STATUTORY INSTRUMENTS

1994 No. 1531

MEDICINES

The Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1994

Made - - - -	*9th June 1994*
Laid before Parliament	*10th June 1994*
Coming into force - -	*1st July 1994*

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(1) 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 European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1994 and shall come into force on 1st July 1994.

Amendment

2. The Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992(**5**) shall be amended in accordance with the following regulations.

(**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.

(**5**) S.I. 1992/1520.

3. For regulation 3 (Register of manufacturers of animal feeding stuffs) there shall be substituted the following regulation:

"**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 comprising parts A and B, each being a list of persons entitled in the course of a business carried on by them—

(a) as to Part A—

(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,

(ii) to store on those premises any animal feeding stuff in which they have incorporated medicinal products, and

(iii) to place on the market such animal feeding stuffs; and

(b) as to Part B—

(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, or to incorporate such products in any animal feeding stuff by way of mobile mixing equipment at that rate,

(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 they have incorporated medicinal products, and

(iii) to place on the market such animal feeding stuffs.

(2) Where a person carrying on a business—

(a) elsewhere than in Northern Ireland, applies in writing to the registrar, or

(b) in Northern Ireland, applies in writing to the Department,

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 or the Department as the case may be shall, subject to paragraphs (3) and (4) below, enter his name in Part A or Part B of the Register in respect of those premises.

(3) The registrar or the Department shall refuse to enter in the Register the name of any person in respect of any premises unless that person has paid the appropriate fee and has given a written undertaking that he will comply with the relevant Code of Practice.

(4) The registrar with the approval of the Minister, or the Department, may refuse to enter in the Register the name of any person in respect of any premises if, in the opinion of the registrar or the Department (as the case may be), that person cannot demonstrate that he has taken all reasonable steps to ensure that he will comply with the provisions of the relevant Code of Practice.

(5) 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 1994, and thereafter in the month of April in any subsequent year, make a written application 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.

(6) 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, on or before 31st July in 1994, and thereafter on or before 30th April in any subsequent year, paid the appropriate fee.

(7) A person whose name is removed from the Register in respect of any premises by reason only that he failed either to make proper application for the retention of his name or to pay the appropriate fee in accordance with paragraphs (5) and (6) above respectively, may, in order to restore his name to the Register in respect of those premises, make a written application, within 11 months of the expiry of the registration, for his name to be restored to the Register in respect of those premises.

(8) 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 in accordance with paragraph (7) above, has paid the appropriate fee.

(9) 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 relevant Code of Practice.

(10) The registrar or the Department may remove from the Register the name of any person entered in it in respect of any premises, at the request of that person.

(11) The registrar and the Department, on or before 1st October every year, shall each supply to the Minister a copy of the Register, certified to be a true copy of it as at a date specified in the certificate, not being later than 1st September in the year in question, and shall at monthly intervals supply to the Minister copies of amendments made to the Register in each month following the date specified in the certificate.

(12) In this regulation—

"the appropriate fee" means the fee for the entry or retention in, or restoration to, the Register, specified in Schedule 3, and

"the relevant Code of Practice" means, in relation to entry in Part A of the Register, the Code of Practice for Category A Registered Manufacturers of Medicated Animal Feeding Stuffs, and in relation to entry in Part B of the Register, the Code of Practice for Category B Registered Manufacturers of Medicated Animal Feeding Stuffs, both published by the Ministry of Agriculture, Fisheries and Food in December 1991.".

4. In regulation 6 (Restrictions on placing on the market and importation of animal feeding stuffs in which medicinal products have been incorporated)—

(a) in paragraph (3)—

(i) after the words "animal feeding stuff" where they first appear there shall be inserted the words "which has not been imported",

(ii) in sub-paragraph (a)(i) for the words "pursuant to Council Directive 90/167/EEC" there shall be substituted the words "and with any undertaking in respect of the relevant Code of Practice given pursuant to regulation 3(3)", and

(iii) in sub-paragraph (a)(ii) the words "or imported" shall be omitted;

(b) in paragraph (5) after the word "import" there shall be inserted the words "other than from a member State", and after the word "incorporated" there shall be inserted the words "and place such feeding stuff on the market"; and

(c) for paragraph (6) there shall be substituted the following paragraph:

"(6) No person shall import from a member State any animal feeding stuff in which a prescription only medicine has been incorporated, and place such feeding stuff on the market, unless that feeding stuff—

(a) complies with the provisions of Article 10.1, 1st indent, of Council Directive 90/167/EEC, and

(b) each imported consignment is accompanied by a certificate in the form, including the note thereto, set out Schedule 1.".

5. In regulation 8 (Restrictions on placing on the market final medicated feeding stuff containing medicinal products) for paragraph (7) there shall be substituted the following paragraph:

"(7) 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 prescription only medicine has been incorporated unless—

(a) in the case of a feeding stuff which has not been imported, it has been manufactured in accordance with the provisions of these Regulations and with any undertaking given pursuant to regulation 3(3), or

(b) in the case of a feeding stuff which has been imported other than from a member State, it has been manufactured in accordance with the provisions of Council Directive 90/167/EEC, or

(c) in the case of a feeding stuff which has been imported from a member State, it complies with the provisions of Article 10.1, 1st indent, of that Council Directive.".

6. For regulation 9 (Restriction on use of medicated animal feeding stuffs) there shall be substituted the following regulation:

"**Restriction on use of medicated animal feeding stuffs**

9. No person shall use any medicated animal feeding stuff in which a prescription only medicinal product has been incorporated unless—

(a) in the case of a feeding stuff which has not been imported, it has been manufactured in accordance with the provisions of these Regulations and with any undertaking given pursuant to regulation 3(3), or

(b) in the case of a feeding stuff which has been imported other than from a member State, it has been manufactured in accordance with the provisions of Council Directive 90/167/EEC, or

(c) in the case of a feeding stuff which has been imported from a member State, it complies with the provisions of Article 10.1, 1st indent, of that Council Directive.".

7. In Schedule 2 (Veterinary Written Direction) in Note 2 at the end of Section IV, for the words "if any part of Section IV" there shall be substituted the words "If part 1 of Section IV".

8. After Schedule 2 there shall be added the Schedule set out in the Schedule to these Regulations.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

Gillian Shephard

7th June 1994. Minister of Agriculture, Fisheries and Food

Hector Monro
Parliamentary Under Secretary of State, Scottish Office

9th June 1994

Signed by authority of the Secretary of State for Wales

Wyn Roberts
Minister of State, Welsh Office

7th June 1994

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

L.S.

P. T. Toal
Assistant Secretary

9th day of June 1994.

We consent

Timothy Wood
Andrew MacKay
Two of the Lords Commissioners of Her Majesty's Treasury

8th June 1994

SCHEDULE Regulation 8

"SCHEDULE 3 Regulation 3(12)

FEES

Application in respect of each premises	Previous fee	New fee
	£	£
Part A of the Register		
1. For entry of name in the Register	295	262
2. For retention of name in the Register	185	164
3. For restoration of name to the Register	260	230
Part B of the Register		
1. For entry of name in the Register	90	70
2. For retention of name in the Register	56	44
3. For restoration of name to the Register	80	61"

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992 (the "principal Regulations").

The main changes made by the Regulations are that they alter the fees payable in respect of the entry or retention in, or restoration to, the Register of manufacturers of animal feeding stuffs. From 1995 the commencement of the registration year is changed from 1st July to 1st April, and the fees which would otherwise have been charged are adjusted accordingly for the period 1st July 1994 to 31st March 1995 (regulations 3, 8 and the Schedule). Other drafting changes are made to regulation 3 of the principal Regulations.

The Regulations also clarify the requirements in respect of medicated feeding stuffs in which prescription only medicines have been incorporated which have been manufactured in the United Kingdom and those which have been imported from other member States and elsewhere, provide that such products imported from other member States should comply with Article 10.1, 1st indent, of Council Directive 90/167/EEC (OJ No. L92, 7.4.90, p.42) and amend the restriction concerning

placing on the market of final medicated feeding stuffs so that it applies only to final medicated feeding stuffs in which prescription only medicines are incorporated (regulations 4, 5 and 6). They also remove in certain circumstances the requirement that a copy of a Veterinary Written Direction should be sent to the Royal Pharmaceutical Society of Great Britain (regulation 7).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament.