

Statutory Instrument 1998 No. 1046

The Medicated Feedingstuffs Regulations 1998

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STATUTORY INSTRUMENTS

1998 No. 1046

MEDICINES

The Medicated Feedingstuffs Regulations 1998

<i>Made</i>	<i>9th April 1998</i>
<i>Laid before Parliament</i>	<i>15th April 1998</i>
<i>Coming into force</i>	<i>6th May 1998</i>

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The Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated[[1](#)] for the purposes of section 2(2) of the European Communities Act 1972[[2](#)] in relation to medicinal products and the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

PART I

GENERAL

Title and commencement

1. These Regulations may be cited as the Medicated Feedingstuffs Regulations 1998 and shall come into force on 6th May 1998.

Interpretation

2. - (1) In these Regulations, except where the context requires otherwise -

"agricultural merchant" means a person who carries on a business involving in whole or in part the sale of agricultural requisites (being things used for soil cultivation or keeping of animals for production of food or game, equipment for collecting produce from animals kept for production of food, things for the maintenance of that equipment and protective clothing) and whose name is for the time being entered in the Register of Merchants in accordance with the provisions of the Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998[[3](#)]; "animal test certificate" has the same meaning as in section 32 of the Medicines Act 1968[[4](#)];

"the appropriate fee" means, in relation to any description of application for approval, renewal of approval or late renewal of approval of premises or as distributor listed in Schedule 1 by number, the fee specified opposite the application in question;

"approved distributor" means -

(a) a distributor who has been approved as a distributor to retail supply a medicated feedingstuff pursuant to regulation 11 and whose approval as such has not been withdrawn pursuant to regulation 15 and remains valid, or

(b) until and including 30th September 1998, a person who immediately before these Regulations came into force was listed in Category 2 of the Register of Merchants as referred to in the Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992[5];

"approved premises" means -

(a) premises which have been approved pursuant to regulation 4 as premises on which a medicated feedingstuff may be manufactured and the approval for which has not been withdrawn pursuant to regulation 8 and remains valid, or

(b) until and including 30th September 1998, premises that immediately before these Regulations came into force were referred to in Part A or B of the Register of Manufacturers of Animal Feedingstuffs kept pursuant to regulation 3 of the Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992[6];

"an Article 7.2 scientific test" means a test to which the provisions of Article 7.2 of the Medicated Feedingstuffs Directive apply;

"authorised intermediate product" means an intermediate product prepared from authorised medicated pre-mixes;

"authorised medicated pre-mix" has the meaning given by Article 2(a) of the Medicated Feedingstuffs Directive;

"authorised person" means a person (whether or not an officer of the enforcement authority) who is authorised by the enforcement authority, either generally or specially, to act in matters arising under these Regulations;

"Directive 81/851/EEC" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products[7] as amended by Council Directives 90/676/EEC[8] and 93/40/EEC[9];

"E.E.A. Agreement" means the Agreement on the European Economic Area[10], signed at Oporto on 2nd May 1993 as adjusted by the Protocol[11] signed at Brussels on 17th March 1993;

"E.E.A. State" means a State which is a contracting party to the E.E.A. Agreement other than the United Kingdom;

"the enforcement authority" means -

(a) in relation to Great Britain, the Royal Pharmaceutical Society of Great Britain, and

(b) in relation to Northern Ireland, the Department of Agriculture for Northern Ireland;

"financial year" means the 12 months from and including 1st April and ending with 31st March;

"the Medicated Feedingstuffs Directive" means Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[[12](#)] as adapted by the E.E.A.

Agreement;

"medicinal test on animals" has the meaning given by section 32(6) of the Medicines Act 1968;

"an MFS certificate" means a certificate corresponding to the specimen in Annex B to the Medicated Feedingstuffs Directive;

"an MFS prescription" means a prescription made out by a registered veterinarian in a form containing the headings shown on the specimen in Annex A to the Medicated Feedingstuffs Directive and personally signed and dated by such veterinarian;

"personal licence" means a licence granted under section 4 of the Animals (Scientific Procedures) Act 1986[[13](#)];

"placing on the market" has the meaning given by Article 2(b) of the Medicated Feedingstuffs Directive and cognate expressions shall be construed accordingly;

"premises" includes a farm;

"prohibition notice" means a notice served under regulation 17(1);

"project licence" means a licence granted under section 5 of the Animals (Scientific Procedures) Act 1986;

"proper", in relation to an application, means required by these Regulations to be processed by the relevant authority to which the application is made;

"the Register of Merchants" means the register of merchants in veterinary drugs kept in accordance with section 57(2A)(a) of the Medicines Act 1968;

"regulated procedure" has the meaning given by section 2 of the Animals (Scientific Procedures) Act 1986; and

"the relevant authority" means -

(a) in the case of -

(i) premises situated in, and

(ii) persons operating as distributors, or intending to operate as distributors from,

Great Britain, the Royal Pharmaceutical Society of Great Britain, and

(b) in the case of -

(i) premises situated in, and

(ii) persons operating as distributors, or intending to operate as distributors from,

Northern Ireland, the Department of Agriculture for Northern Ireland.

(2) The expressions listed in Part I of Schedule 2 have the same meaning as in the Medicated Feedingstuffs Directive and any other expression which is used in these Regulations and the Medicated Feedingstuffs Directive, other than an expression which is listed in Part II of Schedule 2, shall have, insofar as the context admits, the same meaning as in that Directive.

(3) The expressions listed in Part II of Schedule 2 have, insofar as the context admits, the same meaning as in Directive 81/851/EEC.

(4) In these Regulations -

(a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation or the Schedule to these Regulations so numbered in these Regulations, and

(b) any reference in a regulation or a Schedule to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which the reference occurs.

PART II

APPROVAL OF PREMISES

Applications for the approval of premises

3. - (1) A person may apply to the relevant authority to approve premises as premises on which medicated feedingstuffs may be manufactured.

(2) An application made under paragraph (1) shall be in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by particulars that seek to demonstrate that the premises are suitable and adequate premises on which to manufacture medicated feedingstuffs.

Approval of premises

4. - (1) Subject to paragraph (3) and regulation 35, where an application is made under regulation 3 the relevant authority shall approve the premises in respect of which the application is made as premises on which medicated feedingstuffs may be manufactured if it is satisfied that the premises are suitable and adequate premises on which to manufacture medicated feedingstuffs.

(2) In deciding whether premises are suitable and adequate premises on which to manufacture medicated feedingstuffs, the relevant authority shall take into account the matters specified in Schedule 3.

(3) Where an application is made under regulation 3 in respect of a farm, the relevant authority may make the approval of the premises subject to such additional guarantees, if any, as it considers appropriate.

(4) An approval granted pursuant to paragraph (1) shall remain valid until withdrawn pursuant to regulation 8, so long as proper renewal applications are made under regulation 5 or 6 and are granted or await a decision.

Renewal of approvals

5. - (1) To renew a valid approval granted pursuant to regulation 4(1), a person shall apply to the relevant authority in the month of April in each financial year subsequent to the financial year in which approval was first granted.

(2) An application made under paragraph (1) shall be in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by particulars that seek to demonstrate that the premises continue to be suitable and adequate premises on which to manufacture medicated feedingstuffs, and, if applicable, that each additional guarantee to which the approval is subject continues to be met.

Late renewal

6. Where a person has failed to make proper application under regulation 5, he may apply to the relevant authority in accordance with regulation 5(2) for late renewal of a valid approval, but such application must be made no later than the end of the financial year in which he was required to apply for renewal in accordance with regulation 5.

Grant of renewal

7. - (1) Subject to paragraph (3) and regulation 35, where an application is made under regulation 5 or 6, the relevant authority shall renew the approval granted pursuant to regulation 4, if it is satisfied that the premises continue to be suitable and adequate premises on which to manufacture medicated feedingstuffs.

(2) In deciding whether premises continue to be suitable and adequate premises on which to manufacture medicated feedingstuffs, the relevant authority shall take into account the matters specified in Schedule 3.

(3) Where an application is made under regulation 5 or 6 in respect of a farm, the relevant authority may make the renewal of approval of the premises subject to such additional guarantees, if any, as it considers appropriate.

Withdrawal of approvals

8. - (1) The relevant authority may withdraw an approval granted in respect of premises pursuant to regulation 4, whether or not it has been renewed pursuant to regulation 7 if, following the procedure in regulation 9, it is not satisfied as to the relevant condition.

(2) For the purposes of this regulation and regulation 9, "the relevant condition" means the condition that the premises are suitable and adequate premises on which to manufacture medicated feedingstuffs and (if applicable) that each additional guarantee to which the approval is subject is being met.

Procedure relating to the withdrawal of approvals

9. - (1) Where the relevant authority proposes to withdraw an approval granted pursuant to regulation 4, whether or not it has been renewed pursuant to regulation 7, it shall not withdraw the approval unless -

- (a) it serves a notice complying with the requirements of paragraph (2) on the person manufacturing medicated feedingstuffs on the premises, and
- (b) it is not satisfied, after the time for compliance with the notice has expired, that he has complied with the requirements specified in the notice.

(2) A notice served by the relevant authority under paragraph (1) shall -

- (a) state that it proposes to withdraw the approval of the premises because it is not satisfied as to the relevant condition;
- (b) specify why the relevant authority is not satisfied as to the relevant condition;
- (c) specify the requirements to be complied with by him to satisfy it as to that condition; and
- (d) specify that, unless it is satisfied that he has complied with the requirements specified in the notice within such reasonable time as is specified in the notice, the approval of the premises as premises on which medicated feedingstuffs may be manufactured will be withdrawn.

PART III

APPROVAL OF DISTRIBUTORS

Applications for the approval of distributors

10. - (1) A person may apply to the relevant authority to be approved as a distributor to retail supply medicated feedingstuffs.

(2) An application made under paragraph (1) shall be in writing, in the English language, signed by or on behalf of the applicant and shall contain the name and address of the applicant and shall be accompanied by particulars that seek to demonstrate that the applicant is a fit and proper person to retail supply medicated feedingstuffs.

Approval of distributors

11. - (1) Subject to regulation 35, where an application is made under regulation 10 the relevant authority shall approve the applicant as a distributor to retail supply medicated feedingstuffs if it is satisfied that the applicant is a fit and proper person to retail supply such feedingstuffs.

(2) In deciding whether an applicant is a fit and proper person to retail supply medicated feedingstuffs, the relevant authority shall take into account the matters specified in Schedule 4.

(3) An approval granted pursuant to paragraph (1) shall remain valid until withdrawn pursuant to regulation 15, so long as proper renewal applications are made under regulation 12 or 13 and are granted or await a decision.

Renewal of approvals

12. - (1) To renew a valid approval granted pursuant to regulation 11, a person shall apply to the relevant authority in the month of January in each year subsequent to the year in which approval was first granted.

(2) An application made under paragraph (1) shall be in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by particulars that seek to demonstrate that the applicant continues to be a fit and proper person to retail supply medicated feedingstuffs.

Late renewal

13. Where a person has failed to make proper application under regulation 12 he may apply to the relevant authority in accordance with regulation 12(2) for late renewal of a valid approval, but such application must be made no later than the end of the calendar year in which he was required to apply for renewal in accordance with regulation 12.

Grant of renewal

14. - (1) Subject to regulation 35, where an application is made under regulation 12 or 13, the relevant authority shall renew the approval granted pursuant to regulation 11 if it is satisfied that the applicant continues to be a fit and proper person to retail supply medicated feedingstuffs.

(2) In deciding whether an applicant continues to be a fit and proper person to retail supply medicated feedingstuffs, the relevant authority shall take into account the matters specified in Schedule 4.

Withdrawal of approvals

15. - (1) The relevant authority may withdraw the relevant approval from an approved distributor if:

- (a) it decides that he is not a fit and proper person to retail supply medicated feedingstuffs, or

(b) following the procedure in regulation 16, it is not satisfied as to the relevant condition.

(2) In paragraph (1) above "relevant approval", in relation to any person, means -

(a) an approval granted to him pursuant to regulation 11, whether or not renewed pursuant to regulation 14, or

(b) a right to be an approved distributor derived from sub-paragraph (b) of the definition of "approved distributor" in regulation 2(1).

(3) For the purposes of this regulation and regulation 16 "the relevant condition" means the condition that the approved distributor is a fit and proper person to retail supply medicated feedingstuffs.

Procedure relating to the withdrawal of approvals

16. - (1) Where the relevant authority proposes to withdraw an approval from an approved distributor pursuant to regulation 15(1)(b), it shall not withdraw the approval unless -

(a) it serves a notice in accordance with the requirements of paragraph (2) on him, and

(b) it is not satisfied, after the time for compliance with the notice has expired, that he has complied with the requirements specified in the notice.

(2) A notice served by the relevant authority under paragraph (1) shall -

(a) state that it proposes to withdraw the approval because it is not satisfied as to the relevant condition;

(b) specify why the relevant authority is not satisfied as to the relevant condition;

(c) specify the requirements to be complied with by him to satisfy it as to that condition; and

(d) specify that, unless it is satisfied that he has complied with the requirements specified in the notice within such reasonable time as is specified in the notice, his approval as a distributor to retail supply medicated feedingstuffs will be withdrawn.

PART IV

CONTROL OF AGRICULTURAL MERCHANTS

Prohibition notice on agricultural merchant

17. - (1) Where the relevant authority concludes following the steps set out in this regulation that it is not satisfied that an agricultural merchant is a fit and proper person to carry on a relevant transaction in relation to any medicated product, the relevant authority may serve on the agricultural merchant a notice ("a prohibition notice") preventing him from carrying on the relevant transaction in relation to the medicated product.

(2) Where the relevant authority proposes to serve a prohibition notice, it shall not serve the prohibition notice unless -

(a) it serves prior notice in accordance with the requirements of paragraph (3) on the agricultural merchant, and

(b) it is not satisfied, after the time for compliance with the prior notice has expired, as to the relevant condition.

(3) Where the relevant authority serves a notice under paragraph (2)(a), it shall -

(a) specify why the relevant authority is not satisfied as to the relevant condition; and

(b) specify -

(i) how (by the production of evidence or the compliance with requirements or both) the agricultural merchant may satisfy it as to the relevant condition,

(ii) the time by which he must do so, and

(iii) that, unless the agricultural merchant does so within such time as is specified in the notice, he will be served with a prohibition notice in respect of the medicated product.

(4) In this regulation -

"medicated product" means (either individually or in any combination) an authorised medicated pre-mix, an authorised intermediate product and a medicated feedingstuff;

"relevant condition" means the condition that the agricultural merchant is a fit and proper person to carry on a relevant transaction in relation to the medicated product; and

"relevant transaction" means -

(a) in the case of an authorised medicated pre-mix or an authorised intermediate product, retail supply, and

(b) in the case of a medicated feedingstuff, supply in accordance with regulation 28.

PART V

CONTROL OF AUTHORISED MEDICATED PRE-MIXES

Retail supply of authorised medicated pre-mixes

18. - (1) No person shall retail supply an authorised medicated pre-mix unless he is the person responsible for placing the pre-mix on the market, an agricultural merchant who is not subject to a prohibition notice in relation to the pre-mix or a manufacturer of medicated feedingstuffs.

(2) Subject to paragraph (3), no person shall retail supply an authorised medicated pre-mix unless he supplies it (either directly or via a preparer of an authorised intermediate product) to a manufacturer of medicated feedingstuffs -

(a) who is neither a stockfarmer nor a holder of animals, or

(b) who is a stockfarmer or holder of animals, and

(i) possesses an MFS prescription in which he is named as the manufacturer of the medicated feedingstuff prescribed and which provides for the medicated feedingstuff to be manufactured using the authorised medicated pre-mix, or

(ii) has received an order from an approved distributor to manufacture a medicated feedingstuff in accordance with an MFS prescription in which the distributor is named as the supplier of the prescribed medicated feedingstuff and which provides for the medicated feedingstuff to be manufactured using the authorised medicated pre-mix.

(3) Nothing in paragraph (2) shall prohibit the retail supply (whether direct or via a preparer of an authorised intermediate product) of authorised medicated pre-mixes which are anthelmintic medicinal products (vermifuges) to a manufacturer of medicated feedingstuffs who, while being a stockfarmer or holder of animals, does not come within paragraph (2)(b)(i) or (ii) if -

(a) the pre-mixes come within the first indent of Article 8.2 of the Medicated Feedingstuffs Directive, and

(b) any medicated feedingstuffs obtained from such pre-mixes are used in accordance with the second indent thereof.

Duties on persons engaged in the retail supply of authorised medicated pre-mixes

19. A person engaged in the retail supply of an authorised medicated pre-mix shall, in respect of the pre-mix, keep detailed records of the type specified in the first paragraph of Article 50b.2 of Directive 81/851/EEC and comply with the provisions in the second and third paragraphs of Article 50b.2.

PART VI**CONTROL OF INTERMEDIATE PRODUCTS****Manufacture of intermediate products**

20. - (1) No person shall manufacture an intermediate product other than an authorised intermediate product.

(2) No person shall manufacture an authorised intermediate product except on approved premises.

(3) A person who manufactures an authorised intermediate product shall make a declaration of the type required by the second paragraph of Article 3.1 of the Medicated Feedingstuffs Directive to the enforcement authority within a reasonable time notified to him by the enforcement authority.

Retail supply of authorised intermediate products

21. - (1) No person shall retail supply an authorised intermediate product unless he is the person responsible for placing the product on the market or an agricultural merchant who is not subject to a prohibition notice in relation to the product or a manufacturer of medicated feedingstuffs.

(2) Subject to paragraph (3), no person shall retail supply an authorised intermediate product unless the person to whom it is supplied is a manufacturer of medicated feedingstuffs -

(a) who is neither a stockfarmer nor a holder of animals, or

(b) who is a stockfarmer or holder of animals, and

(i) possesses an MFS prescription in which he is named as the manufacturer of the medicated feedingstuff prescribed and which provides for the medicated feedingstuff to be manufactured using the authorised intermediate product, or

(ii) has received an order from an approved distributor to manufacture a medicated feedingstuff in accordance with an MFS prescription in which the distributor is named as the supplier of the prescribed medicated

feedingstuff and which provides for the medicated feedingstuff to be manufactured using the authorised intermediate product.

(3) Nothing in paragraph (2) shall prohibit the retail supply of authorised intermediate products prepared from authorised medicated pre-mixes which are anthelmintic medicinal products (vermifuges) to a manufacturer of medicated feedingstuffs who, while being a stockfarmer or holder of animals, does not come within paragraph (2)(b)(i) or (ii) if -

(a) the pre-mixes come within the first indent of Article 8.2 of the Medicated Feedingstuffs Directive, and

(b) any medicated feedingstuffs obtained from such intermediate products are used in accordance with the second indent thereof.

Duties on persons engaged in the retail supply of authorised intermediate products

22. A person engaged in the retail supply of an authorised intermediate product shall, in respect of the product, keep detailed records of the type specified in the first paragraph of Article 50b.2 of Directive 81/851/EEC and comply with the provisions in the second and third paragraphs of that Article.

Labelling and packaging of intermediate products

23. No person shall place an intermediate product on the market unless it is labelled and packaged in accordance with the provisions of Articles 43 to 48 of Directive 81/851/EEC.

PART VII

CONTROL OF MEDICATED FEEDINGSTUFFS

Manufacture of medicated feedingstuffs

24. - (1) No person shall manufacture a medicated feedingstuff unless -

(a) subject to paragraphs (2) and (3), the medicinal component in the feedingstuff is a single authorised medicated pre-mix;

(b) the premises on which the feedingstuff is manufactured are approved premises which -

(i) are equipped with the necessary technical equipment;

(ii) have suitable and adequate storage and inspection facilities; and

(iii) are manned by staff of the type specified in Article 4.1(b) of the Medicated Feedingstuffs Directive;

and the premises, equipment and staff comply with the provisions of Article 4.1(d) of the Medicated Feedingstuffs Directive;

(c) the feedingstuff used in the medicated feedingstuff complies with the first and second indented paragraphs, and sub-paragraph (iii) of the third indented paragraph, of Article 4.1(c) of the Medicated Feedingstuffs Directive;

(d) any authorised medicated pre-mix used in the medicated feedingstuff is used in accordance with the third indented paragraph of Article 4.1(c) of the Medicated Feedingstuffs Directive, and the use is in accordance with sub-paragraphs (i), (ii) and (iii) of that indented paragraph;

(e) the medicinal product contained in the medicated feedingstuff complies with the fourth indented paragraph of Article 4.1(c) of the Medicated Feedingstuffs Directive;

(f) regular checks are carried out on the feedingstuff in accordance with the provisions of Article 4.1(e) of the Medicated Feedingstuffs Directive;

(g) daily records are kept in accordance with the provisions of Article 4.1(f) of the Medicated Feedingstuffs Directive; and

(h) pre-mixes and medicated feedingstuffs are stored on the approved premises in accordance with the provisions of Article 4.1(g) of the Medicated Feedingstuffs Directive.

(2) Nothing in paragraph (1)(a) shall prohibit a person from manufacturing a medicated feedingstuff containing an authorised intermediate product if a medicated feedingstuff containing the product has been prescribed by an MFS prescription issued in accordance with the provisions of regulation 29.

(3) Nothing in paragraph (1)(a) shall prohibit a person from manufacturing a medicated feedingstuff containing several authorised medicated pre-mixes if a medicated feedingstuff containing the pre-mixes has been prescribed by an MFS prescription issued in accordance with the provisions of regulation 29.

Packaging of medicated feedingstuffs

25. - (1) No person shall place a medicated feedingstuff on the market unless it is packaged in accordance with the provisions of Article 5.1 of the Medicated Feedingstuffs Directive.

(2) No person shall place a medicated feedingstuff on the market using a road tanker or similar container except in accordance with the provisions of Article 5.2 of the Medicated Feedingstuffs Directive.

Labelling of medicated feedingstuffs

26. - (1) Subject to paragraph (2), no person shall put a medicated feedingstuff into circulation unless -

(a) it is labelled in accordance with the provisions of the first paragraph of Article 6.1 of the Medicated Feedingstuffs Directive, and

(b) the package or container containing it is marked in accordance with the provisions of the second paragraph of Article 6.1 of the Medicated Feedingstuffs Directive.

(2) Where a medicated feedingstuff is placed on the market using a road tanker or similar container, the provisions of Article 6.2 of the Medicated Feedingstuffs Directive shall apply to the labelling of the feedingstuff.

Restrictions on the holding, placing on the market and use of medicated feedingstuffs

27. - (1) Subject to paragraphs (2) and (3), no person shall hold, place on the market or use a medicated feedingstuff unless it has been manufactured in accordance with the provisions of regulation 24.

(2) Nothing in paragraph (1) shall prohibit a person from holding or placing on the market a medicated feedingstuff in connection with an Article 7.2 scientific test if the intended subsequent use of it in connection with the test will constitute -

(a) a medicinal test on animals for which the person identified as the person who will be conducting the test has been issued with an animal test certificate, or

(b) a regulated procedure for which the person identified as the person who will be carrying out the procedure holds a personal licence and which is specified in a project licence that authorises the procedure.

(3) Nothing in paragraph (1) shall prohibit a person from using a medicated feedingstuff in connection with an Article 7.2 scientific test if the test constitutes -

(a) a medicinal test on animals for which he has been issued with an animal test certificate, or

(b) a regulated procedure for which he holds a personal licence and which is specified in a project licence that authorises the procedure.

Supply of medicated feedingstuffs

28. - (1) No person shall supply a person with a medicated feedingstuff unless the supplier is the manufacturer of it, an approved distributor, or an agricultural merchant who is not subject to a prohibition notice in relation to the feedingstuff.

(2) Subject to paragraph (4), no person shall supply a medicated feedingstuff to a stockfarmer or holder of animals -

(a) except on the presentation of an MFS prescription prescribing the medicated feedingstuff, and

(b) except to the stockholder or holder of animals named in the prescription.

(3) A person engaged in the retail supply of a medicated feedingstuff shall, in respect of the product, keep detailed records of the type specified in the first paragraph of Article 50b.2 of Directive 81/851/EEC and comply with the provisions in the second and third paragraphs of that Article.

(4) Nothing in paragraph (2) shall prohibit the supply, to a stockfarmer or holder of animals, of medicated feedingstuffs obtained from (or from authorised intermediate products prepared from) authorised medicated pre-mixes which are anthelmintic medicinal products (vermifuges) if -

(a) the authorised medicated pre-mixes come within the first indent of Article 8.2 of the Medicated Feedingstuffs Directive, and

(b) the medicated feedingstuffs are used in accordance with the second indent thereof.

MFS prescriptions

29. - (1) No registered veterinarian shall issue an MFS prescription relating to the manufacture of a medicated feedingstuff -

(a) except in respect of animals treated by him;

(b) unless he is satisfied as to the matters specified in Article 8.1(d) and (e)(ii) of the Medicated Feedingstuffs Directive;

(c) unless the quantity of medicated feedingstuff prescribed is in accordance with the provisions of Article 8.1(e)(i) of the Medicated Feedingstuffs Directive; and

(d) except for one treatment.

(2) No registered veterinarian shall issue an MFS prescription relating to the manufacture of a medicated feedingstuff from an authorised intermediate product or several authorised medicated pre-mixes unless -

(a) there is no authorised medicinal product for the condition to be treated;

(b) the medicated feedingstuff is to be administered by the veterinarian, or under his direct personal responsibility, to an animal or a small number of animals on a

particular holding;

(c) he considers the administration of the feedingstuff to be necessary to avoid causing unacceptable suffering to the animal or animals concerned;

(d) in the case of a medicated feedingstuff to be manufactured from several authorised medicated pre-mixes, there is no specific authorised therapeutic agent in pre-mix form for the disease to be treated or for the species concerned; and

(e) where the medicated feedingstuff is to be administered to an animal or animals whose flesh or products are intended for human consumption -

(i) the medicated feedingstuff will not contain any substance other than a substance found in a veterinary medicinal product authorised for such animals, and

(ii) an appropriate withdrawal period is specified in the prescription in accordance with the provisions of the second paragraph of Article 4.4 of Directive 81/851/EEC to ensure that food produced from the treated animal or animals does not contain residues harmful to consumers.

(3) A registered veterinarian who issues an MFS prescription relating to the manufacture of a medicated feedingstuff of the type specified in paragraph (2) shall -

(a) make a record of the matters specified in the third paragraph of Article 4.4 of Directive 81/851/EEC, and

(b) shall keep that record, and make it available for inspection by the enforcement authority, in accordance with the provisions of that paragraph.

(4) When issuing an MFS prescription, a registered veterinarian shall -

(a) issue the prescription in triplicate;

(b) present the original of the prescription to a manufacturer of medicated feedingstuffs, an approved distributor, or an agricultural merchant who is not subject to a prohibition notice served on him in relation to the feedingstuff;

(c) present a copy of the prescription to the stockholder or holder of the animal which is to be treated under the prescription; and

(d) keep a copy of the prescription.

(5) The manufacturer of a medicated feedingstuff, approved distributor or agricultural merchant who has been presented with an MFS prescription pursuant to paragraph (4) shall keep the prescription for a period of three years beginning with the date specified in

the prescription as the "to be used before" date.

(6) A stockholder or holder of an animal who has been presented with a copy of an MFS prescription pursuant to paragraph (4) shall keep the copy for a period of three years beginning with the date specified in the prescription as the "to be used before" date.

(7) A registered veterinarian who keeps a copy of an MFS prescription pursuant to paragraph (4) shall keep the copy for a period of three years beginning with the date specified in that prescription as the "to be used before" date.

(8) An MFS prescription shall be valid for a period of three months beginning with the day on which it is issued.

Restrictions on the quantity of medicated feedingstuffs that may be supplied

30. No person shall supply any person with a medicated feedingstuff for the treatment of an animal whose meat, flesh, offal or products are intended for human consumption except in a quantity which is in accordance with the provisions of the first and second indented sub-paragraphs of the second paragraph of Article 9.1 of the Medicated Feedingstuffs Directive.

Restrictions on the slaughter of treated animals and the disposal of products obtained from such animals

31. Where a medicated feedingstuff has been administered to an animal whose meat, flesh, offal or products are intended for human consumption, the stockholder or holder of the animal shall ensure that -

- (a) the animal is not slaughtered in order to be offered for consumption, and
- (b) no product obtained from the animal is disposed of with a view to being offered for human consumption,

before the end of the withdrawal period specified in the MFS prescription relating to the administration of the medicated feedingstuff.

Import of medicated feedingstuffs from E.E.A. States

32. No person shall import a medicated feedingstuff from an E.E.A. State other than a medicated feedingstuff of the type specified in the first indented paragraph of Article 10.1 of the Medicated Feedingstuffs Directive.

Import of medicated feedingstuffs from third countries

33. No person shall import a medicated feedingstuff from a third country other than a medicated feedingstuff manufactured in accordance with provisions equivalent to those in regulation 24.

Export of medicated feedingstuffs to E.E.A. States

34. Where a medicated feedingstuff is to be exported to an E.E.A. State, and that State

so requires, the relevant authority shall issue the State with an MFS certificate in respect of each consignment of it which is to be exported to that State.

PART VIII

MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

Recovery of fees

35. - (1) Subject to paragraphs (5) to (10), the appropriate fee shall be payable by a person who makes an application of a description listed in Schedule 1.

(2) Any fee payable under paragraph (1) shall be paid at the time the application is submitted to the relevant authority.

(3) Any unpaid sum due by way of a fee payable under paragraph (1), or any part of such fee, shall be recoverable as a debt.

(4) Where any fee is payable under paragraph (1) in relation to any application the relevant authority need not process any application under these Regulations, unless the application is accompanied by the appropriate fee.

(5) Where an applicant under regulation 3, in relation to the same premises, applies on the same date (evidenced by the date on the application forms) to the enforcement authority under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998^[14] for an establishment to be approved as an establishment on which an establishment activity may be exercised, he shall be liable to pay only one fee under both these Regulations and the Feedingstuffs (Zootechnical Products) Regulations 1998 and, where the appropriate fee differs in amount from the fee payable under the Feedingstuffs (Zootechnical Products) Regulations 1998, the fee payable shall be the higher amount.

(6) An applicant under regulation 3 shall not be liable to pay the appropriate fee in relation to the manufacture of medicated feedingstuffs on premises, where he has applied to the enforcement authority under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for approval of an establishment on the same premises as an establishment on which an establishment activity may be exercised, if he applies under regulation 3 within twelve months of his application under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998 and at the date of his application under regulation 3:

(a) an on the spot verification by the enforcement authority is pending in relation to his application under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998, or

(b) the enforcement authority has conducted an on the spot verification in relation to his application under regulation 10 and has granted approval pursuant to

regulation 11 of the Feedingstuffs (Zootechnical Products) Regulations 1998 which has not been withdrawn.

(7) Where an applicant under regulation 3 of these Regulations, in relation to the same premises, applies on the same date (evidenced by the date on the application forms) to the relevant authority under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for an establishment to be approved as an establishment on which a new establishment activity may be exercised, he shall be liable to pay only one fee under both these Regulations and the Feedingstuffs (Zootechnical Products) Regulations 1998 and, where the appropriate fee differs in amount from the fee payable under the Feedingstuffs (Zootechnical Products) Regulations 1998, the fee payable shall be the higher amount.

(8) An applicant under regulation 3 shall not be liable to pay the appropriate fee in relation to the manufacture of medicated feedingstuffs on premises, where he has applied to the enforcement authority under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for an establishment on the same premises to be approved as an establishment on which a new establishment activity may be exercised, if he applies under regulation 3 within twelve months of his application under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 and at the date of his application under regulation 3:

(a) an on the spot verification by the enforcement authority is pending in relation to his application under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998, or

(b) the enforcement authority has conducted an on the spot verification in relation to his application under regulation 12 and has granted approval pursuant to regulation 12(2) of the Feedingstuffs (Zootechnical Products) Regulations 1998 which has not been withdrawn.

(9) A person who has paid a sum by way of a fee under regulation 3 of the Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992^[15] for entry or retention of premises in, or restoration of premises to, Part A or B of the Register of Manufacturers of Animal Feedingstuffs in respect of the financial year commencing 1st April 1998 shall by virtue of this provision be treated for the purposes of this regulation as having paid that sum towards payment of the appropriate fee (in respect of the financial year ending on 31st March 1999) referred to under the column headed "Applications for approvals of premises" in item 1 or 2 of Schedule 1, and shall be entitled to a refund of any surplus over that appropriate fee.

(10) A person who has paid a sum by way of a fee under regulation 8 of the Medicines (Pharmacy and Merchants' List Order) 1992^[16] for entry or retention of his name in, or restoration of his name to, the Register of Merchants in respect of the year commencing 1st January 1998 shall by virtue of this provision be treated for the purposes of this regulation as having paid that sum towards payment of the appropriate fee (in respect of

the year ending on 31st December 1998) referred to under the column headed "Applications for approvals to retail supply as distributor" in item 1 of Schedule 1, and shall be entitled to a refund of any surplus over that appropriate fee.

(11) A fee payable under combined regulations as described in paragraphs (5) and (7) shall be treated for the purposes of paragraphs (2) to (4) as included among fees payable under paragraph (1).

Sampling checks and enforcement

36. It shall be the duty of the enforcement authority to make sampling checks in accordance with the provisions of Article 13 of the Medicated Feedingstuffs Directive and to enforce these Regulations.

Powers of authorised persons

37. - (1) An authorised person may at all reasonable times and on producing, if so required, some duly authenticated document showing his authority, exercise the powers specified in this regulation for the purposes of -

- (a) carrying out sampling checks, and
- (b) ascertaining whether an offence under regulation 38 has been or is being committed.

(2) An authorised person shall have the right to enter any premises (not being premises used only as a dwelling) on which he has reasonable cause to believe that -

- (a) a medicated pre-mix or intermediate product is being or has been retail supplied or is being kept there for the purpose of being retail supplied;
- (b) an intermediate product or medicated feedingstuff is being or has been manufactured;
- (c) a medicated feedingstuff is being or has been placed on the market, put into circulation, supplied or used or is being kept there for the purpose of being placed on the market, put into circulation, supplied or used; or
- (d) a medicated feedingstuff is being or has been held.

(3) An authorised person entering any premises by virtue of this regulation may take with him such other persons and such equipment as may appear to him to be necessary.

(4) An authorised person shall have the right to inspect -

- (a) any substance appearing to him to be a medicated pre-mix, an intermediate product or a medicated feedingstuff;
- (b) any article appearing to him to be a container or package used or intended to be used to contain a medicated feedingstuff, or to be a label used or intended to be used in connection with the labelling of any such feedingstuff; and
- (c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture of an intermediate product or medicated feedingstuff and any process of manufacture of such a product or feedingstuff, and the means employed, at any stage in the process of manufacture, for testing the product or feedingstuff after it has been subject to those processes.

(5) An authorised person shall have the right to take a sample of -

- (a) any substance appearing to him to be a medicated pre-mix and to be in the course of being, or having been, retail supplied;
- (b) any substance appearing to him to be an intermediate product and to be in the course of being, or having been, manufactured or retail supplied;
- (c) any substance appearing to him to be a medicated feedingstuff and to be in the course of being, or having been, manufactured, placed on the market, put into circulation, supplied or used or to be otherwise being held; and
- (d) a substance appearing to him to be used or intended to be used in the manufacture of an intermediate product or medicated feedingstuff.

(6) An authorised person shall have the right -

- (a) to require any person carrying on a business which consists of or includes the activities of -
 - (i) retail supply of a medicated pre-mix or intermediate product;
 - (ii) manufacture of an intermediate product or medicated feedingstuff;
 - (iii) placing on the market, putting into circulation, supply or use of a medicated feedingstuff,

and any person employed in connection with such a business, to produce any records relating to those activities which are in his possession or under his control, including records kept pursuant to regulations 19, 22 and 24(1)(g) and an MFS

prescription, or a copy of such a prescription, and

(b) to take copies of, or of any entry in, any record, produced in pursuance of the preceding paragraph.

(7) An authorised person exercising the power conferred by paragraph (6) in respect of a record held by means of a computer -

(a) shall be entitled at any reasonable time to have access to, and inspect and check the operation of, any computer and associated apparatus or material which is or has been in use in connection with the record in question;

(b) may require -

(i) the person by whom or on whose behalf the computer is or has been so used, or

(ii) any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material,

to afford the authorised person such reasonable assistance as he may require for the purpose; and

(c) may require the record, or an extract from the record, to be produced in a form in which it may be taken away.

(8) An authorised person shall have the right to seize and detain any medicated pre-mix, intermediate product or medicated feedingstuff which he has reason to believe to be a medicated pre-mix, an intermediate product or a medicated feedingstuff in relation to which, or by means of which, an offence under these Regulations is being or has been committed, and any record, including a record kept pursuant to regulations 19, 22 and 24(1)(g) and an MFS prescription, or a copy of such prescription, which he has reasonable cause to believe to be a record which may be required as evidence in proceedings under these Regulations.

Offences

38. It shall be an offence for a person -

(a) without reasonable excuse, to contravene any provision of regulation 18, 20(1) or (2), 21, 23, 24(1), 25, 26, 27(1), 28(1) or (2), 29(1) or (2), 30, 32 or 33;

(b) without reasonable excuse, to fail to comply with any provision of regulation 19, 20(3), 22, 28(3), 29(3) to (7) or 31;

(c) intentionally to obstruct an authorised person in the exercise of a power conferred by regulation 37; or

(d) without reasonable excuse, to fail to comply with any requirement made of him, pursuant to regulation 37 by an authorised person.

Punishment of offences

39. - (1) Any person who commits any of the offences set out in regulation 38(a) shall be liable -

(a) on summary conviction, to a fine not exceeding the statutory maximum; and

(b) on conviction on indictment, to a fine.

(2) Any person who commits any of the offences set out in regulation 38(b) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) Any person who commits any of the offences set out in regulation 38(c) or 38(d) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Offences by bodies corporate and Scottish partnerships

40. - (1) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to be attributable to, any neglect on the part of -

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person who was purporting to act in any such capacity,

he as well as the body corporate, shall be guilty of the offence and liable to be proceeded against and punished accordingly.

(2) For the purposes of paragraph (1), "director" in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(3) Where a Scottish partnership is guilty of an offence under these Regulations in respect of an act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner in the partnership, he, as well as the partnership, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Defence

41. Any person who manufactures, places on the market, puts into circulation, supplies or uses a medicated feedingstuff in accordance with a forged MFS prescription shall not be guilty of an offence under these Regulations if, having exercised all due diligence, he believes on reasonable grounds that the MFS prescription is genuine.

Service of notices

42. Any notice required to be served on a person under any provision of these Regulations may be served -

- (a) by delivering it to him;
- (b) by leaving it at the usual or last known place of abode or business of that person or, in a case where an address for service has been given by that person, at that address;
- (c) by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to that person at his usual or last-known place of abode or business or, in a case where an address for service has been given by that person, at that address; or
- (d) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to the secretary or clerk of that body corporate at that office.

Exclusion of the application of the Medicines Act 1968

43. - (1) Except as specified in paragraph (2), the Medicines Act 1968^[17], and instruments made wholly or partly under that Act, shall not apply -

- (a) to the retail supply of medicated pre-mixes, or intermediate products or
- (b) to the activities in relation to medicated feedingstuffs regulated by Part VII of these Regulations.

(2) The provisions of sections 32 to 36 (other than section 35(8)(a)), 38 and 39 of the Medicines Act 1968, and instruments made under any of those provisions shall apply to -

- (a) the retail supply of intermediate products, and
- (b) the activities so regulated in relation to medicated feedingstuffs

being used in connection with an Article 7.2 scientific test as if paragraph (1) had not come into force.

Sewel

Parliamentary Under Secretary of State, Scottish Office

1st April 1998

Jeff Rooker

Minister of State, Ministry of Agriculture, Fisheries and Food

9th April 1998

SCHEDULE 1

Regulations 2(1) and 35(1)

Fees

Applications for approvals of premises	£
1. Application for approval under regulation 3 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of below 2 kilograms per tonne	405
2. Application for approval under regulation 3 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of at least 2 kilograms per tonne	113
3. Application for renewal of approval under regulation 5 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of below 2 kilograms per tonne	253
4. Application for renewal of approval under regulation 5 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of at least 2 kilograms per tonne	71
5. Application for late renewal of approval under regulation 6 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of below 2 kilograms per tonne	356
6. Application for late renewal of approval under regulation 6 to manufacture on premises containing equipment capable of incorporating medicated pre-mixes into medicated feedingstuffs at a rate of at least 2 kilograms per tonne	110
Applications for approvals to retail supply as distributor	£

1. Application under regulation 10 for approval to retail supply	151
2. Application under regulation 12 for renewal of approval to retail supply	90
3. Application under regulation 13 for late renewal of approval to retail supply	134

SCHEDULE 2

Regulation 2(2) and (3)

INTERPRETATION

PART I

Expressions having the same meaning as in the Medicated Feedingstuffs Directive

additional guarantees

consumption

daily record

distributor

farm

hold

holder of animals

intended for human consumption

intermediate product

inspection facilities

manufacture

manufacturing plant

medicinal component
medicated feedingstuffs
mixing technology
one treatment
place on the market
premises
prescription
put into circulation
registered veterinarian
regular checks
road tanker or similar container
sampling checks
several authorised medicated pre-mixes
stockfarmer
storage facilities
suitable and adequate
supply
technical equipment
third country
use
withdrawal period

PART II

Expressions having the same meaning as in Directive 81/851/EEC

authorised medicinal product

consumers

direct personal responsibility

holding

person responsible for placing on the market

retail supply

small number of animals

unacceptable suffering

SCHEDULE 3

Regulation 4(2)

APPROVAL OF PREMISES:

MATTERS TO BE TAKEN INTO ACCOUNT

- 1.** The technical equipment which is, or will be, available on the premises for manufacturing medicated feedingstuffs.
- 2.** The storage facilities which are, or will be, available on the premises for storing pre-mixes and medicated feedingstuffs.
- 3.** The inspection facilities which are, or will be, available on the premises for carrying out regular checks on medicated feedingstuffs.
- 4.** The knowledge and qualifications in mixing technology of the staff who man, or will man, the medicated feedingstuffs manufacturing plant on the premises.
- 5.** The arrangements made, or to be made, to ensure compliance with the provisions of Article 4.1(c) to (g) of the Medicated Feedingstuffs Directive in relation to medicated feedingstuffs manufactured on the premises.

SCHEDULE 4

Regulation 10(2)

APPROVAL OF DISTRIBUTORS: MATTERS TO BE TAKEN INTO ACCOUNT

1. The storage facilities which are, or will be, available to the applicant for storing medicated feedingstuffs.
2. The arrangements made, or to be made, to ensure that records of the type specified in Article 50b.2 of Directive 81/851/EEC will be kept in relation to medicated feedingstuffs to be held and distributed by the applicant and that the records will be available to the enforcement authority.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Council Directive 90/167/EEC (OJ No. L92, 7.4.90, p.42) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community. These Regulations control the manufacture and distribution of medicated feedingstuffs.

These Regulations provide for the approval (regulations 3 and 4), renewal of approval (regulation 5), late renewal (regulation 6) and withdrawal of approval (regulations 8 and 9) of premises for manufacturing medicated feedingstuffs. Regulations 10 to 16 also provide for a system of approval, renewal of approval and withdrawal of approval of distributors of medicated feedingstuffs. Regulation 17 covers the controls on agricultural merchants.

Applications for approval, renewal of approval or late renewal of approval of premises or as distributor, subject to exceptions, must be accompanied by payment of such fee as specified in Schedule 1 (regulations 2(1) and 35).

Regulations 19, 22 and 28(3) place record keeping requirements on persons engaged in the supply of medicated feedingstuffs and in the retail supply of products used to manufacture them.

There are provisions controlling the manufacture, retail supply, packaging and labelling of particular products used to make medicated feedingstuffs (regulations 20, 21 and 23)

and manufacture, packaging, labelling and supply of medicated feedingstuffs (regulations 24 to 28). Further controls are contained in regulations 29 to 34.

Breach of the regulations is an offence under regulation 38, with penalties set out in regulation 39 and a defence in regulation 41.

The Regulations exclude the application of the Medicines Act 1968 save for matters in relation to animal test certificates (regulation 43).

A Regulatory Appraisal has been prepared and a copy has been placed in the library of each House of Parliament.

Notes:

[1] S.I. 1972/1811.[back](#)

[2] 1972 c. 68.[back](#)

[3] S.I. 1998/1044.[back](#)

[4] 1968 c. 67.[back](#)

[5] S.I. 1992/33, amended by S.I. 1992/3081, 1994/599, 3142 and 3169, 1995/3193, 1996/3034 and 1997/2892 and revoked by S.I. 1998/1044.[back](#)

[6] S.I. 1992/1520; relevant amending instruments are S.I. 1994/1531 and 1995/799. Revoked by S.I. 1998/1048.[back](#)

[7] OJ No. L317, 6.11.81, p.1.[back](#)

[8] OJ No. L373, 31.12.90, p.15.[back](#)

[9] OJ No. L214, 24.8.93, p.31.[back](#)

[10] OJ No. L1, 3.1.94, p.3.[back](#)

[11] OJ No. L1, 3.1.94, p.572.[back](#)

[12] OJ No. L92, 7.4.90, p.42.[back](#)

[13] 1986 c. 14.[back](#)

[14] S.I. 1998/1047.[back](#)

[15] S.I. 1992/1520; relevant amending instruments are S.I. 1994/1531, 1995/799 and 1997/638; Revoked by S.I. 1998/1048.[back](#)

[16] S.I. 1992/33, amended by S.I. 1992/3081, 1994/599, 3142 and 3169, 1995/3193, 1996/3034 and 1997/2892 and revoked by S.I. 1998/1044.[back](#)

[17] 1968 c. 67.[back](#)