
STATUTORY INSTRUMENTS

2000 No. 2686

MEDICINES

**The Medicines (Exemptions for Merchants in
Veterinary Drugs) (Amendment) Order 2000**

Made - - - - *29th September 2000*
Laid before Parliament *29th September 2000*
Coming into force - - *9th October 2000*

The Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, 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, hereby make the following Order:

Title and commencement

1. This Order may be cited as the Medicines (Exemptions for Merchants in Veterinary Drugs) (Amendment) Order 2000 and shall come into force on 9th October 2000.

Amendment of previous Order

2.—(1) The Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998(3) is amended in accordance with the following paragraphs of this article.

(2) In paragraph (3) of article 6 (conditions of exemption for agricultural merchants)—

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- (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).
- (2) In the case of the Minister of Agriculture, Fisheries and Food (so far as concerns functions previously vested in the Secretaries of State respectively concerned with agriculture in Scotland and—in consequence of S.I.1978/272—Wales), by virtue of articles 2(2) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I.1999/3142); in the case of the Secretary of State concerned with health in England (so far as concerns functions previously vested in the Secretaries of State respectively concerned with health in Scotland and—in consequence of S.I. 1969/388—Wales), by virtue of articles 2(1) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999; in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1)).
- (3) S.I. 1998/1044.

- (a) at the end of sub-paragraph (a) the word “and” shall be deleted;
 - (b) in sub-paragraph (b), for the words “an organophosphorus sheep dip, or after 30th December 1998 if the product is a sheep dip” there shall be substituted the words “a sheep dip of any type”;
 - (c) at the end of sub-paragraph (b) there shall be inserted the word “, and” followed by the following sub-paragraph:
 - “(c) if the product is an organophosphorus sheep dip, not intended for export, the sale is effected together with the provision to the buyer of—
 - (i) a double side laminated notice meeting the specification set out in the Schedule to this Order (unless the notice has been provided to the buyer within the previous twelve months and the agricultural merchant knows or has reasonable cause to believe that the buyer still has it available for use), and
 - (ii) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described”.
- (3) For article 7 (exemption and conditions of exemption for authorisation holders relating to sale) these shall be substituted the following article:

“Exemption and conditions of exemption for authorisation holders relating to supply

7.—(1) The provisions of section 52 of the Act shall not apply to the supply (in circumstances corresponding to 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) the supply is free of charge and takes place at premises which are occupied by him and under his control at all times when the premises are open for business and which are capable of being secured so as to exclude the public,
 - (b) each veterinary drug supplied is in the container in which it was made up for supply by the manufacturer or assembler and 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 supply is not by self-service methods,
 - (d) if the product is not a horse wormer the supply is to a person who the authorisation holder 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 supply is to a person who the authorisation holder 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 a sheep dip of any type, not intended for export, the supply is to a person who the authorisation holder 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 supply,
 - (g) if the product is an organophosphorus sheep dip, not intended for export, the supply is effected together with the provision to the recipient of—

- (i) a double side laminated notice meeting the specification set out in the Schedule to this Order (unless the notice has been provided to the recipient within the previous twelve months and the authorisation holder knows or has reasonable cause to believe that the recipient still has it available for use), and
- (ii) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described, and

(h) the authorisation holder complies with the requirements as to records specified in article 8;

and in this paragraph “premises” includes a stall of a permanent nature at a market or agricultural showground.”.

(4) In article 8(1) (records) after the word “applies” then shall be inserted the words “and which are intended for administration to animals whose flesh or products are intended for human consumption”.

(5) At the end of the Order there shall be added the Schedule set out in the Schedule to this Order.

20th September 2000

Hayman
Minister of State, Ministry of Agriculture,
Fisheries and Food

Signed by authority of the Secretary of State for Health

29th September 2000

Hunt
Minister of State,
Department of Health

25th September 2000

Bairbre de Brún
Minister of Health, Social Services and Public
Safety

25th September 2000

Brid Rodgers
Minister of Agriculture and Rural Development

Status: This is the original version (as it was originally made).

SCHEDULE

Article 2 (5)

**Schedule to be added to the Medicines (Exemptions
for Merchants in Veterinary Drugs) Order 1988**

“SCHEDULE

Articles 6 (3) and 7 (2)

Specification of notice on double sided laminated sheet

1. The notice shall be at least 29.8cm x 21cm with a laminated transparent cover, coloured and printed to scale on front and back substantially (subject to paragraph 2 below) in accordance with the following two diagrams:

SHEEP DIPPING

PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY

1. The product label carries important advice. Please read it and do what it says.
2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.
3. Always wash protective clothing before taking it off.
4. If you get sheep dip on your skin wash it off immediately.
5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the AMTRA qualified person.
6. Read the label for instructions on measuring and diluting concentrate.
7. Check that you have spare protective clothing, especially gloves, in case of damage.

Status: This is the original version (as it was originally made).

A well designed sheep dip, with splash screens to limit contamination, reduces the risks, makes the job easier and makes wearing protective clothing more practical.

Everyone doing the job must be adequately trained. If they are not absolutely sure how to dip safely consider a training course.

The recommended protective clothing is:



Face Shield (when handling dip concentrate)

Bib apron (over boiler suit) or waterproof coat (PVC or nitrile)

Gloves (Non-lined, PVC or nitrile, heavy duty gauntlet style - 0.5 mm thick and at least 300 mm long)

Waterproof leggings/trousers (PVC or nitrile)

Wellington boots

For more information you are recommended to read the Government's leaflet 'Sheep dipping' (A529rev2).

2. The notice may be in Welsh when provided in Wales.”

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends articles 6 and 7 of the Medicines (Exemption for Merchants in Veterinary Drugs) Order 1998. It provides for gloves and laminated sheets with safety warnings to be supplied by agricultural merchants on any sale or supply of organophosphorus sheep dips. It takes away the right of marketing authorisation holders to sell veterinary medicines directly to users (though reserving their right to supply them free, subject to similar requirements in relation to such dips).

This Order also amends article 8 of the 1998 Order so as to provide that records of sales are to be kept only for products to which the 1998 Order applies which are intended for food-producing animals. Article 8 implemented Article 50b.2 of Council Directive [81/851/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products (OJNo. L317, 6.11.81, p.1), which sets out provisions for record keeping by retailers of those products, and this Order derogates from the 1998 Order to the extent authorised by Article 50b.3 of that Directive.

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, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.