

STATUTORY INSTRUMENTS

1986 No. 228

MEDICINES

**The Medicines (Veterinary Drugs) (Exemption from Licences)
(Importation) Order 1986***Made* - - - - - 10th February 1986*Laid before Parliament* 19th February 1986*Coming into Operation* 12th March 1986

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 13(2) and (3) and 15(1) and (2) 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 order in accordance with section 129(6) of that Act, hereby make the following order:—

Title and commencement

1. This order may be cited as the Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986 and shall come into operation on 12th March 1986.

Interpretation

2. In this order—

“the Act” means the Medicines Act 1968;

“immunological veterinary drug” means a veterinary drug which when administered to an animal produces an immune response;

“member State” means a member State of the Communities;

“prescription only medicine” means a medicinal product of a description or falling within a class for the time being specified for the purposes of section 58 of the Act in an order made under that section(c).

(a) 1968 c. 67.

(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) For the current relevant order see S.I. 1985/1288.

Exemption from product licences for certain imported veterinary drugs

3. Subject to the conditions specified in Article 4 below, the restrictions imposed by section 7 of the Act (restrictions as to dealing in medicinal products) shall not apply to the importation of a veterinary drug (not being an immunological veterinary drug) or to the sale or supply of any such imported veterinary drug.

Conditions

4.—(1) The exemption conferred by Article 3 above is subject to the conditions that—

- (a) there is for the time being in force in respect of the veterinary drug a product licence granted for the purposes of section 7(2) of the Act;
- (b) the veterinary drug has been assembled in a member State in accordance with the provisions of the product licence referred to in sub-paragraph (a) above;
- (c) the veterinary drug is in the container or package in which it was placed by the person to whom the product licence referred to in sub-paragraph (a) above was granted or by the person named in that licence as the assembler of the drug and which container or package is labelled in accordance with the requirements of regulations made under section 85(1) of the Act for the time being in force^(a);
- (d) the person importing the veterinary drug makes a record containing the particulars specified in paragraph (2) below and keeps such record for a period of two years from the date of the sale or supply of the drug; and
- (e) in the case of the importation of a veterinary drug which is a prescription only medicine, it is imported by—
 - (i) a veterinary surgeon or veterinary practitioner,
 - (ii) a pharmacist, or
 - (iii) a person who is the holder of a wholesale dealer's licence for the time being in force in respect of that veterinary drug or of a class of veterinary drugs of which that drug forms part.

^(a) For the current relevant regulations see S.I. 1976/1726, amended by S.I. 1977/996, 2168, 1981/1791, 1983/1729 and 1985/2008.

- (2) The particulars referred to in paragraph (1)(d) above are—
- (a) in respect of the importation of the veterinary drug, the name and quantity of the drug, the name and address of the manufacturer or assembler, or if different, the supplier and the date of such importation;
 - (b) in respect of the sale or supply of the veterinary drug, the name and address of the person to whom the drug is sold or supplied, the quantity and the date of such sale or supply.

Norman Fowler,
Secretary of State for Social Services.

5th February 1986.

Malcolm Rifkind,
Secretary of State for Scotland.

6th February 1986.

Nicholas Edwards,
Secretary of State for Wales.

4th February 1986.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 31st January 1986.



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 February 1986.



M. N. Hayes,
Permanent Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 10th day of February 1986.



W. H. Jack,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order grants exemptions from restrictions imposed by section 7 of the Medicines Act 1968 on the importation, sale or supply of a medicinal product without a product licence (Article 3).

The Order applies to veterinary drugs (other than immunological veterinary drugs as defined in Article 2 of the Order) and the exemptions, which relate to the importation and the subsequent sale or supply of such veterinary drugs, are subject to the conditions specified in Article 4.

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