STATUTORY INSTRUMENTS

1977 No. 180

MEDICINES

The Medicines (Renewal Applications for Licences and Certificates) Amendment Regulations 1977

Made - - - - 4th February 1977

Laid before Parliament 8th February 1977

Coming into Operation 1st March 1977

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture 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 section 18(1) of the Medicines Act 1968 (as read with section 24(4) of that Act) 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 regulations, hereby make the following regulations:—

Citation, commencement and interpretation

- 1.—(1) These regulations may be cited as the Medicines (Renewal Applications for Licences and Certificates) Amendment Regulations 1977 and shall come into operation on 1st March 1977.
- (2) These regulations shall be read as one with the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974(2) (hereinafter referred to as "the principal regulations").

Addition to the principal regulations

2. After regulation 7 of the principal regulations there shall be added the following—

⁽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 Northern Ireland Departments 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).

^{(2) (1974} II, p. 3241).

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"Transitional provision relating to the renewal of product licences which are licences of right

8. Regulation 4 of these regulations shall have effect in relation to any application for the first renewal of a product licence which is a licence of right where such application is made during the period commencing with 1st March 1977 and ending with 30th June 1977 or such other later date as the licensing authority may in any particular case allow, and in relation to such application regulations 5 and 6 of these regulations shall not have effect.".

David Ennals 27th January 1977 Secretary of State for Social Services John Morris Secretary of State for Wales 27th January 1977 Bruce Millan Secretary of State for Scotland 28th January 1977 In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 31st January 1977. 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 2nd day of February 1977.

N. Dugdale
Permanent Secretary

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Sealed with the official seal of the Department of Agriculture for Northern Ireland this 4th day of February 1977.

L.S.

J.A. Young
Permanent Secretary

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EXPLANATORY NOTE

These Regulations amend the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974 by providing that regulation 4 of the regulations is to have effect and not regulations 5 and 6 in respect of applications for the first renewal of product licences of right made between 1st March and 30th June 1977 or such later date as the licensing authority allows. The requirements of regulation 4 are less extensive than those of regulations 5 and 6.