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STATUTORY INSTRUMENTS

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**1992 No. 1520**

**MEDICINES**

**The Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992**

<i>Made</i>	- - - -	<i>25th June 1992</i>
<i>Laid before Parliament</i>		<i>25th June 1992</i>
<i>Coming into force</i>	- -	<i>1st July 1992</i>

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(1), (4) and (5) of the Medicines Act 1968(1) and now vested in them(2), 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 with the consent of the Treasury in accordance with section 40(7) of that Act, and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated(3) for the purposes of section 2(2) of the European Communities Act 1972(4) 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 revocation**

1.—(1) These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992 and shall come into force on 1st July 1992.

(2) The Medicines (Medicated Animal Feeding Stuffs) Regulations 1992(5) are hereby revoked.

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- (1) 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 the Medicines Act 1968 (c. 67) ( see also the following footnote).
- (2) 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 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).
- (3) S.I. 1972/1811.
- (4) 1972 c. 68; for the purposes of these Regulations, section 2 is subject to Schedule 2 to that Act and is to be read, as regards England and Wales, with section 32(7) and (9) of the Magistrates' Courts Act 1980 (c. 43), and S.I. 1984/447, as regards Scotland, with section 289B(4) and (6) of the Criminal Procedure (Scotland) Act 1975 (c. 21), as inserted by paragraph 5 of Schedule 11 to the Criminal Law Act 1977 (c. 45) and amended by section 55(2) of the Criminal Justice Act 1982 (c. 48) and S.I. 1984/526, as regards Northern Ireland, with S.I. 1984/703 (N.I. 3) and S.R.(N.I.) 1984 No. 253.
- (5) S.I. 1992/32.

## Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

“the Department” means the Department of Agriculture for Northern Ireland;

“the Department of Health (N.I.)” means the Department of Health and Social Services for Northern Ireland;

“final medicated feeding stuff” means any substance, not being a medicinal product, which is for use wholly or mainly by being fed to one or more animals for a medicinal purpose, or for purposes that include that purpose, without further processing;

“fish farmer” means—

(a) a person carrying on a business of fish farming or shellfish farming which is registered in a register kept by the Minister or the Secretary of State (as the case may be) pursuant to the Registration of Fish Farming and Shellfish Farming Businesses Order 1985<sup>(6)</sup>; or

(b) a person to whom a licence has been granted by the Department under section 11 of the Fisheries Act (Northern Ireland) 1966<sup>(7)</sup>;

“intermediate feed” means a medicated feeding stuff (not being a final medicated feeding stuff) sold, supplied or imported for use wholly or mainly as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose, with or without further processing;

“licensed medicinal product” means a medicinal product licensed under the Act;

“medicinal product” means a medicinal product as defined in section 130 of the Act<sup>(8)</sup> and, for the purposes of these Regulations, includes “intermediate feed”;

“the Minister” means the Minister of Agriculture, Fisheries and Food;

“placing on the market” means the holding for sale or disposal in any other form whatever to third parties, whether or not for consideration, and actual sale or disposal;

“prescription only medicine” means a medicinal product falling within a description or class for the time being specified for the purposes of section 58 of the Medicines Act 1968 in an Order made under that section<sup>(9)</sup>;

“the Register” means the Register kept under regulation 3(1)—

(a) by the registrar as respects Great Britain, or

(b) by the Department as respects Northern Ireland;

“the registrar” means any person appointed under section 1 of the Pharmacy Act 1954<sup>(10)</sup> as registrar for the purpose of that Act;

“the Society” means the Royal Pharmaceutical Society of Great Britain;

“veterinary surgeon” means a person registered in the register of veterinary surgeons and includes a person who is a veterinary practitioner registered in the supplementary veterinary register;

“veterinary written direction” means a written direction given by a veterinary surgeon in accordance with regulation 7;

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<sup>(6)</sup> S.I. 1985/1391.

<sup>(7)</sup> 1966 c. 17 (N.I.); amended by S.I. 1991/1466.

<sup>(8)</sup> Section 130 was amended by the Animal Health and Welfare Act 1984 (c. 40), section 13(2).

<sup>(9)</sup> The current order is S.I. 1991/1392, amended by S.I. 1991/2568.

<sup>(10)</sup> 1954 c. 61.

“withdrawal period”, in relation to a veterinary medicinal product administered to an animal, means the period, specified in a current product licence relating to the product or (in the absence of any such specification) specified in a prescription or veterinary written direction given by a veterinary surgeon in respect of the administration of the product, which is required to elapse from the cessation of the administration of the product to the animal before its slaughter for human consumption or the taking of products derived from it for human consumption,

and any other expression which is used in Council Directive 90/167/EEC(11) (laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community) has the same meaning as in that Directive.

(2) Without prejudice to section 11 of the Interpretation Act 1978(12), references in these Regulations to the incorporation of a medicinal product in an animal feeding stuff shall be construed as provided in section 40(11) of the Act.

(3) Any reference in these Regulations to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule which bears that number in these Regulations.

### **Register of manufacturers of animal feeding stuffs**

3.—(1) For the purposes of these Regulations the registrar and the Department shall each continue to keep a Register—

(a) Part A of which shall be a list of persons entitled in the course of a business carried on by them—

- (i) to incorporate medicinal products in any animal feeding stuff on premises in respect of which their names are entered in that Part of the Register, and to place on the market animal feeding stuffs in which medicinal products have been incorporated by them;
- (ii) to store on premises in respect of which their names are entered in that Part of the Register any animal feeding stuff in which medicinal products have been incorporated by them; and

(b) Part B of which shall be a list of persons as being persons entitled, in the course of a business carried on by them—

- (i) to incorporate medicinal products in any animal feeding stuff on premises in respect of which their names are entered in that Part of the Register at a rate of at least 2 kilograms per tonne, and to place on the market animal feeding stuffs in which medicinal products have been so incorporated by them;
- (ii) to store on premises in respect of which their names are entered in that Part of the Register any animal feeding stuff in which medicinal products have been incorporated by them.

(2) Where a person who, whilst carrying on a business elsewhere than in Northern Ireland, makes an application in writing to the registrar on or after the date these Regulations come into force for his name to be entered in Part A or Part B of the Register, in respect of any premises on which any medicinal product is to be incorporated in an animal feeding stuff by him in the course of that business or, in the case of a person using mobile mixing equipment, in respect of the premises where that equipment is normally kept, the registrar shall, subject to paragraphs (7) and (8) below, enter his name in Part A or Part B of the Register in respect of those premises.

(3) Where a person who, whilst carrying on a business in Northern Ireland, makes an application in writing to the Department on or after the date these Regulations come into force for his name to be entered in Part A or Part B of the Register, in respect of any premises on which any medicinal

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(11) OJ No. L92, 7.4.90, p.42.

(12) 1978 c. 30.

product is to be incorporated in an animal feeding stuff by him in the course of that business or, in the case of a person using mobile mixing equipment, in respect of the premises where that equipment is normally kept, the Department shall, subject to paragraphs (7) and (8) below, enter his name in Part A or Part B of the Register in respect of those premises.

(4) Subject to paragraphs (9) and (11) below, a person whose name is entered in the Register in respect of any premises shall, in order to retain his name in the Register in respect of those premises in any year subsequent to the year in which his name is first entered in it, in the month of July in any such year make an application in writing to the registrar or the Department (as the case may be) for his name to be retained in the Register in respect of those premises.

(5) Subject to paragraphs (10) and (11) below, a person whose name is removed from the Register in respect of any premises by reason only that he failed either to make proper application for the retention of his name in the Register pursuant to paragraph (4) above or to pay the fee due in respect of the retention of his name in the Register pursuant to paragraph (9) below may, in order to restore his name to the Register in respect of those premises, make an application in writing, within 11 months of the expiry of the registration, to the registrar or the Department (as the case may be) for his name to be restored to the Register in respect of those premises.

(6) There shall be paid to the registrar or the Department—

(a) in respect of the entry of the name of any person in respect of any premises—

(i) in Part A of the Register a fee of £295 for each premises;

(ii) in Part B of the Register a fee of £90 for each premises;

(b) in respect of the retention of the name of any person in respect of any premises—

(i) in Part A of the Register a fee of £185 for each premises;

(ii) in Part B of the Register a fee of £56 for each premises;

(c) in respect of the restoration of the name of any person in respect of any premises—

(i) to Part A of the Register a fee of £260 for each premises;

(ii) to Part B of the Register a fee of £80 for each premises.

(7) The registrar or the Department shall refuse to enter in the Register the name of any person in respect of any premises unless—

(a) that person—

(i) has paid to the registrar or the Department (as the case may be) the fee specified in paragraph (6)(a)(i) above for the entry of his name in Part A of the Register, and

(ii) has given an undertaking in writing to the registrar or the Department (as the case may be) that he will comply with the provisions of the Code of Practice for Category A Registered Manufacturers of Medicated Animal Feeding Stuff published by the Ministry of Agriculture, Fisheries and Food in December 1991; or

(b) that person—

(i) has paid to the registrar or the Department (as the case may be) the fee specified in paragraph (6)(a)(ii) above for the entry of his name in Part B of the Register, and

(ii) has given an undertaking in writing to the registrar or the Department (as the case may be) that he will comply with the provisions of the Code of Practice for Category B Registered Manufacturers of Medicated Animal Feeding Stuff published by the Ministry of Agriculture, Fisheries and Food in December 1991.

(8) The registrar, with the approval of the Minister, or the Department, may refuse to enter in the Register the name of any person in respect of any premises if, in the opinion of the registrar or the Department (as the case may be), that person cannot demonstrate that he has taken all reasonable

steps to ensure that he will comply with the provisions of the Code of Practice referred to in paragraph (7)(a)(ii) or (7)(b)(ii) above.

(9) The registrar or the Department shall refuse to retain in the Register in any year subsequent to the year in which his name is first entered in it the name of any person in respect of any premises unless that person has paid to the registrar or the Department (as the case may be) on or before 31st July in that year the fee specified in paragraph (6)(b)(i) or (ii) above as appropriate for the retention of his name in the Register.

(10) The registrar or the Department shall refuse to restore to the Register the name of any person in respect of any premises unless that person, having made proper application pursuant to paragraph (5) above, has paid to the registrar or the Department (as the case may be) the fee specified in paragraph (6)(c)(i) or (ii) above as appropriate for the restoration of his name to the Register.

(11) The registrar, with the approval of the Minister, or the Department, may refuse to retain in or to restore to, or may remove from, the Register the name of any person in respect of any premises if, in the opinion of the registrar or the Department (as the case may be), that person has failed to comply with any of the provisions of the Code of Practice referred to in paragraph (7)(a)(ii) or (7)(b)(ii) above as appropriate.

(12) In respect of any premises the registrar or the Department may remove from the Register the name of any person entered in it, at the request of that person.

(13) The registrar and the Department shall each furnish to the Minister, on or before 1st October in each year, a copy of the Register kept thereby certified to be a true copy of that Register as at a date specified in the certificate, not being later than 1st September in the year in question and, pending the furnishing of a further copy of the Register in the following year, shall furnish to the Minister at monthly intervals copies of amendments made to the Register in each month following the date so specified.

#### **Restrictions on incorporation of medicinal products in animal feeding stuffs**

4.—(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 (exemptions from licences and certificates in respect of medicinal tests on animals) of the Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986(13), 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 Part A or Part B of 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.

- (2) The requirement for his name to be entered in the Register, specified in paragraph (1)(a)(i) or (ii) above, shall not apply—
- (a) to a fish farmer;
  - (b) to a person incorporating a medicinal product in accordance with a veterinary direction where—
    - (i) a veterinary surgeon or veterinary practitioner has reason to believe it necessary to authorise a derogation from that paragraph on grounds of immediate danger to the health of animals under his care and the veterinary written direction authorises such derogation on those grounds, and
    - (ii) the person incorporating the medicinal product sends a copy of the veterinary written direction to the Society (if he is carrying on a business elsewhere than in Northern Ireland) or to the Department (if he is carrying on a business in Northern Ireland) within 28 days of incorporation; or
  - (c) to a person operating mobile mixing equipment if—
    - (i) his name is entered in the Register in respect of the premises where his mobile equipment is normally kept, and
    - (ii) in a case where his name is entered in Part B of the Register, the medicinal product is incorporated in the animal feeding stuff at a rate of at least 2 kilograms per tonne.
- (3) Any person who exports medicinal animal feeding stuffs, 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) No person shall, in the course of a business carried on by him, incorporate in an animal feeding stuff a combination of prescription only medicinal products except in accordance with a veterinary written direction and then only where in the opinion of a veterinary surgeon there is no effective licensed medicinal product for the disease to be treated or for the species concerned.
- (5) A person who, in the course of a business carried on by him, incorporates in an animal feeding stuff any medicinal product in accordance with a veterinary written direction, shall ensure that—
- (a) the daily dose of medicinal product is contained in a quantity of final feeding stuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirement of non-mineral complementary or supplementary feedings stuffs;
  - (b) the feeding stuff to be used for producing the medicated feeding stuff does not contain the same antibiotic nor the same coccidiostat as those used as an active substance in the medicinal product.

### **Storage in registered premises**

5. Where, in pursuance of regulation 4, a person would not be entitled to incorporate in an animal feeding stuff a medicinal product but for his name being entered in the Register, he shall not, in the course of a business carried on by him, store that animal feeding stuff in which that medicinal product has been incorporated by him otherwise than on the premises in respect of which his name is entered in the Register.

### **Restrictions on placing on the market and importation of animal feeding stuffs in which medicinal products have been incorporated**

6.—(1) No person shall, in the course of a business carried on by him, place on the market any animal feeding stuff in which a medicinal product, not being a prescription only medicine, has been incorporated unless the medicinal product was incorporated in accordance with regulation 4.

(2) No person shall, in the course of a business carried on by him, import any animal feeding stuff in which a medicinal product, not being a prescription only medicine, has been incorporated unless 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 the medicinal product was incorporated as mentioned in regulation 4(1)(a).

(3) Subject to paragraph (4) below, no person shall, in the course of a business carried on by him, place on the market any animal feeding stuff in which a prescription only medicine has been incorporated unless—

- (a) (i) it has been manufactured in accordance with the provisions of these Regulations pursuant to Council Directive [90/167/EEC](#) and then only if the medicinal product was incorporated in accordance with regulation 4(1)(a); and
- (ii) subject to paragraph (4) below, 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 the animal feeding stuff is placed on the market or imported in accordance with a veterinary written direction;

or

- (b) that person is satisfied that the placing on the market has been requested by a veterinary surgeon who, by reason of any emergency, is unable to furnish a veterinary written direction immediately but who has undertaken to furnish that person with a veterinary written direction within 72 hours.

(4) Paragraph (3)(a)(ii) above shall not apply where any animal feeding stuff in which a prescription only medicine has been incorporated as mentioned in regulation 4(1)(a) is sold or supplied to a person—

- (a) whose name is entered in Part A of the Register and whom the seller or supplier knows, or has reasonable cause to believe, to be a person who does not have animals under his control for the purposes of, and in the course of carrying on a business, either as his sole business activity or as a part of his business activities unless for research or educational purposes only, or
- (b) whose name is entered in the register kept by the Society (in the case of a person carrying on a business elsewhere than in Northern Ireland) or by the Department of Health (N.I.) (in the case of a person carrying on a business in Northern Ireland) under article 5(1) of the Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992(14) .

(5) No person shall, in the course of a business carried on by him, import any animal feeding stuff in which a prescription only medicine has been incorporated unless it has been manufactured in accordance with the provisions of Council Directive [90/167/EEC](#) and then only if 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 the animal feeding stuff is placed on the market or imported in accordance with a veterinary written direction.

(6) No person shall import from a member State any animal feeding stuff in which a prescription only medicinal product has been incorporated unless that feeding stuff—

- (a) has been manufactured in accordance with the provisions of Council Directive [90/167/EEC](#);
- (b) has been manufactured with medicinal products authorised by the exporting member State and which have the same active ingredient as licensed medicinal products; and
- (c) is accompanied by a certificate in the form, including the note thereto, set out in Schedule 1.

(7) Any person who intends to export to a member State any animal feeding stuff in which a medicinal product has been incorporated shall, where that Member State requires a certificate corresponding in form to that set out in Schedule 1, in the case of a person carrying on a business elsewhere than in Northern Ireland make an application in writing to the Society and, in the case of a person carrying on a business in Northern Ireland make an application in writing to the Department, for such a certificate and, in either case, not less than 72 hours before the date of exportation and upon payment of the appropriate fee.

#### **Veterinary written direction**

7. A veterinary written direction given for the purposes of regulation 4 or 6 shall be—
- (a) in the form, including the notes thereto, set out in Schedule 2 to these Regulations or in a form substantially to the like effect,
  - (b) written in ink or otherwise so as to be indelible, and
  - (c) signed in ink in his own name by the veterinary surgeon giving it.

#### **Restrictions on placing on the market final medicated feeding stuff containing medicinal products**

8.—(1) The requirements of this regulation shall not apply to any person who, in the course of a business carried on by him, places on the market any final medicated feeding stuff in which a medicinal product has been incorporated, other than a prescription only medicinal product, provided that that feeding stuff is packed in pack sizes of 5 kg or less and is intended for retail sale to the keepers of pets or companion animals.

(2) No person shall, in the course of a business carried on by him, place on the market any final medicated feeding stuff in which a medicinal product has been incorporated unless his name is—

- (a) entered in the Register of Merchants kept pursuant to article 8(1) of the Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992 in respect of each premises on which such final medicated feeding stuff is sold or stored as a Category I or Category II merchant; or
- (b) entered in Part A or Part B of the Register of Manufacturers kept pursuant to regulation 3(1) in respect of each premises on which such final medicated feeding stuff is sold or stored

and the conditions contained in paragraphs (3) to (8) below are complied with.

(3) No person shall, in the course of a business carried on by him, place on the market or sell or supply any final medicated feeding stuff in which a medicinal product has been incorporated except to a person—

- (a) whose name is entered in the Register of Merchants (as aforesaid) as a Category I or Category II merchant;
- (b) whose name is entered in Part A or Part B of the Register of Manufacturers (as aforesaid); or
- (c) whom the seller knows, or has reasonable cause to believe, to be a person who has animals under his control for the purposes of, and in the course of carrying on, a business, either as his sole business activity or as part of his business activities.



(4) No person shall, in the course of a business carried on by him, place on the market any final medicated feeding stuff in which a medicinal product has been incorporated except—

- (a) in the container in which it was made up for sale or disposal by the manufacturer;
- (b) in a container which has not been opened since the feeding stuff was made up for sale or disposal in it; and
- (c) on premises which are occupied by, and under the control of, the seller at the time of sale or disposal.

(5) No final medicated feeding stuff in which a medicinal product has been incorporated shall be sold by retail by self-service methods.

(6) In respect of the placing on the market of any final medicated feeding stuff in which a medicinal product has been incorporated the seller shall make a record of the sale containing particulars of—

- (a) the date on which the feeding stuff was sold;
- (b) the name, identification and quantity of the feeding stuff sold; and
- (c) the name and address of the person to whom the feeding stuff was sold;

and shall keep such a record for a period of 3 years from the date of the sale.

(7) No person shall, in the course of a business carried on by him, place on the market any final medicated feeding stuff in which a medicinal product has been incorporated unless that feeding stuff has been manufactured in accordance with the provisions of these Regulations pursuant to Council Directive [90/167/EEC](#).

(8) In paragraph (2) above, “premises” includes a stall of a permanent nature situated at a market or an agricultural showground.

### **Restriction on use of medicated animal feeding stuffs**

**9.** No person shall use any medicated animal feeding stuff in which a prescription only medicinal product has been incorporated unless it has been manufactured in accordance with the provisions of these Regulations pursuant to Council Directive [90/167/EEC](#).

### **Packaging and containers**

**10.** Where medicated feeding stuffs are made up for sale in packages or containers, no person shall, in the course of a business carried on by him, place on the market such a package or container unless it is sealed in such a way that, when the package or container is opened, the closure or seal is damaged and the package or container cannot be re-used.

### **Restriction on slaughter of animals**

**11.** Where medicated feeding stuffs are administered to animals whose meat, flesh, offal or products are intended for human consumption, the stock farmer or holder of the animals concerned shall ensure that treated animals are not slaughtered in order to be offered for human consumption before the end of the withdrawal period (if any) and that products obtained from a treated animal before the end of such a withdrawal period (if any) are not disposed of with a view to their being offered for human consumption.

### **Enforcement**

**12.** To the extent that these Regulations are made under the European Communities Act 1972, the provisions of sections 108 to 114 and section 119 (which relate to enforcement and matters connected therewith) of the Medicines Act 1968 shall apply as if they were made under the 1972 Act.

## Offences

13.—(1) Any person who contravenes any provision of regulations 4, 5, 6, 8, 9 or 11 of these Regulations shall be guilty of an offence and

- (a) shall be liable on summary conviction to a fine not exceeding the statutory maximum; and
- (b) shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

(2) Any person who contravenes any provision of regulation 10 of these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

## Defence

14. Any person who, in the course of a business carried on by him, places on the market, imports or incorporates a medicinal product of any description in an animal feeding stuff in accordance with a forged veterinary written direction, shall not be guilty of an offence under these Regulations if, having exercised all due diligence, he believes on reasonable grounds that the veterinary written direction is genuine.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd June 1992.

L.S.

*John Selwyn Gummer*  
Minister of Agriculture, Fisheries and Food

23rd June 1992

*Hector Monro*  
Parliamentary Under Secretary of State, Scottish  
Office

19th June 1992

*David Hunt*  
Secretary of State for Wales

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 25th day of June 1992.

L.S.

*D. M. Carnson*  
Under Secretary

We consent

22nd June 1992

*Tim Wood*  
*Irvine Patnick*  
Two of the Lord Commissioners of Her  
Majesty's Treasury

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 1

regulation 6(6)(c) and (7)

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE

Name and address of the manufacturer or approved distributor:

.....  
.....  
.....

Name of the medicated feedingstuff: .....

- Type of animal for which the medicated feedingstuff is intended: .....

- Name and composition of the authorized medicated premix: .....

.....

- Dosage of the medicated pre-mix authorized in the medicated feeding stuff: .....

.....

Quantity of medicated feedingstuff: .....

Name and address of the recipient: .....

.....

.....

I hereby certify that the medicated feedingstuff as described above has been manufactured by an authorized person in accordance with Directive 60/167/EEC.

Stamp of the veterinary authority  
or other competent authority

.....  
Place and date

.....  
(signature)  
Name and position

**Note:** A copy of this Certificate relating to imported medicated animal feeding stuffs must be sent to the Royal Pharmaceutical Society of Great Britain, 1 Leinster House, London SE1 6TN, or the Department of Agriculture, Northern Ireland, Bedford Square, York Street, Belfast BT1 3AG within 72 hours of the arrival of those feeding stuffs in the United Kingdom.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 2

regulation 7(a)

DIRECTION FOR THE INCORPORATION OF A MEDICINAL PRODUCT IN AN ANIMAL FEEDING STUFF OR FOR THE PLACING ON THE MARKET OF IMPORTATION OR MEDICATED ANIMAL FEEDING STUFFS

\_\_\_\_\_
| This Direction |
| shall not be |
re-used |
\_\_\_\_\_

REFERENCE NUMBER

SECTION I - TO BE COMPLETED UNDER THE DIRECTION OF A VETERINARY SURGEON AND SIGNED BY HIM

1. Please manufacture/sell/supply/import ..... tonnes/kg\* of (name/type of feed)

..... meal/pellets/crumb\* containing -

..... (proprietary name(s) and

..... g/tonne (mg/kg)\* of ..... product licence number(s)

..... and/or generic name(s)

to give in total -

..... (please describe description of

..... g/tonne (mg/kg)\* of ..... active substance(s);

in the final medicated feeding stuff for administration to the following animals which are under my care:

Species ..... Approx. number .....

Note. The amount shall not exceed 21 days' supply.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

2. The medicated feeding stuff shall be sold/supplied\* to (name of farmer and address of farm)

.....  
.....

Recommendations For Use On The Farm

- (i) Disease to be treated (to appear on the veterinary surgeon's copy only) .....
- (ii) Quantity of medicated feeding stuff to be given daily .....
- (iii) Duration of treatment .....
- (iv) Animals must not be slaughtered for human consumption until .....  
..... after the last treatment.  
Milk/eggs\* must not be taken for human consumption until .....  
..... after the last treatment.
- (v) Special precautions .....

3. This direction is valid for 31 days from the date of signature.

Signature of Veterinary Surgeon  
.....

SECTION II - TO BE COMPLETED BY

VETERINARY SURGEON OR FARMER

Name in block letters .....

Practice Address .....

Name and address of manufacturer/seller/

Date ..... Telephone No .....

supplier/importer\* .....

.....  
.....

SECTION III - TO BE COMPLETED BY THE MANUFACTURER/SELLER/SUPPLIER

Date(s) of delivery .....

To be used before .....

Signature of manufacturer/seller/supplier\* .....

.....

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

**SECTION IV – IF APPLICABLE, TO BE COMPLETED BY VETERINARY SURGEON**

1. Reason(s) for authorising incorporation by a manufacturer (including an on-farm mixer) not in the appropriate Part of the Register.....  
.....

\*Delete as appropriate.

2. Reason(s) for authorising incorporation by a manufacturer of an unlicensed combination of medicinal products.....  
.....

**NOTES**

1. This form must be completed in triplicate, in ink or by other indelible means, and signed in ink in his own name by the Veterinary Surgeon, who will retain one copy and give one copy each to the manufacturer and the farmer.
2. If any part of Section IV has been completed, the manufacturer must send a copy of the form to the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JX, or the Department of Agriculture, Northern Ireland, Bradford Square, Tont Street, Belfast BT1 3AQ within 28 days of incorporation.
3. A telefacsimile copy may be sent to the incorporator in an emergency. The original veterinary written direction must be sent within 72 hours.

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations replace the Medicines (Medicated Animal Feeding Stuff) Regulations 1992. These Regulations correct several minor drafting errors in the 1992 Regulations. In addition the Regulations—

- (a) substitute a new definition of “withdrawal period” (regulation 2(1));

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- (b) substantially increase the fee payable by manufacturers on registration, increase the fee for retention in the Register and decrease the fee for reinstatement in the Register (regulation 3(6));
- (c) restrict the requirements relating to feeding stuffs imported from a member State to those in which a prescription only medicinal product has been incorporated (regulation 6(6));
- (d) exempt pet shop owners, who sell final medicated feeding stuff in which a medicinal product has been incorporated (not being a prescription only product) by retail in pack sizes of 5 kg or less, from the requirement to be registered in either the Register of Merchants or of Manufacturers (regulation 8(1)).

The Codes of Practice (for Category A and for Category B Registered Manufacturers of Medicated Animal Feeding Stuff) are priced publications and are available from MAFF Publications, London SE99 7TP.