
STATUTORY INSTRUMENTS

1979 No. 1760

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

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;

“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 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

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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⁽¹⁾ 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;”.

Amendment to the Medicines (Data Sheet) Regulations 1972

6. In regulation 1(2) of the Medicines (Data Sheet) Regulations 1972 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 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⁽²⁾ 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 or 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.

(1) , amended by S.I. 1972/1201, 1975/681, 1977/1051.

(2) 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.

20th December 1979

Patrick Jenkin
Secretary of State for Social Services

21st December 1979

Nicholas Edwards
Secretary of State for Wales

20th December 1979

George Younger
Secretary of State for Scotland

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