STATUTORY INSTRUMENTS

# 1983 No. 1725

# MEDICINES

## The Medicines (Applications for Manufacturer'S and Wholesale Dealer'S Licences) Amendment Regulations 1983

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| *Made - - - -* | *21st November 1983* |
| *Laid before Parliament* | *30th November 1983* |
| *Coming into Operation* | *21st December 1983* |

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 the 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 these regulations in accordance with section 129(6) of the said Act, hereby make the following regulations:—

**Title and commencement**

**1.** These regulations may be cited as the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Amendment Regulations 1983 and shall come into operation on 21st December 1983.

**Amendment of regulations**

**2.** The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**2**) shall be amended as follows—

(a) in regulation 2(1) (interpretation)—

(i) for the definition of "imported proprietary product" there shall be substituted the following definition—

(**1**) In the case of the Secretaries of State concerned with health in England and Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of 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).

(**2**) Amended by S.I. 1977/1052.

""imported proprietary product" means a proprietary medicinal product imported other than from a member State of the European Communities;",

(ii) after the definition of "imported proprietary product" (as substituted) there shall be inserted the following definition—

""imported ready-made veterinary drug" means a ready-made veterinary drug imported other than from a member State of the European Communities;",

(iii) for the definition of "proprietary medicinal product" there shall be substituted the following definition—

""proprietary medicinal product" and "ready-made veterinary drug" have the same meanings as in sections 7(7) and 8(4) of the Act(**3**);",

(b) in paragraph 7(5) of Schedule 1 (particulars required on an application for the grant of a manufacturer's licence) after the words "in paragraph 16(3)" there shall be inserted the words "or 17(3), as the case may be";

(c) in paragraphs 3(e) and 6 of Schedule 2 (particulars required on an application for the grant of a wholesale dealer's licence) after the words "imported proprietary products" wherever they occur in those paragraphs there shall be inserted the words "or imported ready-made veterinary drugs"; and

(d) for paragraph 9 of Schedule 2 there shall be substituted the following paragraph—

"**9.** Where the licence is to relate to an imported proprietary product or an imported ready-made veterinary drug and is to be subject to the provisions of paragraph 8 or 9, as the case may be, of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**), the name and address and degrees, diplomas or qualifications of the person who is to carry out the functions specified in the appropriate said paragraph.".

*Norman Fowler*
21st November 1983 — Secretary of State for Social Services

*George Younger*
1st November 1983 — Secretary of State for Scotland

*Nicholas Edwards*
2nd November 1983 — Secretary of State for Wales

(**3**) Sections 7(7) and 8(4) were inserted by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724.
(**4**) S.I. 1971/972 relevant amending instrument is S.I. 1977/1053.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th October 1983.

L.S.

*Michael Jopling*
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 10th day of November 1983.

L.S.

*N. Dugdale*
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 10th day of November 1983.

L.S.

*W.H. Jack*
Permanent Secretary

## EXPLANATORY NOTE

These Regulations further amend the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 which prescribed the form and manner in which an application for the grant of a manufacturer's licence or a wholesale dealer's licence is to be made and the information that is to be furnished with each application.

The 1971 Regulations, as amended, prescribed particulars which are to be contained in, or accompany, every application, for the grant of a wholesale dealer's licence relating to an imported proprietary medicinal product. A proprietary medicinal product was defined for the purposes of the 1971 Regulations as having the same meaning as in sections 7(7) and 8(4) of the Medicines Act 1968, which sections were inserted in that Act by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170.

These Regulations amend the 1971 Regulations so that such particulars are to be contained in, or accompany, every application for the grant of a wholesale dealer's licence relating to a proprietary medicinal product, as defined in sections 7(7) and 8(4) of the Medicines Act 1968 as those sections were amended by S.I. 1983/1724, and to a ready-made veterinary drug, as similarly defined, and which, in each case, is imported other than from a member State of the European Communities (Regulation 2).

The Regulations implement in part Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products.