

SCHEDULE 7

FEES

PART 6

General

Testing samples

41. The fee for testing a sample required to be submitted by the Secretary of State is the full economic cost of the test.

Commencement Information

I1 Sch. 7 para. 41 in force at 1.10.2006, see [reg. 1](#)

Animal test certificates

42.—(1) The fee for an animal test certificate is £330 in the case of—

- (a) an immunological veterinary medicinal product that has been authorised in another member State for the species on which the proposed test will be conducted;
- (b) a pharmaceutical veterinary medicinal product which has been authorised in another member State for use with a food-producing species on which the proposed test will be conducted where the same or similar dosage regime and method of administration is to be used in the medicinal test as is authorised; or
- (c) a pharmaceutical veterinary medicinal product authorised in another member State for human or animal use where the test is to be conducted on non-food-producing animals only.

(2) In any other case the fee is £785.

(3) The fee for an application for a variation of the certificate is £255 for each change.

(4) The fee for an application to renew a certificate is £125.

Commencement Information

I2 Sch. 7 para. 42 in force at 1.10.2006, see [reg. 1](#)

Treatment under the cascade

43. The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product authorised in another member State for treatment under the cascade is £15.

Commencement Information

I3 Sch. 7 para. 43 in force at 1.10.2006, see [reg. 1](#)

Treatment in exceptional circumstances

44.—(1) The fee for a certificate to import (if necessary), be in possession of and administer a veterinary medicinal product authorised in a third country is £30 for the initial certificate and £30 for its renewal (£15 for a renewal if the certificate is renewed on-line using the website of the Veterinary Medicines Directorate) payable in respect of each animal treated.

(2) In the case of administration to and treatment of a discrete group of animals, the Secretary of State may notify the applicant in writing that a fee for only one animal is payable.

Commencement Information

I4 Sch. 7 para. 44 in force at 1.10.2006, see [reg. 1](#)

Specific batch control

45. The fee for an authorisation to release a veterinary medicinal product under specific batch control is £535.

Commencement Information

I5 Sch. 7 para. 45 in force at 1.10.2006, see [reg. 1](#)

Submission of control tests of an immunological product

46. The fee for the submission of the results of tests carried out on a batch of immunological products prior to release is £80.

Commencement Information

I6 Sch. 7 para. 46 in force at 1.10.2006, see [reg. 1](#)

Export certificates

47. The fee for an application for an export certificate is £30, and £15 for each certified copy.

Commencement Information

I7 Sch. 7 para. 47 in force at 1.10.2006, see [reg. 1](#)

Fees relating to premises for supply by suitably qualified persons

48.—(1) The fee to approve premises for the retail supply of veterinary medicinal products by suitably qualified persons is—

- (a) £245, or
- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £135.

(2) The subsequent annual fee is—

- (a) £175, or £205 if the fee is not paid within 60 days of the invoice, or

- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £90, or £110 if the fee is not paid within 60 days of the invoice.

Commencement Information

18 Sch. 7 para. 48 in force at 1.10.2006, see [reg. 1](#)

Application to the Veterinary Products Committee

49.—(1) If the Secretary of State refuses to grant a marketing authorisation or an animal test certificate, or grants one that is different from what was applied for, the fee for making representations to the Veterinary Products Committee is in accordance with the following table.

Application to the Veterinary Products Committee: authorisations and animal test certificates

<i>Type of application</i>	<i>Fee (£)</i>
Application involving a new active substance:	1,865
Standard application:	495
Application for a pharmacologically equivalent product:	495
Application using identical data:	195
Application for an animal test certificate:	650

(2) If the holder of a marketing authorisation applies for a variation and the Secretary of State refuses it, the fee for making representations to the Veterinary Products Committee is in accordance with the following table—

Application to the Veterinary Products Committee: variations

<i>Type of application</i>	<i>Fee (£)</i>
Type 1A variation:	195
Type 1B variation:	195
Type II variation:	260

Commencement Information

19 Sch. 7 para. 49 in force at 1.10.2006, see [reg. 1](#)

Non-payment of fees

50. Where fees (other than fees relating to a manufacturing authorisation or wholesale dealer's authorisation) are not paid, the Secretary of State may, after giving one month's written warning, suspend the authorisation to which the fee relates.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, PART 6. (See end of Document for details)

Commencement Information

I10 Sch. 7 para. 50 in force at 1.10.2006, see [reg. 1](#)

Waiver or reduction of fees

51.—(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market he may waive or reduce any fees payable under these Regulations.

(2) An applicant or the holder of a marketing authorisation must provide full written justification for any waiver or reduction.

Commencement Information

I11 Sch. 7 para. 51 in force at 1.10.2006, see [reg. 1](#)

Reduction of application fee

52.—(1) Where an application for a marketing authorisation is withdrawn before determination, or refused on the grounds that data requested by the Secretary of State have not been supplied within the time limit specified in the request, the applicant may request a refund of a proportion of the fee (or, if the fee has not yet been paid, a reduction of the fee) in accordance with this paragraph.

(2) The request for a reduced fee must be made in writing within two months of the withdrawal of the application, or of the date of notification of a refusal.

(3) No reduction is payable if the application is withdrawn after all the data have been fully assessed, or if the application has been referred to the Veterinary Products Committee.

Reduction in fees where an application is withdrawn

<i>Stage at which application is withdrawn</i>	<i>Percentage reduction or refund</i>
The assessment (veterinary, scientific or pharmaceutical) has not yet begun:	90%
The assessment has begun but the Secretary of State has not yet requested further data:	50%
The Secretary of State has requested further information but it has not yet been provided:	25%
The Secretary of State has been supplied with further information requested but has not yet fully assessed it, or the application has not been referred to the Veterinary Products Committee:	10%

Commencement Information

I12 Sch. 7 para. 52 in force at 1.10.2006, see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, PART 6.