#### STATUTORY INSTRUMENTS

# 2014 No. 599

# **MEDICINES**

# The Veterinary Medicines (Amendment) Regulations 2014

Made - - - - 11th March 2014

Laid before Parliament 14th March 2014

Coming into force - - 14th April 2014

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

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c).

In accordance with section 56(1) of the Finance Act 1973(**d**), the Treasury consent to the making of these Regulations.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

## Title and commencement

**1.** These Regulations may be cited as the Veterinary Medicines (Amendment) Regulations 2014 and come into force on 14th April 2014.

# **Amendments of the Veterinary Medicines Regulations 2013**

**2.** The Veterinary Medicines Regulations 2013(e) are amended in accordance with Regulations 3 to 6.

### Amendment of Schedule 5

**3.**—(1) Schedule 5 (medicated feedingstuffs and specified feed additives) is amended as follows.

<sup>(</sup>a) S.I. 1999/2027.

**<sup>(</sup>b)** 1972 c. 68.

<sup>(</sup>c) OJ No L131, 1.2.2002, p. 1, last amended by Regulation EC No 596/2009, OJ No L188 18.7.2008, p, 14.

<sup>(</sup>d) 1973 c. 51.

<sup>(</sup>e) S.I. 2013/2033.

- (2) In paragraph 20 (writing the prescription) for sub-paragraph (3) substitute—
  - "(3) The person must prescribe a veterinary medicinal product authorised for incorporation in feedingstuffs but may, if there is no veterinary medicinal product authorised for a condition in a particular species—
    - (a) prescribe a veterinary medicinal product authorised for another species or for another condition in the same species, and
    - (b) prescribe more than one veterinary medicinal product,

provided all veterinary medicinal products prescribed are authorised for incorporation in feedingstuffs."

- (3) In paragraph 29 (import for incorporation into premixture or feedingstuffs for export) for sub-paragraph (1) substitute—
  - "(1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in another Member State or third country for the purposes of incorporating it into premixture or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product)".
- (4) In paragraph 31(q) (prescription writing offences) for the words "20(1) or (2)" substitute "20".

#### Amendment of Schedule 7

- **4.**—(1) Schedule 7 is amended as follows—
- (2) In Part 2 (fees relating to marketing authorisations) in paragraph 17 (application for a variation to a marketing authorisation dealt with under national or mutual recognition variation procedures) in paragraph (i) of the entry in the table relating to the change of route of administration or the addition of a new one, for the word "food-producing" substitute "non-food-producing".
- (3) In Part 6 (general) in paragraph 50 (wholesale dealer's import certificate) for "£1,320" substitute "£760".
  - (4) In Part 6 (general) for paragraph 51 (specific batch control) substitute—
    - "51. The fee for an authorisation to release a veterinary medicinal product under specific batch control is—
      - (a) £560; and
      - (b) £100 for each additional batch affected by the same issue where the specific batch control application is made at the same time.".

George Eustice
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

5th March 2014

We consent

Mark Lancaster
Stephen Crabb
Two of the Lords Commissioners of Her Majesty's Treasury

11th March 2014

## **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations correct errors in the Veterinary Medicines Regulations 2013 (S.I. 2013/2033). In Schedule 5 paragraph 20(3) failed to create an enforceable obligation and paragraph 29(1) contained incorrect cross references. In Schedule 7 paragraph 17 the word "non" was omitted, in paragraph 50 the figure £1,320 appeared instead of £720 and paragraph 51 failed correctly to express the fee for specific batch release.

No impact assessment has been prepared for this instrument as no impact, or no significant impact, on the private, voluntary or public sectors is foreseen.

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