1990 No. 1210

MEDICINES

The Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1990

Made -8th June 1990

Laid before Parliament 11th June 1990

Coming into force 1st July 1990

The Minister of Agriculture, Fisheries and Food, the Secretaries of State respectively concerned with agriculture in Scotland and in Wales and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by sections 40 and 129 (5) 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 Regulations in accordance with section 129(6) of that Act, and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated (c) for the purposes of section 2(2) of the European Communities Act 1972(d) in relation to medicinal products and the common agricultural policy of the Economic Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

Title, commencement and interpretation

- 1.—(1) These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1990 and shall come into force on 1st July 1990.
- (2) In these Regulations, "the principal Regulations" means the Medicines (Medicated Animal Feeding Stuffs) Regulations 1989(e).

Amendment of the principal Regulations

- 2.—(1) The principal Regulations shall be amended in accordance with the provisions of this regulation.
- (2) In regulation 2(1) (interpretation) after the definition of "the Register" there shall be inserted the following definition-
 - "the registrar" means any person appointed under section 1 of the Pharmacy Act 1954 as registrar for the purposes of that Act;".

⁽a) 1968 (c.67); section 40 was substituted by the Animal Health and Welfare Act 1984 (c.40), section 13(1); "the Agriculture Ministers" referred to in section 40 is defined in section 1(1)(b) of 1968 (c.67) (see also the following

⁽b) In the case of the Secretaries of State concerned with Agriculture in Wales by virtue of S.I. 1978/272 and in the case of the Department of Agriculture for Northern Ireland by virtue of the Northern Ireland Constitution Act 1973 (c.36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c.28), section 1(3) and Schedule 1, paragraph 2(1)(b).

⁽c) S.I. 1972/1811. (d) 1972 c.68.

⁽e) S.I. 1989/2320.

- (3) In regulation 3 (restrictions on incorporation of medicinal products in animal feeding stuffs)-
 - (a) for paragraph (1) there shall be substituted the following paragraph-
 - "(1) No person shall, in the course of a business carried on by him, incorporate in an animal feeding stuff a medicinal product of any description, except a veterinary drug which is exempted under article 3 (exemption from licences and certificates in respect of medicinal tests on animals) of the Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986 (a), unless—
 - (a) there is a valid product licence or animal test certificate relating to the incorporation of that medicinal product (whether held by him or another person) and, subject to paragraph (2) below—
 - (i) where the medicinal product is incorporated at a rate below 2 kilograms per tonne, his name is entered in Part A of the Register in respect of the premises where the medicinal product is incorporated, or
 - (ii) in any other case, his name is entered in Part A or Part B of the Register in respect of the premises where the medicinal product is incorporated,

and the medicinal product is incorporated either in accordance with provisions relating to its incorporation contained in a product licence or animal test certificate (whether held by him or another person) or, in the case of medicinal products to which a product licence relates, in accordance with a veterinary written direction; or

- (b) his name is entered in the Register and he intends to export the animal feeding stuff in accordance with a written export order and he stores such animal feeding stuff in a part of a building separate from the storage of any other animal feeding stuff.";
- (b) after paragraph (2) there shall be added the following paragraph-
- "(3) Any person who, pursuant to paragraph (1)(b) above, exports such animal feeding stuff, shall keep, for a period of at least 2 years from the date of export, a record of—
 - (a) the name and address of the person to whom the animal feeding stuff was exported;
 - (b) the written export order; and
 - (c) the name, identification and quantity of the animal feeding stuff.".
- (4) In regulation 3(2), for the words "for this name" there shall be substituted the words "for his name".
- (5) In regulation 4(5)(b) for the reference to "article 3(7)" there shall be substituted "article 5(1)".
- (6) In regulation 6(1) (registration of persons incorporating medicinal products in animal feeding stuffs) for the words "The registrar and the Department shall each keep for the purposes of these Regulations a Register—" there shall be substituted the words "For the purposes of these Regulations the registrar and the Department shall each continue to keep a Register—".

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th June 1990.



John Selwyn Gummer Minister of Agriculture, Fisheries and Food

8th June 1990

Sanderson of Bowden Minister of State, Scottish office

8th June 1990

David Hunt Secretary of State for Wales

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 8th day of June 1990.



W. J. Hodges Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Medicated Animal Feeding Stuffs) Regulations 1989 by-

- (1) defining the registrar who will keep the register of manufacturers (regulation 2(2));
- (2) providing that a person, in the course of a business carried on by him, may incorporate in animal feeding stuffs a veterinary drug which is already exempted from the licensing and certification requirements of the Medicines Act 1968 without the need to be registered (regulation 2(3)(a));
- (3) providing that incorporation of a medicinal product in animal feeding stuffs in accordance with a written veterinary direction applies only in respect of medicinal products to which a product licence relates and not in respect of medicinal products to which an animal test certificate relates (regulation 2(3)(a));
- (4) redrafting regulation 3 to clarify the provisions relating to the keeping of written records in respect of medicated animal feeding stuffs intended for export (regulation 2(3)(b));
 - (5) making other minor drafting amendments (regulation 2(4) and (5) and (6));

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