EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2005. They also amend the Medicines Act 1968, the Medicines Act 1971 and associated legislation so that they no longer apply to veterinary medicinal products.

Principal changes to the 2005 Regulations

The principal changes to the 2005 Regulations are as follows.

The Regulations re-introduce requirements for recording specific batches of veterinary medicinal products administered to food-producing animals (regulations 18 and 19).

They introduce provisions for the approval of a manufacturer of a veterinary medicine for administration under the cascade (Part 4 of Schedule 2).

They clarify the existing regulations in respect of retail supply by veterinary surgeons, pharmacists and suitably qualified persons (Part 1 of Schedule 3).

They re-introduce requirements in respect of labelling veterinary medicinal products at the time of retail supply to avoid essential safety warnings and other information being obscured (Schedule 3 paragraph 11).

They extend the requirement to hold a Certificate of Competence from those purchasing a product to those who are engaged in dipping sheep (Part 3 of Schedule 3).

They introduce a provision that the incorporation of veterinary medicinal products into feed for animals for domestic consumption or non-food animals no longer requires approval (Schedule 5 paragraph 6).

They change the way that fees are charged for a marketing authorisation to reflect more accurately the work involved in any individual application (Schedule 7).

The Regulations

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

They implement Directive 2001/82/EC of the European Parliament and of the Council on the Community Code relating to veterinary medicinal products (OJNo. L311, 28.11.2001, p. 1), as amended by Directive 2004/28/EC (OJ No. L136, 30.4.2004, p. 58).

They also identify the competent authority for, and provide for enforcement of, Regulations (EC) No. 178/2002 (OJ No. L31, 1.2.2002, p. 1), (EC) No. 1831/2003 (OJ No. L268, 18.10.2003, p. 29), (EC) No. 882/2004 (corrected version at OJ No. L191, 28.5.2004, p. 1) and (EC) No. 183/2005 (OJ No. L35, 8.2.2005, p. 1), in so far as they apply to veterinary medicinal products used in feedingstuffs, and to the following additives used in feedingstuffs:

(a) coccidiostats;

(b) histomonostats;

(c) all other zootechnical additives except—

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

(iii) substances incorporated with the intention of favourably affecting the environment.

In addition they implement Council Directive 90/167 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ No. L92, 7.4.90, p. 42) so far as they are not rendered spent by Regulation (EC) No. 183/2005.

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 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 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 "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).

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 offences of importation, possession and supply of unauthorised veterinary medicinal products (regulations 25 to 27).

They make provision for the existence of the Veterinary Products Committee (regulation 28). They make provision for a representations procedure in the case of a refusal, etc., of a marketing authorisation (regulation 29).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 41).

Under regulation 42 breach of the Regulations is an offence punishable—

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

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

A Regulatory 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.gov.uk at "Publications, Veterinary Medicines Regulations and Guidance, new legislative developments".

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Veterinary Medicines Regulations 2006. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 8 Pt. 2 para. 12 revoked by S.I. 2022/90 Sch.
- Sch. 9 Pt. 1 para. 6 and heading revoked by S.I. 2012/3039 reg. 36