EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2006.

Principal changes to the 2006 Regulations

The new Regulations introduce a requirement for the registration of veterinary premises for the supply of veterinary medicinal products.

They implement Commission Directive 2006/130/EC and enforce Commission Regulation (EC) No 1950/2006.

They permit the advertising of POM-V medicines to veterinary nurses.

They extend the provision that the holder of a Marketing Authorisation for an immunological product must submit to the Secretary of State the results of all tests carried out on each batch of the product before he places the product on the market, to require that the holder must wait for confirmation from the Secretary of State before the product is placed on the market.

They control exports to other member States.

They update fees.

The Regulations

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

They implement Directive 2001/82/EC.

They enforce Regulations (EC) No. 178/2002, No. 1831/2003, No. 882/2004, No. 183/2005, in so far as they apply to veterinary medicinal products used in feedingstuffs, and to some specified feed additives used in feedingstuffs.

They implement Council Directive 90/167 so far it is not superseded by Regulation (EC) No. 183/2005.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 an appeals 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”.