

1989 No. 2320

MEDICINES

The Medicines (Medicated Animal Feeding Stuff)  
Regulations 1989

<i>Made</i> - - - -	<i>8th December 1989</i>
<i>Laid before Parliament</i>	<i>11th December 1989</i>
<i>Coming into force</i>	<i>1st January 1990</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(4) and (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 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 (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 revocation**

1.—(1) These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuff) Regulations 1989 and shall come into force on 1st January 1990.

(2) The Medicines (Medicated Animal Feeding Stuff) Regulations 1988(e) are hereby revoked.

**Interpretation**

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

“the Act” means the Medicines Act 1968;

“animal feeding stuff” means any substance which is intended for use either by being fed to one or more animals or as an ingredient in the preparation of such a substance, not being in either case a medicinal product;

“the Department” means the Department of Agriculture 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;

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(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 footnote).

(b) 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 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. 1988/976.

“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(a); or
- (b) a person to whom a licence has been granted by the Department under section 11 of the Fisheries Act (Northern Ireland) 1966(b);

“intermediate feed” means a 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;

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

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

“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(d);

“the Register” means the Register kept under regulation 6(1)—

- (a) by the registrar as respects Great Britain, or
- (b) by the Department as respects Northern Ireland;

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

“veterinary written direction” means a written direction given by a veterinary surgeon or a veterinary practitioner in accordance with regulation 5.

(2) Reference in these Regulations to the incorporation of a medicinal product in an animal feeding stuff do not include a reference to it being so incorporated in the course of making a medicinal product; but subject to that, they include a reference to the incorporation—

- (a) for a medicinal purpose of a substance or article other than a medicinal product, or
- (b) of a substance in which a medicinal product has been incorporated, in an animal feeding stuff.

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

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

3.—(1) No person shall, in the course of a business carried on by him, incorporate a medicinal product of any description in an animal feeding stuff 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
- (b) the medicinal product is incorporated—
  - (i) in accordance with provisions relating to the incorporation of the medicinal product in animal feeding stuffs contained in a product licence or animal test certificate (whether held by him or another person), or
  - (ii) in accordance with a veterinary written direction; or

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(a) S.I. 1985/1391.

(b) 1966 c.17 (N.I.).

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

(d) The current order is S.I. 1989/2319.

- (c) his name is entered in the Register and he—
  - (i) intends to export the animal feeding stuff in accordance with a written export order;
  - (ii) stores such animal feeding stuff in a part of a building separate from the storage of any other animal feeding stuff; and
  - (iii) keeps, for a period of at least 2 years from the date of the sale or supply, a record of—
    - (aa) the name and address of the purchaser;
    - (bb) the written export order; and
    - (cc) the name, identification and quantity of the animal feeding stuff.

(2) The requirement for this 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 written 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 or the Department 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.

#### **Restrictions on sale, supply and importation of animal feeding stuffs in which medicinal products have been incorporated**

4.—(1) No person shall, in the course of a business carried on by him, sell or supply 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 3.

(2) No person, shall 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 in accordance with regulation 3(1)(b).

(3) No person shall, in the course of a business carried on by him, sell or supply any animal feeding stuff in which a prescription only medicine has been incorporated unless—

- (a) subject to paragraph (5) 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 sold or supplied in accordance with a veterinary written direction; or
- (b) that person is satisfied that the sale or supply has been requested by a veterinary surgeon or a veterinary practitioner 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) No person shall import any animal feeding stuff in which 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 animal feeding stuff is sold, supplied or imported in accordance with a veterinary written direction.

(5) Paragraph (3)(a) above shall not apply where any animal feeding stuff in which a prescription only medicine has been incorporated in accordance with regulation 3(1)(b)(i) 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 or by the Department of Health and Social Services for Northern Ireland under article 3(7) of the Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (No. 2) Order 1989(a).

#### **Veterinary written directions**

5. A veterinary written direction given for the purposes of regulation 3 or 4 shall—

- (a) be in the form, including the notes thereto, set out in the Schedule to these Regulations or in a form substantially to the like effect,
- (b) be written in ink or otherwise so as to be indelible, and
- (c) be signed in ink in his own name by the veterinary surgeon or veterinary practitioner giving it.

#### **Registration of persons incorporating medicinal products in animal feeding stuffs**

6.—(1) The registrar and the Department shall each keep for the purposes of these Regulations a Register—

- (a) Part A of which shall be a list of persons entitled in the course of businesses carried on by them, to incorporate medicinal products in animal feeding stuffs on premises in respect of which their names are entered in that Part of the Register, and to sell or supply animal feeding stuffs in which medicinal products have been incorporated; and
- (b) Part B of which shall be a list of persons as being persons entitled, in the course of businesses carried on by them, to incorporate medicinal products in animal feeding stuffs 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 sell or supply animal feeding stuffs in which medicinal products have been so incorporated.

(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 operating 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 B (as the case may be) 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 on 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 Department shall, subject to paragraphs (7) and (8) below, enter his name in Part A or B (as the case may be) 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

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(a) S.I. 1989/2318.

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 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 £150 for each premises;
  - (ii) in Part B of the Register a fee of £50 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 £150 for each premises;
  - (ii) in Part B of the Register a fee of £50 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 £270 for each premises;
  - (ii) to Part B of the Register a fee of £95 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 on 18th December 1987; 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 on 18th December 1987.

(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 the standards required by the Code of Practice referred to in paragraph (7)(a)(ii) or (7)(b)(ii) above as appropriate are met.

(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 observe 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 furnish to the Minister on or before 1st November each year an up to date copy of the Register and at monthly intervals thereafter any amendments to the Register.

#### **Defences**

7.—(1) Any person who, in the course of a business carried on by him, sells, supplies, 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 7th December 1989.



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

7th December 1989

*Sanderson of Bowden*  
Minister of State, Scottish Office

8th December 1989

*Peter Walker*  
Secretary of State for Wales

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 8th day of December 1989.

*W. J. Hodges*  
Permanent Secretary

We consent

7th December 1989

*John Taylor*  
*David Lightbown*  
Two of the Lords Commissioners of  
Her Majesty's Treasury

SCHEDULE

Regulation 5

DIRECTION FOR THE INCORPORATION OF A MEDICINAL PRODUCT IN AN ANIMAL FEEDING STUFF OR FOR THE SALE, SUPPLY OR IMPORTATION OF MEDICATED ANIMAL FEEDING STUFFS

REFERENCE NUMBER

SECTION I - TO BE COMPLETED IN ITS ENTIRETY BY VETERINARY SURGEON OR VETERINARY PRACTITIONER

1. Please manufacture/sell/supply/import\* ..... tonnes/kg\* of (name/type of feed) ..... meal/pellets/crumbs\* containing - ..... } (proprietary name(s) and ..... } g/tonne (mg/kg)\* of ..... } product licence number(s) ..... } and/or generic name(s)

to give -

..... } (precise 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 .....

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

Recommendations For Use On The Farm

- (i) Quantity of medicated feeding stuff to be given daily .....
(ii) Duration of treatment .....
(iii) 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.
(iv) Special precautions .....

3. This direction is valid for 30 days from the date of signature.

Signature of Veterinary Surgeon or Veterinary Practitioner ..... SECTION II - TO BE COMPLETED BY VETERINARY SURGEON OR VETERINARY PRACTITIONER OR FARMER
Practice Address ..... Name and address of manufacturer/seller/ supplier/importer\*
Date ..... Telephone No. ....

\*Delete as appropriate.

**SECTION III – IF APPLICABLE, TO BE COMPLETED BY VETERINARY SURGEON OR VETERINARY PRACTITIONER**

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

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2. Reason(s) for authorising incorporation by a manufacturer not in Part A or B of the Register .....

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**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 or Veterinary Practitioner, who will retain one copy and give one copy each to the manufacturer and the farmer.

2. If any part of Section III has been completed, the manufacturer must send a copy of the form to RPSGB, 1 Lambeth High Street, London SE1 7JN, or DANI, "Duniris", 15 Galway Park, Dundonald, Belfast BT16 0AN, within 28 days of incorporation.





## EXPLANATORY NOTE

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

These Regulations replace the Medicines (Medicated Animal Feeding Stuff) Regulations 1988.

The Regulations continue to prohibit a person, in the course of a business carried on by him, from incorporating a medicinal product (which now includes intermediate feed as defined in regulation 2(1)) unless (additionally) it is a licensed product, and it is incorporated in accordance with a product licence, an animal test certificate or a veterinary written directions given by a veterinary surgeon or veterinary practitioner (regulation 3(1)(a) and (b)). In addition, a person can incorporate medicinal products in animal feeding stuffs if he is registered in the Register kept under the Regulations and, subject to specified conditions, intends to export such animal feeding stuffs (regulation 3(1)(c)).

The Regulations continue to prohibit a person, in the course of a business carried on by him, from selling or supplying any animal feeding stuff in which a medicinal product, not being a prescription only medicine (that is to say, a medicinal product which may be sold or supplied by retail only in accordance with a prescription given by a veterinary surgeon or veterinary practitioner), has been incorporated or from importing any such animal feeding stuff unless the medicinal product was incorporated in the animal feeding stuff in accordance with a product licence, an animal test certificate or a veterinary written direction (regulation 4(1) and (2)).

The Regulations continue to prohibit a person, in the course of a business carried on by him, from selling or supplying any animal feeding stuff in which a prescription only medicine has been incorporated or from importing any such animal feeding stuff except in accordance with a veterinary written direction, subject to certain exceptions (regulation 4(3) and (4)).

As medicinal products not licensed for incorporation in animal feeding stuff (or without an appropriate animal test certificate) can no longer be incorporated in animal feeding stuffs pursuant to a veterinary written direction, consequential provisions in respect of the sale or supply of feeding stuffs requiring a certificate of analysis or a certificate of compliance with a monograph have been deleted and the content of the veterinary written direction has been modified.

The Regulations continue to impose detailed requirements relating to registration in the Register, including provision for payment of fees and giving an undertaking to comply with a specified Code of Practice (regulation 1(2) and 6). (The Codes of Practice are priced publications and are available from MAFF Publications, London SE99 7TP). Additionally a defence is available to any person who, having exercised all due diligence, sells, supplies, imports or incorporates a medicinal product in an animal feeding stuff against a forged veterinary written direction (regulation 7).