STATUTORY INSTRUMENTS

1976 No. 968

MEDICINES

The Medicines (Specified Articles and Substances) Order 1976

Laid before Parliament in draft

Made - - - - 21st June 1976 Coming into Operation 12th July 1976

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 their powers under section 104(1) of the Medicines Act 1968 and now vested in them(1) 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, a draft of which has been laid before Parliament and has been approved by resolution of each House of Parliament:—

Citation, commencement and interpretation

- 1.—(1) This order may be cited as the Medicines (Specified Articles and Substances) Order 1976 and shall come into operation on 12th July 1976.
- (2) In this order unless the context otherwise requires "the Act" means the Medicines Act 1968, and other expressions have the same meanings as in the Act.
- (3) Except in so far as the context otherwise requires, any reference in this order to any provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.
- (4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889 shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

⁽¹⁾ 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; 1969 I, p. 1070), 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 paragraph 2(1)(b) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

Application of specified provisions of the Act to articles and substances described in Schedule 1

2. For the purposes of section 104(1) of the Act, the articles or substances described in Schedule 1 to this order are hereby specified as being articles or substances appearing to the Health Ministers to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose and it is hereby directed that, subject to the exceptions and modifications specified in Part II of Schedule 2 to this order, the provisions of the Act set out in Part I of the said Schedule 2 shall have effect in relation to such articles or substances as those provisions have effect in relation to medicinal products.

David Ennals
14th June 1976 Secretary of State for Social Services

John Morris
14th June 1976 Secretary of State for Wales

Bruce Millan
16th June 1976 Secretary of State for Scotland

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 21st day of June 1976.

L.S.

J.H. Copeland Deputy Permanent Secretary

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SCHEDULE 1 Article 2

- 1. 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 or any blank from which a contact lens is to be prepared.
- **2.** Any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens described in paragraph 1 of this Schedule 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 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.
- **3.** Any instrument, apparatus or appliance for use by being inserted in the uterus of a human being for the purpose of contraception.

SCHEDULE 2 Article 2

PART I Provisions of the Act applied to the specified articles and substances

| 1. In Part I (Administration) | all sections. |
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| 2. In Part II (Licences) | sections 6 to 8; |
| | section 13; |
| | section 15(1) and (2); |
| | sections 16 to 24 other than section 19(7); |
| | sections 28 to 31; |
| | sections 35 and 36; |
| | section 37(1) to (3); |
| | sections 38 and 39; |
| | sections 43 to 47; |
| | section 50. |
| 3. In Part III (Dealings) | section 58(1), 2(b), (4) to (6); |
| | section 59; |
| | sections 62 to 67. |
| 4. In Part V (Containers and Packages) | all sections other than section 90. |
| 5. In Part VI (Promotion of Sales) | all sections. |
| | |

6. In Part VIII (Miscellaneous)

all sections other than sections 104, 105 and 117.

PART II

Exceptions to and modifications of the provisions of the Act applied to the specified articles and substances

- 1. Section 16(1) shall have effect in relation to any of the articles or substances described in Schedule 1 to this order where an order under that subsection is made which relates specifically to those articles or substances or to any class of those articles or substances and which specifies in relation to those articles or substances or classes one or more days and any reference in the Act to "the first appointed day" in any provisions of the Act which by virtue of Article 2 above are to have effect in relation to any of those articles or substances shall, in their application to them, be construed as referring to the day or days specified by virtue of this paragraph.
- **2.** Section 17 shall have effect in relation to any of the articles or substances described in Schedule 1 to this order where any order under that section is made which relates specifically to those articles or substances or to any class of those articles or substances and which appoints in relation to those articles or substances or classes one or more days subsequent to the day or days specified by virtue of paragraph 1 above for the purposes of subsections (2) to (5) of section 16.
 - 3. After section 19(2) there shall be inserted the following subsection—
 - "(2A) Notwithstanding the provisions of subsection (1) of this section, the licensing authority shall leave out of account considerations of efficacy and quality (as mentioned in paragraphs (b) and (c) of that subsection) if satisfied that in the circumstances it is reasonable to do so."
- **4.** In section 23(4) for the words "If by virtue of an order" to the words "the order" there shall be substituted the words "An order made under section 15 of this Act".
- **5.** Section 37(3) shall have effect in relation to any of the articles or substances described in Schedule 1 to this order where an order under that subsection is made which relates specifically to those articles or substances and which appoints a day in relation to them for the purposes of section 37.
- **6.** Section 96 shall not have effect in relation to any article or substance described in Schedule 1 to this order in respect of which the restrictions imposed by section 7 of the Act do not apply.
 - 7. After section 58(1)(c) there shall be inserted the following paragraph—"and (d) other suitably qualified persons,".
- **8.** In section 130(8), in relation to the articles described in paragraphs 1 and 3 of Schedule 1 to this order, the word "pharmaceutical" shall be omitted.
- **9.** In section 130(9), in relation to the substances described in paragraph 2 of Schedule 1 to this order, the definition of "administer" shall be construed as extending to include the application of such substances to contact lenses or blanks.

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EXPLANATORY NOTE

This Order, made under section 104(1) of the Medicines Act 1968, extends the application of specified provisions of the Act to contact lenses, associated substances and intra-uterine contraceptive devices. The Order also modifies specified provisions of the Act in relation to those articles or substances.