STATUTORY INSTRUMENTS

2012 No. 2711

MEDICINES

The Veterinary Medicines (Amendment) Regulations 2012

Made - - - -	*26th October 2012*
Laid before Parliament	*2nd November 2012*
Coming into force - -	*1st December 2012*

The Secretary of State is a Minister designated(**a**) for the purposes of making Regulations under section 2(2) of the European Communities Act 1972(**b**) in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines (Amendment) Regulations 2012 and come into force on 1st December 2012.

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products

2. For paragraph 7 of Schedule 5 to the Veterinary Medicines Regulations 2011(**c**) substitute—

> **"Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products**
>
> **7.**—(1) For the purposes of Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**d**) the competent authority is the Secretary of State.
>
> (2) It is an offence to incorporate a veterinary medicinal product into a premixture or feedingstuffs, or to act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.
>
> (3) The conditions which govern approval of feed business establishments under Regulation (EC) No 183/2005 laying down requirements for feed hygiene(**e**) also govern approval of manufacturers and distributors under sub-paragraph (2).

(**a**) S.I. 1999/2027.
(**b**) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by section 3(3) of, and the Schedule to, the European Union (Amendment) Act 2008 (c. 7).
(**c**) S.I. 2011/2159.
(**d**) OJ No L 92, 7.4.1990, p. 42.
(**e**) OJ No L 35, 8.2.2005, p. 1, last amended by Commission Regulation (EU) No 225/2012 (OJ No L 77, 16.3.2012, p. 1).

(4) A manufacturer must ensure that, so far as is reasonably practicable, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.

(5) In the case of the refusal, suspension or revocation of an approval under this paragraph the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

(6) The provisions of this paragraph do not apply in relation to any person breeding or selling ornamental fish not intended for human consumption provided that the person does not use more than a total of 1kg of veterinary medicinal product annually for that purpose.".

Supply of a complementary feedingstuff

3.—(1) In paragraph 17(3) of Schedule 5 to the Veterinary Medicines Regulations 2011 for "my" substitute "may".

(2) After paragraph 17(3) of that Schedule insert—

"(3A) It is an offence for a manufacturer or distributor of a complementary feedingstuff to supply it to a person not specified in sub-paragraph (2) or (3).".

Sampling and analysis

4. In paragraph 22(1) of Schedule 5 to the Veterinary Medicines Regulations 2011 for "Council Directive 76/371/EEC (establishing Community methods of sampling for the official control of feedingstuffs)" substitute "Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(**a**)".

David Heath
Minister of State
Department for Environment, Food and Rural Affairs

26th October 2012

(**a**) OJ No L 54, 26.2.2009, p. 1, amended by Commission Regulation (EU) No 278/2012 (OJ No L 91, 29.3.2012. p. 8).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend Schedule 5 (medicated feedingstuffs and specified feed additives) to the Veterinary Medicines Regulations 2011 (S.I. 2011/2159) ("the 2011 Regulations").

Regulation 2 amends paragraph 7 of Schedule 5 to the 2011 Regulations to provide that manufacturers and distributors of feedingstuffs containing veterinary medicinal products must be approved (as required by Council Directive 90/167/EEC (OJ No L 92, 7.4.1990, p. 42)) in accordance with the conditions governing approval of feed business establishments under Regulation (EC) No 183/2005 (OJ No L 35, 8.2.2005, p. 1).

Regulation 3 makes it an offence to fail to comply with paragraph 17(2) and (3) of Schedule 5 to the 2011 Regulations.

Regulation 4 amends paragraph 22 of Schedule 5 to the 2011 Regulations to replace a reference to a repealed EU instrument, Council Directive 76/371/EEC (OJ No L 102, 15.4.1976, p. 1) with a reference to the current EU instrument, Commission Regulation (EC) No 152/2009 (OJ No L 54, 26.2.2009, p. 1).

A full impact assessment has not been produced for this instrument as no impact on the private, voluntary or public sectors is foreseen.

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