STATUTORY INSTRUMENTS

1988 No. 976

MEDICINES

The Medicines (Medicated Animal Feeding Stuffs) Regulations 1988

Made - - - -	*26th May 1988*
Laid before Parliament	*10th June 1988*
Coming into force	
Regulations 3(1)(a)(ii) and (2)(c)(ii) and 6(1)(b), (6)(a)(ii), (b)(ii) and (c)(ii) and (7)(b)	*1st July 1989*
Remainder	*1st July 1988*

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(**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 and commencement

1.—(1) These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuffs) Regulations 1988.

(**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 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.

(2) Regulations 3(1)(a)(ii) and (2)(c)(ii) and 6(1)(b), (6)(a)(ii), (b)(ii) and (c)(ii) and (7)(b) below shall come into force on 1st July 1989 and the remainder of these Regulations shall come into force on 1st July 1988.

Interpretation

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

"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;

"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) for the purposes of an order made under section 7 of the Diseases of Fish Act 1983(**5**), or

(b) a person to whom a licence has been granted by the Department under section 11 of the Fisheries Act (Northern Ireland) 1966(**6**);

"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(**7**);

"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 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) References 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—

(**5**) 1983 c. 30.
(**6**) 1966 c. 17 (N.I.).
(**7**) The current orders are S.I. 1985/1288 and 1983/1212, amended by S.I. 1984/756, 1986/586, 1987/674, 1250.

(a) 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.

(2) Paragraph (1)(a) 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 mixing 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) No person, other than a person whose name is entered in Part A of the Register or a fish farmer, shall, in the course of a business carried on by him, incorporate in an animal feeding stuff a medicinal product in respect of which there is no product licence or animal test certificate relating to the incorporation of that product in an animal feeding stuff as provided for in paragraph (1)(b)(ii) above unless—

(a) the veterinary written direction states the reason for authorising incorporation of that medicinal product, and

(b) 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.

(4) No person, other than a fish farmer, shall, in the course of a business carried on by him, incorporate in an animal feeding stuff a medicinal product in respect of which there is no product licence or animal test certificate unless there is attached to his copy of the veterinary written direction—

(a) in the case of a medicinal product which is the subject of a monograph in the 1980 edition of the British Pharmacopoeia, the 1985 edition of the British Pharmacopoeia (Veterinary) or the second edition of the European Pharmacopoeia, together with in each case any amendments, additions and deletions made to it up to 26th May 1988, a certificate stating that the medicinal product is of the standard specified for that product in that edition, or

(b) in any other case, a certificate of analysis.

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—

(a) the medicinal product was incorporated in accordance with regulation 3, or

(b) the animal feeding stuff is sold or supplied in accordance with a veterinary written direction.

(2) No person shall import any animal feeding stuff in which a medicinal product, not being a prescription only medicine, has been incorporated unless—

(a) the medicinal product was incorporated in accordance with regulation 3(1)(b), or

(b) the animal feeding stuff is imported in accordance with a veterinary written direction.

(3) No person shall—

(a) subject to paragraph (4) below, 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, or

(b) import any such animal feeding stuff,

unless the animal feeding stuff is sold, supplied or imported in accordance with a veterinary written direction.

(4) 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 (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1985(**8**).

(5) Subject to paragraph (6) below, no person shall, in the course of a business carried on by him, sell or supply a final medicated feeding stuff in which there has been incorporated a medicinal product in respect of which there is no product licence or animal test certificate relating to the incorporation of that product in an animal feeding stuff unless—

(a) the final medicated feeding stuff has been analysed to determine the quantity of every ingredient included in the medicated feeding stuff for a medicinal purpose, and

(b) the results of that analysis have been attached to his copy of the veterinary written direction.

(6) Paragraph (5) above shall not apply—

(a) to a fish farmer; or

(b) where—

(i) a veterinary surgeon or veterinary practitioner believes it necessary to authorise analysis to be done after sale or supply of the final medicated feeding stuff on

(**8**) S.I. 1985/1823, to which there are amendments not relevant to these Regulations.

grounds of immediate danger to the health of animals under his care and the veterinary written direction authorises such analysis on those grounds, and

(ii) within 7 days of such sale or supply the seller or supplier of the final medicated feeding stuff analyses it or sends it for analysis and in either case attaches the results of the analysis to his copy of the veterinary written direction.

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 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, 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—

(a) on or after 1st July 1988 for his name to be entered in Part A of the Register, or

(b) on or after 1st July 1989 for his name to be entered in 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—

(a) on or after 1st July 1988 for his name to be entered in Part A of the Register, or

(b) on or after 1st July 1989 for his name to be entered in 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 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 Stuffs 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 Stuffs 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.

Revocation

7. The Medicines (Medicated Animal Feeding Stuffs) Regulations 1985(**9**) are revoked.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 25th May 1988.

L.S.

John MacGregor
Minister of Agriculture, Fisheries and Food

Sanderson of Bowden
25th May 1988 Minister of State, Scottish Office

Peter Walker
26th May 1988 Secretary of State for Wales

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 26th day of May 1988.

L.S.

W. H. Jack
Permanent Secretary

(**9**) S.I. 1985/1533.

We consent,

Mark Lennox-Boyd
Michael Neubert
Two of the Lords Commissioners of Her Majesty's Treasury

26th May 1988

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–

..... } g/tonne (mg/kg)* of ..... } (proprietary name(s) and product licence number(s) and/or generic name(s)
.... }
....

to give–

..... } g/tonne (mg/kg)* of ..... } (precise description 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 .....
Name in block letters .....
Practice Address .....
.....
Date ..... Telephone No .....

SECTION II—TO BE COMPLETED BY VETERINARY SURGEON OR VETERINARY PRACTITIONER OR FARMER

Name and address of manufacturer/seller/supplier/importer* .....
.....

*Delete as appropriate.

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

1. Reason(s) for authorising incorporation at a rate below 2 kg/tonne by a manufacturer (including an on-farm mixer) not in Part A of the Register .....

.....

.....

2. Reason(s) for authorising a manufacturer not in Part A of the Register to incorporate a medicinal product for which there is no product licence or animal test certificate relating to the incorporation of that product in an animal feeding stuff .....

.....

.....

3. Reason(s) for authorising incorporation at a rate of at least 2 kg/tonne by a manufacturer not in Part A or B of the Register .....

.....

4. Reason(s) for authorising analysis of final medicated feeding stuff after sale or supply ...

.....

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 paragraph 1, 2 or 3 of Section III has been completed, the manufactuer must send a copy of the form to PSGB, 1 Lambeth High Street, London SE1 7JN, or DANI, "Duniris", 15 Galway Park, Dundonald, Belfast BT16 0AN, within 28 days of incorporation. Paragraph 3 need only be completed with effect from 1st July 1989.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate with amendments the Medicines (Medicated Animal Feeding Stuffs) Regulations 1985 and implement in part the provisions of Article 13 of Council Directive 70/524/EEC (OJNo. L270, 14.12.70, p. 1 (OJ/SE 1970 (III) p. 840)) concerning additives in feeding stuffs, as substituted by Article 1 of Council Directive 84/587/EEC (OJ No. L319, 8.12.84, p. 13). The relevant provisions of the Regulations which implement provisions in that Article are to be found in regulations 3(1)(a), 4(1)(a) and 6.

The Regulations continue to prohibit a person, in the course of a business carried on by him, from incorporating a medicinal product in an animal feeding stuff unless it is incorporated in accordance with a product licence, an animal test certificate or a veterinary written direction given by a veterinary surgeon or verterinary practitioner. Additionally, with effect from 1st July 1988 these Regulations generally require the person incorporating the medicinal product to be registered in Part A of a Register ("the Register") kept by the person appointed as registrar under section 1 of the Pharmacy Act 1954 (c. 61) or by the Department of Agriculture for Northern Ireland in respect of the premises where the medicinal product is incorporated, if the medicinal product is incorporated at a rate below 2 kilograms per tonne. In any other case with effect from 1st July 1989 he must generally be registered in either Part A or Part B of the Register (regulations 1(2) and 3). The Regulations generally prohibit a person not registered in Part A of the Register from incorporating in an animal feeding stuff a medicinal product for which there is no product licence or animal test certificate relating to the incorporation of that product in an animal feeding stuff (regulation 3(3)). A person operating mobile mixing equipment may be registered in respect of the premises where that equipment is normally kept (regulation 3(2)(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. Additionally, these Regulations require that in the case of sale or supply all the other requirements of regulation 3 must have been complied with (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)).

The Regulations also—

(a) require analysis of the medicinal product and final medicated feeding stuff in certain circumstances (regulations 3(4) and 4(5) and (6));

(b) continue to prescribe the form of a veterinary written direction for the purposes of the Regulations and add a new Section at the end of the form (regulations 3(2)(b) and (3), (4) (6)(b) and 5 and Schedule);

(c) 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

(regulations 1(2) and 6). (The Codes of Practice are priced publications and are available from MAFF Publications Unit, Willowburn Estate, Alnwick, Northumberland, NE66 2PF.)

Copies of the British Pharmacopoeia and British Pharmacopoeia (Veterinary) may be obtained from HMSO, and copies of the European Pharmacopoeia may be obtained from the Pharmaceutical Society of Great Britain.