STATUTORY INSTRUMENTS

1977 No. 1052

MEDICINES

The Medicines (Applications for Manufacturer'S and Wholesale Dealer'S Licences) Amendment Regulations 1977

Made - - - -	*21st June 1977*
Laid before Parliament	*24th June 1977*
Coming into Operation	*15th July 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 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 regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Amendment Regulations 1977 and shall come into operation on 15th July 1977.

(2) These regulations shall be read as one with the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**2**) (hereinafter referred to as "the principal regulations").

Amendment of regulation 2(1) of the principal regulations

2. In regulation 2(1) of the principal regulations (definitions) after the definition of "application" there shall be inserted the following definitions—

> ""imported proprietary product" means a proprietary medicinal product imported other than from a member State of the European Economic Community;

(**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 section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**2**) (1971 II, p. 2836).

"proprietary medicinal product" has the same meaning as in sections 7(7) and 8(4) of the Act, as amended(**3**)

Amendment of Schedule 1 to the principal regulations

3. In paragraph 7 of Schedule 1 to the principal regulations (manufacturer's licences) there shall be inserted the following sub-paragraph—

"(5) The name and address and degrees, diplomas or qualifications and experience of the person who is to carry out the functions specified in paragraph 16(3) of Schedule 2 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**), as amended(**5**) ("qualified person")."

Amendment of Schedule 2 to the principal regulations

4.—(1) In paragraph 3 of Schedule 2 to the principal regulations (wholesale dealer's licences) after sub-paragraph (d) there shall be inserted the following sub-paragraph—

"(e) dealing in imported proprietary products."

(2) At the end of paragraph 6 of the said Schedule there shall be inserted the following sentence—

"Where the licence is to relate to imported proprietary products the statement shall indicate the description of the medicinal products."

(3) After paragraph 8 of the said Schedule there shall be inserted the following paragraph—

"**9.** Where the licence is to relate to imported proprietary products and is to be subject to the provisions of paragraph 8 of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, as amended, ("qualified person"), the name and address and degrees, diplomas or qualifications and experience of the person who is to carry out the functions specified in the said paragraph.".

David Ennals
13th June 1977 Secretary of State for Social Services

John Morris
14th June 1977 Secretary of State for Wales

Bruce Millan
16th June 1977 Secretary of State for Scotland

(**3**) See regulations 2 and 3 of the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1977/1050(1977 II, p. 2986)) and regulations 3 and 4 of the Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977 (S.R. of N.I. 1977/170).
(**4**) S.I 1971/972 (1971 II, p. 2809).
(**5**) The relevant amending instruments are S.I. 1972/1226, 1977/1053 (1972 II, p. 3708; 1977 II, p. 2996).

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th June 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 20th day of June 1977.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of June 1977.

L.S.

J. A. Young
Permanent Secretary

EXPLANATORY NOTE

These Regulations amend the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 by prescribing particulars of persons who are to act as qualified persons to be furnished in applications for manufacturer's licences relating to medicinal products and in applications for wholesale dealer's licences relating to imported proprietary medicinal products. To the extent that the regulations relate to proprietary medicinal products they implement certain Community obligations under two Council Directives Nos.65/65/EEC and 75/319/EEC.