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 STATUTORY INSTRUMENTS
 

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**1985 No. 1533**

**MEDICINES**

**The Medicines (Medicated Animal Feeding Stuff)  
Regulations 1985**

<i>Made- - - -</i>	<i>1st October 1985</i>
<i>Laid before Parliament</i>	<i>15th October 1985</i>
<i>Coming into Operation</i>	<i>1st January 1986</i>

The Minister of Agriculture, Fisheries and Food, the Secretaries of State respectively concerned with agriculture in Scotland and in Wales and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by section 40(1), (2), (4) and (5) of the Medicines Act 1968 (a), 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 the said Act, hereby make the following regulations:—

*Title and commencement*

1. These regulations may be cited as the Medicines (Medicated Animal Feeding Stuff) Regulations 1985 and shall come into operation on 1st January 1986.

*Interpretation*

2.—(1) In these regulations—

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

“prescription only medicine” means a medicinal product of a description or falling within a class for the time being specified for the purposes of section 58 of the Medicines Act 1968 in an order made under that section;

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

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

(a) for a medicinal purpose of a substance or article other than a medicinal product, or

(b) of a substance in which a medicinal product has been incorporated, in an animal feeding stuff.

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(a) 1968 c.67; section 40 was substituted by section 13(1) of the Animal Health and Welfare Act 1984 (c.40).

*Prohibition of incorporation of medicinal products in animal feeding stuffs*

3. No person shall, in the course of a business carried on by him, incorporate a medicinal product of any description in an animal feeding stuff unless—

- (a) it is incorporated in accordance with the provisions relating to the incorporation of the medicinal product in animal feeding stuffs contained in a product licence or animal test certificate (whether held by him or another person), or
- (b) it is incorporated in accordance with a written direction.

*Prohibition of sale, supply and importation of medicated animal feeding stuffs*

4.—(1) No person shall—

- (a) in the course of a business carried on by him, sell or supply any animal feeding stuff in which a medicinal product, not being a prescription only medicine, has been incorporated, or
- (b) import any such animal feeding stuff,

unless—

- (i) the medicinal product was incorporated in the animal feeding stuff in accordance with the conditions specified in paragraph (a) or (b) of regulation 3 above, or
- (ii) the animal feeding stuff is sold, supplied or imported in accordance with a written direction.

(2) No person shall—

- (a) subject to paragraph (3) below, in the course of a business carried on by him, sell or supply any animal feeding stuff in which a prescription only medicine has been incorporated, or
- (b) import any such animal feeding stuff,

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

(3) The prohibition contained in paragraph (2)(a) above shall not apply where any animal feeding stuff in which a prescription only medicine has been incorporated in accordance with the conditions specified in regulation 3(a) above is sold or supplied—

- (a) to a person whom the seller or supplier knows, or has reasonable cause to believe, to be a person carrying on a business wholly or mainly comprising the manufacture of animal feeding stuffs for sale or supply, or
- (b) to a person whose name is entered in the register kept by the Pharmaceutical Society of Great Britain or by the Department of Health and Social Services for Northern Ireland under Article 3(7) of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1984 (a).

*Written directions*

5. A written direction given by a veterinary surgeon or veterinary practitioner for the purposes of regulations 3 or 4 above shall—

- (a) be in the form set out in the Schedule to these regulations or in a form substantially to the like effect,

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(a) SI 1984/1861, to which there is an amendment not relevant to these regulations.

- (b) be written in ink or otherwise so as to be indelible, and
- (c) be signed in ink in his own name by the veterinary surgeon or veterinary practitioner giving it.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 23rd September 1985.



*Michael Jopling,*  
Minister of Agriculture, Fisheries  
and Food.

*George Younger,*  
Secretary of State for Scotland.

1st October 1985.

*Wyn Roberts,*  
Parliamentary Under Secretary  
of State for Wales.

16th September 1985.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 17th day of September 1985.



*W. H. Jack,*  
Permanent Secretary.

SCHEDULE

Regulation 5

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

REFERENCE NUMBER

SECTION I – TO BE COMPLETED IN ITS ENTIRETY BY A VETERINARY SURGEON OR VETERINARY PRACTITIONER (please read the notes before you complete this form)

1. Please manufacture/sell/supply/import\* ..... tonnes/kg\* of (name or type of feed eg broiler starter) ..... meal/pellets/crums\* containing ..... g/tonne (mg/kg)\* of (please give a precise description of the product by either proprietary name and product licence number and/or the generic name) ..... to give ..... g/tonne (mg/kg)\* of (please give a precise description of the active substance) ..... in the final medicated feeding stuff for administration to the following animals which are under my care: Species ..... Type ..... Number ..... Age .....

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

Recommendations For Use On The Farm

- (i) Animals 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.
(v) Milk/eggs\* must not be taken for human consumption until ..... after the last treatment.
(vi) Special precautions .....

Signature of Veterinary Surgeon or Veterinary Practitioner ..... Date ..... Name in block letters ..... Address of Veterinary Practice ..... Telephone No. ....

\*Delete as appropriate.

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

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

NB This direction is valid for a period of 30 days from the date of signature.

NOTES

1. This form must be completed in triplicate, in ink or otherwise so as to be indelible and be signed in ink in his own name by the Veterinary Surgeon or Veterinary Practitioner.
2. One copy of the form must be retained by the Veterinary Surgeon or Veterinary Practitioner, one copy given to the manufacturer and one copy given to the farmer.
3. The level required and the name of the additive should normally comply with the recommended published level and the data sheet, if available.
4. For bulk deliveries, or pelleted or cubed materials, a minimum order of between 2 and 3 tonnes is normally required by a manufacturer/supplier to obtain a satisfactory mix or product. For meals or mashes smaller quantities may be supplied but the quantity should be confirmed with the manufacturer/supplier before the order is placed.
5. As there are weight losses incurred in manufacture it is difficult to produce the exact quantity specified. The quantity specified should, however, be adhered to so far as is practicable.
6. Not all medicaments will be stocked by all manufacturers/suppliers. You should confirm with them whether they will supply the required medicament when one of the uncommon preparations is being requested.

\*Delete as appropriate.

## EXPLANATORY NOTE

*(This Note is not part of the Regulations.)*

These regulations are made under section 40 of the Medicines Act 1968 as substituted by section 13(1) of the Animal Health and Welfare Act 1984, which section was brought into force on 16th August 1985 by the Animal Health and Welfare Act 1984 (Commencement No. 1) Order 1985 (S.I. 1985/1267).

The regulations—

- (1) prohibit a person, in the course of a business carried on by him, incorporating a medicinal product in an animal feeding stuff unless it is incorporated in accordance with a product licence, an animal test certificate or a written direction given by a veterinary surgeon or veterinary practitioner (regulation 3);
- (2) prohibit a person, in the course of a business carried on by him, selling or supplying any animal feeding stuff in which a medicinal product, not being a prescription only medicine (that is to say a medicinal product which may be sold or supplied by retail only in accordance with a prescription given by a veterinary surgeon or veterinary practitioner), has been incorporated or importing any such animal feeding stuff unless the medicinal product was incorporated in the animal feeding stuff in accordance with a product licence, an animal test certificate or a written direction given by a veterinary surgeon or veterinary practitioner (regulation 4(1)); and
- (3) prohibit a person, in the course of a business carried on by him, selling or supplying any animal feeding stuff in which a prescription only medicine has been incorporated or importing any such animal feeding stuff except in accordance with a written direction given by a veterinary surgeon or veterinary practitioner (regulation 4(2)); and
- (4) prescribe the form of a written direction to be given by a veterinary surgeon or veterinary practitioner for the purposes of these regulations (regulation 5).

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