STATUTORY INSTRUMENTS

# 1983 No. 1731

# MEDICINES

## The Medicines (Fees) Amendment Regulations 1983

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| *Made* - - - - | 21*st November* 1983 |
| *Laid before Parliament* | 30*th November* 1983 |
| *Coming into Operation* | 21*st 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, with the consent of the Treasury, in exercise of the powers conferred by section 1(1) of the Medicines Act 1971**(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 these regulations in accordance with section 129(6) of the Medicines Act 1968**(c)**, hereby make the following regulations:—

*Title and commencement*

**1.** These regulations may be cited as the Medicines (Fees) Amendment Regulations 1983 and shall come into operation on 21st December 1983.

*Amendment of regulations*

**2.** The Medicines (Fees) Regulations 1978**(d)** shall be amended as follows—

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

(i) after the definition of "imported proprietary product" 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;",

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**(a)** 1971 c. 69.

**(b)** 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).

**(c)** 1968 c. 67.

**(d)** S.I. 1978/1121; relevant amending instruments are S.I. 1979/899, 1980/1126, 1982/1121.

(ii) 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**(a)**;",

(iii) in the definition of "wholesale dealer's (import) licence" after the words "imported proprietary products" there shall be inserted the words "or imported ready-made veterinary drugs"; and

(*b*) in column 3 of paragraph 4 of Table A in Part I of Schedule 1 (fee for a wholesale dealer's (import) licence) after the words "imported proprietary products" there shall be inserted the words "or imported ready-made veterinary drugs".

*Norman Fowler,*
Secretary of State for Social Services.

21st November 1983.

*George Younger,*
Secretary of State for Scotland.

1st November 1983.

*Nicholas Edwards,*
Secretary of State for Wales.

2nd November 1983.

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.

**(a)** 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.

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.

We consent,

*T. Garel-Jones,*
*Alastair Goodlad,*
Two of the Lords Commissioners of
Her Majesty's Treasury.

21st November 1983.

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## EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations further amend the Medicines (Fees) Regulations 1978 which provide for the fees payable in connection with licences granted and certificates issued under the Medicines Act 1968.

The 1978 Regulations, as amended, provide for annual fees to be payable for a wholesale dealer's (import) licence relating to a proprietary medicinal product. A proprietary medicinal product was defined for the purposes of the 1978 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) and these Regulations amend the 1978 Regulations so that such fees are now payable in relation to a proprietary medicinal product, as defined in sections 7(7) and 8(4) of the Medicines Act 1968 as those sections are amended by S.I. 1983/1724, and a ready-made veterinary drug, as similarly defined (Regulation 2).

The Regulations implement in part Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p. 1) on the approximation of the laws of the Member States relating to veterinary medicinal products.

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