STATUTORY INSTRUMENTS

1978 No. 1140

MEDICINES

The Medicines (Licensing of Intra-Uterine Contraceptive Devices) (Miscellaneous Amendments) Regulations 1978

| Made | 31st J uly 1978 |
|------------------------|------------------------|
| Laid before Parliament | 10th August 1978 |
| Coming into Operation | 1st October 1978 |

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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, 85(1), 85(4), 86(1), 91(2) and (3) and 129(1) 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, commencement and interpretation

- 1.—(1) These regulations may be cited as the Medicines (Licensing of Intra-Uterine Contraceptive Devices) (Miscellaneous Amendments) Regulations 1978 and shall come into operation on 1st October 1978.
- (2) Except in so far as the context otherwise requires, any reference in these regulations to any enactment, order, rules or regulations shall be construed as a reference to that enactment or order or those rules or regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order, rules or regulations.
- (3) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(c) shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

⁽a) 1968 c. 67 as applied to, and modified for the purposes of, intra-uterine contraceptive devices 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 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).

(c) 1889 c. 63.

Amendment to the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971

- 2. In regulation 2 of the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(a) as amended (b), immediately after paragraph (1) there shall be inserted the following paragraph:—
 - "(1A) In these regulations any reference to medicinal products shall be construed as including a reference to substances or articles in respect of which an application is made.".

Amendment to the Medicines (Labelling) Regulations 1976

- 3. For the definition of "medicinal product" in regulation 3(1) (definitions) of the Medicines (Labelling) Regulations 1976(c) as amended (d) there shall be substituted the definition—
 - ""medicinal product" includes articles or substances specified in the Medicines (Control of Substances for Manufacture) Order 1971(e), the Medicines (Surgical Materials) Order 1971(f) and the articles or substances described in paragraph 3 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976(g) but shall not include any herbal remedy to which the provisions of section 12(2) of the Act are applicable;".

David Ennals, Secretary of State for Social Services.

11th July 1978.

John Morris, Secretary of State for Wales.

17th July 1978.

Bruce Millan, Secretary of State for Scotland.

18th July 1978.

(a) S.I. 1971/974. (c) S.I. 1976/1726. **(b)** S.I. 1977/1052.

(d) The relevant amending instrument is S.I. 1977/996.

⁽e) S.I. 1971/1200.

(f) S.I. 1971/1267.

(g) S.I. 1976/968. The articles or substances described in paragraph 3 of Schedule 1 to that order are any instrument, apparatus or appliance for use by being inserted in the uterus of a human being for the purpose of contraception.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 28th July 1978.

(L.S.) John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 31st day of July 1978.

(L.S.) N. Dugdale, Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 31st day of July 1978.

(L.S.) W. H. Jack, Deputy Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations amend the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 and the Medicines (Labelling) Regulations 1976 so as to make them apply to intra-uterine contraceptive devices as they apply to medicinal products.

Various provisions of the Medicines Act 1968 were applied to these devices by the Medicines (Specified Articles and Substances) Order 1976 with effect from 1st October 1978, the day appointed by the Medicines (Intra-Uterine Contraceptive Devices) (Appointed Day) Order 1978 (S.I. 1978/1138).

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