STATUTORY INSTRUMENTS

2011 No. 2159

The Veterinary Medicines Regulations 2011

PART 5

Miscellaneous provisions, enforcement and offences

Review

45.—(1) Before the end of each review period, the Secretary of State must—

(a) carry out a review of these Regulations other than the fees provisions;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the EU instruments, or provisions of EU instruments, to which this regulation applies are implemented in other Member States.

(3) The EU instruments, and provisions of EU instruments, to which this regulation applies are—

Council Directive 90/167 laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005(**1**)

Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**2**);

Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**3**);

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, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(**1**) OJ L92, 7.4.1990, p. 42.
(**2**) OJ 228, 17.8.1991, p. 70.
(**3**) OJ L311, 28.11.2001, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ L188, 18.7.2009, p. 14).

Commission Regulation (EC) No 1234/2008(**4**);

Regulation (EC) No 470/2009 of the European Parliament and of the Council(**5**);

Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedingstuffs containing specified feed additives(**6**); and

Commission Regulation (EU) No 37/2010(**7**).

(4) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) In this regulation—

(a) "review period" means the period of five years beginning with the day on which these Regulations come into force, and, subject to paragraph (6), each successive period of five years thereafter; and

(b) "the fees provisions" means regulation 16 and Schedule 7.

(6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

(**4**) OJ L334, 12.12.2008, p. 7.
(**5**) OJ L152, 16.6.2009, p. 11.
(**6**) OJ L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).
(**7**) OJ L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.