

---

STATUTORY INSTRUMENTS

---

**1998 No. 1044**

**MEDICINES**

**The Medicines (Exemptions for Merchants  
in Veterinary Drugs) Order 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>

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by sections 57(1), (2) and (2A) and 129(4) 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 Order in accordance with section 129(6) of that Act, and with the consent of the Treasury in accordance with section 57(2A) of that Act in relation to revocations, 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) in relation to revocations, hereby make the following Order:

**Title and commencement**

1. This Order may be cited as the Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998 and shall come into force on 6th May 1998.

**Interpretation**

2.—(1) In this Order, unless the context otherwise requires—

- 
- (1) 1968 c. 67; “the appropriate Ministers” referred to in section 57 is defined in section 1 (see also the following footnote); section 57(2A) was inserted by the Animal Health and Welfare Act 1984 (c. 40), section 14.
- (2) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of S.I. 1969/338, 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 Northern Ireland Departments 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.

“the Act” means the Medicines Act 1968;

“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;

“the appropriate fee” means a fee which is payable to the registration authority of such an amount as the appropriate Ministers may with the consent of the Treasury determine from time to time;

“authorisation” means a marketing authorisation within the meaning of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(5) or a product licence granted in accordance with section 7 of the Act, and “authorised” shall be construed accordingly;

“authorisation holder” includes a person allowed by the authorisation or licence to sell the relevant product under a specified alternative name;

“cat wormer”, “dog wormer” and “horse wormer” mean, respectively, an anthelmintic authorised for administration to cats, dogs and horses and ponies;

“Certificate of Competence” means a Certificate of Competence in the Safe Use of Sheep Dips issued by the National Proficiency Tests Council, or by that Council and the Department of Agriculture for Northern Ireland, showing that Parts 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed;

“the Minister” means the Minister of Agriculture, Fisheries and Food;

“organophosphorus sheep dip” means a sheep dip having as its active ingredient an organophosphorus compound;

“register” means the register of merchants in veterinary drugs kept in accordance with section 57(2A)(a) of the Act;

“registration authority” means, for persons carrying on business in England, Scotland or Wales, the Royal Pharmaceutical Society of Great Britain, and for persons carrying on business in Northern Ireland, the Department of Health and Social Services for Northern Ireland;

“saddler” means a person carrying on a business involving in whole or in part the sale of saddlery requisites, being products and equipment and things for the maintenance of that equipment, for keeping horses or ponies, including human clothing for that purpose;

“sale” means sale by retail, offering or exposing for sale by retail and supply in circumstances corresponding to retail sale, and cognate expressions shall be construed accordingly; and

“suitably qualified person” means a person whose name is included on a list kept for the purposes of this Order by the registration authority.

(2) Unless the context otherwise requires, any reference in this Order to a numbered article or the Schedule is to the corresponding article of, or the Schedule to, this Order.

### **Products to which this Order applies**

3. This Order applies to any veterinary drug whose name and authorisation number appears on a list kept by the Minister by reference to this article.

### **Exemption for agricultural merchants and saddlers**

4. Subject to article 5 and 6, the provisions of section 52 of the Act (sale or supply of medicinal products not on general sale list) shall not apply to the sale of a veterinary drug to which this Order

---

(5) [S.I. 1994/3142](#), to which there are amendments not relevant to this Order.

applies by an agricultural merchant, or the sale of such a veterinary drug which is a cat wormer, dog wormer or horse wormer by a saddler.

### **Conditions of exemption for agricultural merchants and saddlers relating to registration**

5.—(1) The exemption provided by article 4 shall be subject to the condition that the name of the agricultural merchant or saddler is entered in the register in respect of all premises where he sells or stores veterinary drugs to which this Order applies, and he complies with the conditions in respect of the inclusion or retention in the register set out in paragraphs (2) to (9) below.

(2) For the purposes of inclusion in the register an application shall be made in writing to the registration authority, giving details of the applicant's name and address and of the premises in which he proposes to sell or store veterinary drugs to which this Order applies, and, for each such premises, the name and relevant qualifications of a person nominated to be the suitably qualified person for the premises, together with the appropriate fee for each such premises.

(3) For the purposes of retention in the register an application shall be made in writing to the registration authority in the month of January in each year subsequent to the year in which the first registration was granted, accompanied by the appropriate fee for each premises in which the applicant sells or stores veterinary drugs to which this Order applies.

(4) An applicant for retention in the register who failed to make proper application in accordance with the preceding paragraph, shall apply in writing to the registration authority for late retention in accordance with this paragraph, accompanied by the appropriate fee for each premises in which he sells or stores veterinary drugs to which this Order applies, but such application must be made no later than the end of the calendar year in which he was required to make a retention application in accordance with paragraph (3) above.

(5) The agricultural merchant or saddler shall be a fit and proper person to sell veterinary drugs to which this Order applies.

(6) All premises used for the sale or storage of veterinary drugs to which this Order applies must be suitable for the purpose, and premises to be used for sale, which may include a stall of a permanent nature at a market or agricultural showground, must be capable of being closed so as to exclude the public.

(7) Any proposed alteration to premises used for the sale or storage of veterinary drugs to which this Order applies which may affect their suitability for the purpose must be notified to, and approved by, the registration authority.

(8) Any proposed permanent change of suitably qualified person nominated in accordance with paragraph (2) above must be notified to the registration authority.

(9) The applicable conditions relating to sale set out in article 6 must be complied with.

### **Conditions of exemption for agricultural merchants and saddlers relating to sale**

6.—(1) The exemption provided by article 4 shall further be subject to the conditions relating to sale applicable to agricultural merchants and saddlers set out in paragraph (2) below and the additional conditions applicable to agricultural merchants set out in paragraph (3) below.

(2) The conditions which must be complied with by an agricultural merchant and saddler are that:

- (a) premises in which he sells veterinary drugs to which this Order applies must be occupied by him and under his control at all times when the premises are open for business, and he must store those products in a part of the premises partitioned off or otherwise separated from the rest of the premises and to which the public are not permitted access,

- (b) the suitably qualified person nominated or notified in accordance with article 5 or, in the case of his temporary absence, an alternative suitably qualified person, shall authorise each sale of veterinary drugs to which this Order applies,
  - (c) unless allowed by virtue of other legal provisions relating to veterinary drugs, veterinary drugs other than those to which this Order applies may not be sold,
  - (d) each veterinary drug sold is in the container in which it was made up for sale by the manufacturer or assembler which has not been opened since then, the product bears the manufacturer's label which has not been altered and the product is not sold after the date of expiry indicated on its label,
  - (e) the sale is not by self-service methods,
  - (f) if the product is a cat wormer, a dog wormer or a horse wormer, the sale is to a person whom he knows or has reasonable cause to believe has in his charge a cat if the product is cat wormer, a dog if the product is a dog wormer or a horse or pony if the product is a horse wormer and will use the product for the treatment of the animal concerned, and
  - (g) he complies with the requirements as to records specified in article 8.
- (3) The additional conditions which must be complied with by an agricultural merchant are that:
- (a) if the product is not a cat wormer, dog wormer or horse wormer, the sale is to a person whom he knows or has reasonable cause to believe 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, and
  - (b) if the product is an organophosphorus sheep dip, or after 30th December 1998 if the product is a sheep dip, not intended for export, the sale is to a person whom he knows or has reasonable cause to believe is the holder, or the employer of or a person acting on behalf of the holder, of a Certificate of Competence, and the agricultural merchant keeps a record of the Certificate number for three years from the date of sale.

#### **Exemption and conditions of exemption for authorisation holders relating to sale**

7.—(1) The provisions of section 52 of the Act shall not apply to the sale of a veterinary drug to which this Order applies by the authorisation holder for that drug, if he complies with the conditions set out in paragraph (2) below.

- (2) The conditions which must be complied with are that:
- (a) premises used for the sale, which may include a stall of a permanent nature at a market or agricultural showground, must be occupied by him and under his control at all times when the premises are open for business and be capable of being closed so as to exclude the public,
  - (b) each veterinary drug sold is in the container in which it was made up for sale by the manufacturer or assembler which has not been opened since then, the product bears the manufacturer's label which has not been altered and the product is not sold after the date of expiry indicated on its label,
  - (c) the sale is not by self-service methods,
  - (d) if the product is not a horse wormer the sale is to a person whom he knows or has reasonable cause to believe 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,
  - (e) if the product is a horse wormer the sale is to a person whom he knows or has reasonable cause to believe has in his charge a horse or pony and will use the product for the treatment of the animal concerned,

- (f) if the product is an organophosphorus sheep dip, or after 30th December 1998 if the product is a sheep dip, not intended for export, the sale is to a person whom he knows or has reasonable cause to believe is the holder, or the employer of or a person acting on behalf of the holder, of a Certificate of Competence, and the authorisation holder keeps a record of the Certificate number for three years from the date of sale, and
- (g) he complies with the requirements as to records specified in article 8.

## **Records**

8.—(1) An agricultural merchant, saddler or authorisation holder shall comply with the following paragraphs in respect of veterinary drugs to which this Order applies.

- (2) For each incoming and outgoing transaction a record shall be kept of—
  - (a) the date of the transaction,
  - (b) the identity of the product,
  - (c) the manufacturer’s batch number,
  - (d) the quantity received or supplied, and
  - (e) the name and address of the supplier or recipient.

(3) At least once a year a detailed audit of all such transactions shall be carried out and recorded, with incoming and outgoing products reconciled with those held in stock, and any discrepancies recorded.

(4) All records kept in accordance with the preceding paragraphs shall be durable, but may be kept by electronic means, and shall be kept for a period of three years from the date of the transaction or audit, and made available on request to the registration authority or to any person duly authorised in writing by an enforcement authority within the meaning of section 132(1) of the Act.

## **Revocations**

- 9. The instruments set out in the Schedule are hereby revoked.

Signed by authority of the Secretary of State for Health

1st April 1998

*Jay*  
Minister of State,  
Department of Health

1st April 1998

*Sewel*  
Parliamentary Under Secretary of State, Scottish  
Office

---

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

---

Signed by authority of the Secretary of State for Wales

3rd April 1998

*Win Griffiths*  
Parliamentary Under Secretary of State, Welsh  
Office

9th April 1998

*Jeff Rooker*  
Minister of State, Ministry of Agriculture,  
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland  
this

L.S.

9th day of April 1998.

*D C Gowdy*  
Permanent Secretary

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

L.S.

9th day of April 1998.

*P J Small*  
Permanent Secretary

We consent,

2nd April 1998

*Bob Ainsworth*  
*Graham Allen*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

## SCHEDULE

Article 9

## REVOCATIONS

(1) <i>Instruments revoked</i>	(2) <i>References</i>	(3) <i>Extent of revocation</i>
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992	<a href="#">S.I. 1992/33</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment) Order 1992	<a href="#">S.I. 1992/3081</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment) Order 1994	<a href="#">S.I. 1994/599</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment No. 2) Order 1994	<a href="#">S.I. 1994/3169</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment) Order 1995	<a href="#">S.I. 1995/3193</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment) Order 1996	<a href="#">S.I. 1996/3034</a>	The whole Order
The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) (Amendment) Order 1997	<a href="#">S.I. 1997/2892</a>	The whole Order

**EXPLANATORY NOTE***(This note is not part of the Order)*

This Order revokes and replaces, with amendments, the Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992 (“the 1992 Order”), as amended.

The Order continues the exemption from section 52 of the Medicines Act 1968 (“the Act”) for retail sales of veterinary drugs by agricultural merchants, saddlers and authorisation holders subject to conditions relating to registration (for agricultural merchants and saddlers) and sale. The main

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

changes are that this Order applies to retail sales of veterinary drugs whose names and authorisation numbers are on a list kept by the Minister of Agriculture, Fisheries and Food (article 3), which will be open to inspection at the office of the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3NB and copies of which will be made publicly available and published in a regular bulletin. In addition to horse wormers, saddlers are permitted to sell cat and dog wormers, and they and agricultural merchants may sell such products to persons who keep cats and dogs otherwise than for business purposes (article 4 and 6(2)(f)). Fees in respect of registration of agricultural merchants and saddlers are fees of such amounts as the appropriate Ministers may with the consent of the Treasury determine from time to time (article 2(1) and 5(2) to (4)). After 30th December 1998, the requirement in relation to Certificates of Competence will apply to all types of sheep dip (article 6(3) (b) and 7(2)(f)). There is now no exemption for pharmacists from section 52(c) of the Act (which requires retail sales of medicines to which the section applies to be by or under the supervision of a pharmacist) in relation to veterinary drugs to which this Order applies.

The Order also implements Article 50b.2 of Council Directive [81/851/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ No. L317, 6.11.81, p.1), which sets out provisions for record keeping by retailers of those products (article 8).

A Regulatory Appraisal has been prepared and a copy has been placed in the library of each House of Parliament. Copies can be obtained from the Veterinary Medicines Directorate at the address above.