STATUTORY INSTRUMENTS

1992 No. 32

MEDICINES

The Medicines (Medicated Animal Feeding Stuffs) Regulations 1992

Made - - - -	*9th January 1992*
Laid before Parliament	*13th January 1992*
Coming into force - -	*30th January 1992*

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(**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) Regulations 1992 and shall come into force on 30th January 1992.

(2) The Medicines (Medicated Animal Feeding Stuffs) Regulations 1989(**5**) and the Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1990(**6**) are hereby revoked.

(**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. 1989/2320.

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(**7**); or

(b) a person to whom a licence has been granted by the Department under section 11 of the Fisheries Act (Northern Ireland) 1966(**8**);

"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;

"medicinal product" means a medicinal product as defined in section 130 of the Act(**9**) 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 specifed for the purposes of section 58 of the Medicines Act 1968 in an Order made under that section(**10**);

"the Register" means the Register kept under regulation 7(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(**11**) as registrar for the purposes of that Act;

"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 6;

"withdrawal period" means the period from cessation of medication of an animal with a medicated feeding stuff to slaughter of that animal for human consumption or to the taking of products derived from such an animal for human consumption.

(**6**) S.I. 1990/1210.
(**7**) S.I. 1985/1391.
(**8**) 1966 c. 17 (N.I.); amended by S.I. 1991/1466.
(**9**) Section 130 was amended by the Animal Health and Welfare Act 1984 (c. 40), section 13(2).
(**10**) The current order is S.I. 1991/1392, amended by S.I. 1991/2568.
(**11**) 1954 c. 61.

(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 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.

(**12**) 1978 c. 30.

(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 tha the 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 £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 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 Stuffs 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 (asthe case may be), that person cannot demonstrate that he has complied with the provisions of the Code of Practice referred to in paragraph (7) (a) (ii) or (7) (b) (ii) above as appropriate.

(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, inaccordance 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 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

(**13**) S.I. 1986/1180; amended by S.I. 1991/633.

(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 wherehis 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 medicated 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) 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 either a veterinary surgeon or a veterinary practitioner 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 feeding 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,

and any other expression which is also used in Council Directive 90/167/EEC(**14**) (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.

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.

(**14**) OJ No. L 92, 7.4.90, p.42.

(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) 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

(b) 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

(c) that person is satisfied that the placing on the market 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) Paragraph (3)(b) 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(**15**)

(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 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 medicinal products licensed under the Act; and

(c) is accompanied by a certificate in the form, including the Note thereto, set out in Schedule 1.

(**15**) S.I. 1992/33.

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

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 the reto, set out in Schedule 2 tothese 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 or veterinary practitioner giving it.

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

8.—(1) 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 on or before 1st April 1992 he has applied for registration and 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 (2) to (7) below are complied with.

(2) 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.

(3) 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.

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

(5) 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.

(6) 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.

(7) In paragraph (1) 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 medicine has been incorporated unless it has be enmanufactured 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, of fal 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 and that products obtained from a treated animal before the end of such a withdrawal period are not disposed of with a view to their being offered for human consumption.

Enforcement

12.—(1) To the extent that these Regulations are made under the European Community Act 1972, the provisions of the Medicines Act 1968 mentioned in paragraph (2) below shall apply as if they were made under this Act.

(2) The provisions of the said Act of 1968 referred to in paragraph (1) above are those of sections 108 to 114 and section 119 (which relate to enforcement and matters connected herewith).

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.—(1) 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 9th January 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Strathclyde
Parliamentary Under Secretary of State, Scottish Office

8th January 1992

David Hunt
Secretary of State for Wales

8th January 1992

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 7th day of January 1992.

W. J. Hodges
Permanent Secretary

We consent

Sydney Chapman
Thomas Sackville
Two of the Lords Commissioners of Her Majesty's Treasury

7th January 1992

SCHEDULE 1

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

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDING STUFFS 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 pre-mix: .....

.....

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

.....

Quantity of medicated feedingstuff: .....

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

.....

.....

It is hereby certified that the medicated feedingstuff as described above has been manufactured by an authorized person in accordance with Directive 90/167/EEC.

.....
Place and date

Stamp of the veterinary authority
or other competent authority

.....
(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 Lambeth High Street, London SE1 7JN, or the Department of Agriculture, Northern Ireland, "Duniris", 15 Galway Park, Dundonald, Belfast BT16 0AN within 72 hours of the arrival of those feeding stuffs in the United Kingdom.

SCHEDULE 2 regulation 7(a)

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

This Direction shall not be re-used

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 in total –

.....} .....}(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 .....

Note. The amount shall not exceed 31 days' supply.

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

.....

.....

Recommendations For Use On The Farm

(i) Disease to be treated .....

(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 .....

.....12..... after the last treatment.

(v) Special precautions .....

3. This direction is valid for 31 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* .....

.....

.....

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

Date(s) of delivery .....

To be used before .....

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

.....

SECTION IV – 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 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

.....

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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 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 7JN, or the Department of Agriculture, Northern Ireland, "Duniris", 15 Galway Park, Dundonald, Belfast BT16 0AN, 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 Stuffs) Regula tions 1989 as amended in 1990.

These Regulations, pursuant to Council Directive 90/167/EEC (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, OJNo. L 92, 7.4.90, p.42) introduce controls in respect of the holding for sale or disposal in any other form whatever to third parties, whether or not for consideration, of any medicated animal feedingstuffs which include, for the first time, final medicated feeding stuffs.

The powers in section 2(2) of the European Communities Act 1972, are used to give effect to the provisions specified below—

(a) the definition of placing on the market (article 2 of the Directive) and withdrawal period (regulation 2(1));

(b) the incorporation in an animal feeding stuff of a prescription only medicinal product must be done only in accordance with a veterinary written direction and then only in specified circumstances (regulation 4(4) and article 8.1 of the Directive);

(c) the incorporation in an animal feeding stuff of any medicinal product (in accordance with a veterinary written direction) must be in accordance with specified requirements as to daily dosages and non-use of the same antibiotic or coccidiostat (regulation 4(5) and article 4.1 of the Directive);

(d) a person who incorporates a medicinal product in an animal feeding stuff must store the feed only on premises in respect of which he is registered (regulation 5 and article 4.1(a) of the Directive);

(e) any prescription only medicine incorporated in an animal feeding stuff which is placed on the market or imported, must have been manufactured in accordance with the provisions of these Regulations pursuant to article 4 of the Directive (regulation 6(3) and (5)); any importation of animal feeding stuff incorporating a medicinal product from another member State must be accompanied by a certificate in the prescribed form (regulation 6(6), Schedule 1 and article 10.3 of the Directive);

(f) merchants must not place on the market any final medicated feeding stuff containing a medicinal product unless they are registered in the Register of Merchants or the Register of Manufacturers, nor sell otherwise than to specified persons (regulation 8 and article 9.1 of the Directive);

(g) medicated animal feeding stuffs incorporating a prescription only medicine can be used only if they have been manufactured in accordance with the provisions of these Regulations pursuant to the Directive (regulation 9 and article 7 of the Directive);

(h) packages or containers of medicated feeding stuffs must not be re-used (regulation 10 and article 5.1 of the Directive);

(i) the stock farmer or holder of food-producing animals which are fed with medicated feeding stuffs, must observe the withdrawal period (regulation 11 and article 8.3 of the Directive);

(j) the form of the veterinary written direction is amended (regulation 7, Schedule 2 and article 8.1(a) of the Directive).

Under the Medicines Act 1968 provision is made for the Code of Practice for registered manufacturers to be updated (regulation 6(7)). The Code of Practice is a priced publication and is available from MAFF Publications, London SE99 7TP.