EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2011 (S.I. 2011/2159).

Principal changes to the 2011 Regulations

The major change to the Regulations is the adjustment of the fees with a view to achieving full cost recovery while avoiding cross-subsidy of one activity by another.

In Great Britain food businesses will pay a much lower fee on application for approval but will pay a larger fee for any inspection. Premises will be selected for inspection on the basis of risk analysis.

The fees for appeals to the Veterinary Products Committee are simplified.

Criminal offences have also been amended. Instead of creating an individual offence in relation to every obligation there is now a single offence governing all relevant obligations in the body of the Regulations and a single offence in each of Schedules 1 to 5.

Other changes

Regulation 35 extends inspectors' power of seizure to cover anything they reasonably believe to be, or which purports to be, a veterinary medicine.

Veterinary practice premises must be registered with the Royal College of Veterinary Surgeons and paragraph 8 of Schedule 3 gives the Secretary of State a power to require the removal of premises from this register where they fail to meet the necessary standard.

The Regulations

The Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

They implement the following EU instruments that are Directives:

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governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005;

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

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

They provide for the enforcement of the following EU instruments that are Regulations besides that mentioned above:

(d) 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 (OJ No L 31, 1.2.2002 p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs

(e) Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (OJ No L 268, 18.10.2003 p. 29), in so far as it applies to veterinary medicinal products used in feedingstuffs;

(f) 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 (OJ NO L 191, 28.5.2004, p.1), in so far as it applies to veterinary medicinal products used in feedingstuffs;

(g) Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene (OJ No L 35, 8.2.2005, p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs; and

(h) Regulation (EC) No 470/2009 of the European Parliament and of the Council, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ No L152, 16.6.2009, p. 11).

They provide that a veterinary medicinal product must have a marketing authorisation granted by the Secretary of State before being placed on the market, and they make provision for the grant of a marketing authorisation (regulation 4 and Schedule 1).

They specify that a veterinary medicinal product must be manufactured by a person holding a manufacturing authorisation, and make provision for granting an authorisation (regulation 5 and Schedule 2).

They regulate the supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 7 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the rules of the "cascade" (regulation 8 and Schedule 4).

They control bringing a veterinary medicinal product into the United Kingdom (regulation 9) and advertising (regulation 10 to 12).

They control wholesale dealing (regulation 13 and Schedule 3).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 14 and Schedule 5).

They provide for exemptions (regulation 15 and Schedule 6).

They provide for fees (regulation 16 and Schedule 7).

They require records to be kept (regulations 17 to 24).

They create an offence of importation, possession or supply of unauthorised veterinary medicinal products (regulation 43(q) to (s)).

They make provision for the existence of the Veterinary Products Committee (regulation 28). They make provision for an appeals procedure in the case of a refusal, etc., of a marketing authorisation (regulation 30).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 36 and 38 to 42) and create offences of obstructing a person acting in the execution of these Regulations (regulation 43(u)) and of failing to comply with an improvement notice (regulation 43(v)).

Under regulation 44 breach of the Regulations is an offence punishable—

(i) on summary conviction, by a fine not exceeding the statutory maximum or by imprisonment for a term not exceeding three months or both, or

(j) on conviction on indictment, by a fine or to imprisonment for a term not exceeding two years or both.

Regulation 46 requires the Secretary of State to review the operation and effect of these Regulations, other than regulation 16 and Schedule 7 (which relate to fees), and lay a report before Parliament within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

Regulation 47 revokes the Veterinary Medicines Regulations 2011.

A full impact assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note and a table showing fee changes, on www.vmd.defra.gov.uk at "Publications, Veterinary Medicines Regulations and Guidance". It is also published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013.