L.S.) *J. A. Young*,
Permanent Secretary.

SCHEDULE *Regulations 3 and 4*

PARTICULARS REQUIRED IN INFORMATION SHEETS AND DATA SHEETS

1. Each purpose for which the contact lens 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 a contact lens or blank and the human eyeball, for which of those purposes it is to be used.

2. A description of the pharmaceutical form of the contact lens substance.

3. The active ingredients of the contact lens substance and its quantitative composition.

4. The name of any antimicrobial agent which is an ingredient of the contact lens 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.

5. The quantity or amount of the contact lens substance in each size of package or container in which it is available for retail sale.

6. The compatibility and incompatibility of the contact lens substance for use with different types of contact lenses and blanks, other contact lens substances and any other substance commonly applied to the human eyeball.

7. Possibilities of interaction between the contact lens substance and any other contact lens substance or any other substance commonly applied to the human eyeball.

8. The shelf-life of the contact lens substance.

9. A recommended period within which the contact lens substance should be used after the container containing it has first been opened.

10. Any special requirements for the storage of the contact lens substance and, where appropriate, pharmaceutical precautions including recommendations as to excipients and diluents.

11. Those adverse reactions to the contact lens substance which, if experienced, should be reported to a doctor, or to the pharmacist or optician who administered that substance or who sold or supplied it for administration.

12. Appropriate remedial measures in response to any adverse reaction to the contact lens substance which may be taken by the person to whom the substance was administered, sold or supplied.

13. Recommendations as to the antidote to be administered or other action to be taken by a doctor, pharmacist or optician on his becoming aware of any adverse reaction having occurred in connection with the use of the contact lens substance.

14. Any precautions required to be observed in the use of a contact lens substance which is intended to be administered directly to the human eyeball and any warnings relating to its use, either alone or in conjunction with any other substance, which should be given to any person to whom the substance may be sold or supplied.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations lay down requirements as to the particulars which must be contained in advertisements in the form of information sheets sent or delivered to pharmacists and ophthalmic and dispensing opticians relating to certain substances and fluids for use with contact lenses or blanks. They amend the Medicines (Data Sheet) Regulations 1972 so that those Regulations do not apply to data sheets which relate to such substances and fluids, and prescribe special particulars for such data sheets sent or delivered to doctors. They also contain certain transitional provisions.

SI 1979/1760
ISBN 0-11-094760-6