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STATUTORY INSTRUMENTS

1979 No. 1585

MEDICINES

The Medicines (Contact Lens Fluids and Other Substances) (Exemption From Licences) Order 1979

Made - - - -	*3rd December 1979*
Laid before Parliament	*11th December 1979*
Coming into Operation	*1st January 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 13(2), 15(1) and (2), 23(4), 35(8) and 129(4) of the Medicines Act 1968(**1**) and now vested in them(**2**) 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 order, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979 and shall come into operation on 1st January 1980.

(2) In this order, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"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 as a contact lens;

"contact lens substance" means any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens or blank from which the contact lens is to be prepared or any fluid in which such lens or blank is soaked or rinsed or any fluid used as

(**1**) , as applied by the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968).

(**2**) 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).

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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;

"exemption" means an exemption under Article 2 of this order from the restriction on assembly imposed by section 8(2) of the Act; and

"optician" means a person who is registered in either of the registers of ophthalmic opticians established and maintained under section 2(a) of the Opticians Act 1958.

(3) In this order, unless the context otherwise requires, a reference to a numbered Article is a reference to the Article of this order bearing that number and a reference in a paragraph of an Article of this order to a numbered paragraph is a reference to the paragraph of the Article bearing that number.

2.—(1) Subject to the provisions of Article 3, the restrictions on assembly imposed by section 8(2) of the Act (licences for manufacture or assembly) shall not apply to the assembly of a contact lens substance by a doctor, pharmacist or optician where the assembly consists only of labelling the container in which the substance is sold or supplied, before the substance is sold or supplied in it, and the conditions specified in paragraph (2) are fulfilled.

(2) The conditions referred to in paragraph (1) are that—

(a) the contact lens substance is to be sold or supplied by the doctor, pharmacist or optician who labels it in circumstances where he sells or supplies it for use by or on behalf of a particular person after being requested by or on behalf of that person in that person's presence to use his own judgment as to what substance is appropriate for the purpose for which it is required, and

(b) the doctor, pharmacist or optician who intends to carry out the assembly has given notice in writing to the licensing authority of his intention of labelling the containers of contact lens substances and has included in such notice particulars of—

(i) his name and address,

(ii) his professional qualifications,

(iii) the date from which he intends to commence such labelling, and

(iv) the premises at which such labelling will be carried out by him.

Coming into effect, duration and termination of exemptions

3.—(1) An exemption shall have effect from the date of the giving of a notice in accordance with Article 2(2)(b) and shall continue unless and until terminated by the licensing authority under the provisions of paragraph (2).

(2) The licensing authority may terminate an exemption either wholly or so far as it relates to one or more descriptions or classes of contact lens substances, by giving notice in writing to the doctor, pharmacist or optician concerned where—

(a) it appears to the licensing authority at any time on grounds of safety that that exemption should cease to have effect; or

(b) that doctor, pharmacist or optician has been requested in writing by the licensing authority to inform them in writing which descriptions or classes of contact lens substances he has assembled under an exemption and has failed so to inform them within 21 days of the date of such request or within such further time as the licensing authority may in a particular case allow.

(3) The date from which an exemption terminated by a notice under paragraph (2) shall cease to have effect shall be the date on which such notice is given or such later date as may be specified in the notice.

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Amendment to the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

4. In Article 1(2) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**3**) in the definition of "medicinal product" for the words "paragraph 3" there shall be substituted the words "paragraphs 2 and 3".

Amendment to the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1972

5. In Article 1(2) of the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1972(**4**) in the definition of "medicinal product" for the words "paragraph 3" there shall be substituted the words "paragraphs 2 and 3".

Amendment to the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972

6. In Article 1(2) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(**5**) in the definition of "medicinal product" for the words "paragraph 3" there shall be substituted the words "paragraphs 2 and 3".

Patrick Jenkin
26th November 1979 Secretary of State for Social Services

Nicholas Edwards
28th November 1979 Secretary of State for Wales

George Younger
29th November 1979 Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 30th November 1979.

L.S.

Peter Walker
Minister of Agriculture, Fisheries and Food

(**3**) , amended by S.I. 1972/1200, 1978/1139.
(**4**) , amended by S.I. 1978/1139.
(**5**) , amended by S.I. 1978/1139.

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Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 28th day of November 1979.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 3rd day of December 1979.

L.S.

J.A. Young
Permanent Secretary

EXPLANATORY NOTE

This Order gives exemption from the restriction imposed by section 8(2) of the Medicines Act 1968 on the labelling, except in accordance with a manufacturer's licence, of certain substances and fluids for use with contact lenses or blanks. The exemption applies to doctors, pharmacists and registered ophthalmic opticians where certain specified conditions are met.

The Order also amends the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971, the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1972 and the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 so as to enable the provisions of those Orders to apply to such substances where appropriate.