EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 1998 (S.I. 1998/2428) as amended by the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000 (S.I. 2000/2250) and the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2001 (S.I. 2001/1669) ("the principal Regulations"). The principal Regulations prescribe fees in connection with applications and inspections relating to:—

a) marketing authorisations under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S.I. 1994/3142);

b) licences and certificates granted under the Medicines Act 1968 in so far as they apply to medicinal products for animal use; and

c) the registration of homoeopathic veterinary medicinal products.

Regulation 2 prescribes new fees in relation to the provision of the principal Regulations set out in column (1) of the Schedule to these Regulations. The fees in the principal Regulations are set out in column (3) and the new fees prescribed by these Regulations in column (4) of the Schedule.

It also amends Part II and III of Schedule 3 (calculation of annual fees) to the principal Regulations by prescribing new fees and, where the fee is charged on a percentage of turnover, new percentage amounts.

The average level of fees payable under these Regulations is increased by 2.5% in comparison with the principal Regulations.

Regulation 3 provides that the Regulations, subject to the exceptions in regulation 3(2) and (3), apply to applications made after the Regulations come into force and do not affect annual fees relating to a calendar year earlier than 2000.

The fee structure relating to variations for national marketing authorisations has been restructured to reflect operational procedures (Part II of the Schedule).

A Regulatory Impact Assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies may be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3LS.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Medicines (Products for Animal Use—Fees) (Amendment No. 2) Regulations 2001. 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 :

– Regulations revoked by S.I. 2004/2750 reg. 18(e)