

SCHEDULE 7

Fees

PART 7

General

Annual fees for marketing authorisations

39.—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation shall provide her with a statement of his turnover for the previous calendar year; and, if specified in the demand, an audit certificate relating to the turnover.

(2) When he provides the statement of his turnover he shall pay an annual fee, rounded up to the next £10, of—

$$\frac{£0.67T}{100} + £215n$$

where T is the annual turnover in the previous calendar year and n is the number of active marketing authorisations held at any time during the previous calendar year.

(3) In the case of an authorisation holder with a turnover relating to all marketing authorisations held of less than £215,000, the amount, rounded up to the next £10, is—

$$\frac{£0.67T}{100} + £55n$$

where T is the annual turnover in the previous calendar year and n is the number of active marketing authorisations held at any time during the previous calendar year.

(4) In this paragraph—

“turnover” means the gross value at manufacturer’s prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom.

“manufacturers’ prices” means the prices charged for authorised products by manufacturers to wholesalers, except to the extent that—

- (a) the products are supplied by manufacturers direct to retailers, in which case it means the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the Secretary of State, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products;
- (b) a marketing authorisation holder sells or supplies products which he has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by him for those products.

Auditor’s certificate

40.—(1) If the Secretary of State required an audit certificate when she sent out the demand for the statement of turnover, and the holder of the marketing authorisation has not provided it within 30 days, an additional fee is payable for that year of £10,500 plus an additional £2,100 in respect of each marketing authorisation held.

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(2) If the Secretary of State is not satisfied that the audit certificate provides sufficient assurance that the figures fairly present the financial records of the company, she shall require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances she needs; and if this is not provided within those 30 days the additional fee specified in sub-paragraph (1) is payable.

(3) Nothing in this paragraph limits the powers of an inspector to examine financial records.

Late payment of annual fees

41.—(1) Where a person fails to pay the annual fee for a marketing authorisation within 30 days from and including the date of the demand, he must pay an additional fee of—

- (a) where payment is received after 30 but before 60 days have expired from and including the due date, 1% of the annual fee;
- (b) where payment is received after 60 but before 90 days have expired from and including the due date, 2% of the annual fee; and
- (c) where payment has not been received after the expiry of 90 days, 5% of the annual fee,

rounded up to the nearest £10.

(2) Where a marketing authorisation holder has not provided the Secretary of State with a statement of his annual turnover so that the annual fee cannot be determined before the due date, he may make a payment of an amount on account of the annual fee, in which case the additional fee is calculated on the difference between the amount paid on account and the actual amount due.

Submission of samples in connection with applications for marketing authorisations and animal test certificates

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

Animal Test Certificates

43.—(1) The fee for an animal test certificate is £320 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 non-immunological veterinary medicinal product which has been authorised in a 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 non-immunological veterinary medicinal product authorised in another member State for human or animal use where the test is to be conducted on companion animals only.

(2) In any other case the fee is £765.

(3) The fee for an application for a variation of the certificate is £250 for each change.

(4) The fee for an application to renew a certificate is £120.

Treatment under the cascade

44. 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.

Treatment in exceptional circumstances

45.—(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 decide in writing that a fee for only one animal is payable.

Specific batch control

46. The fee for an authorisation to release a veterinary medicinal product under specific batch control is £520.

Submission of control tests of an immunological product

47.—(1) The fee for the submission of the results of tests carried out on a batch of immunological products prior to release is £75.

(2) As a transitional measure, no fee is payable in relation to results submitted before 1st April 2006.

Export Certificates

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

Fees relating to premises for supply by suitably qualified persons

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

- (a) £232, or
- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £127.

(2) The subsequent annual fee is—

- (a) £165, or £197 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, £88, or £107 if the fee is not paid within 60 days of the invoice.

Application to the Veterinary Products Committee

50. —If the Secretary of State refuses to grant a marketing authorisation or an animal test certificate, or grants one that is different from the authorisation applied for in accordance with regulation 29(1)(a) or (b), and the applicant gives notice that he wishes to make representations to the Veterinary Products Committee, the fee is in accordance with the following table—

Application to the Veterinary Products Committee

<i>Type of application</i>	<i>Fee(£)</i>
Application for a new active substance	1,820
Complex application	1,050

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<i>Type of application</i>	<i>Fee(£)</i>
Standard application	485
Application for a pharmacologically equivalent product	485
Application using identical data	190
Application for an animal test certificate	635

Non-payment of fees

51. 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.

Waiver or reduction of fees

52.—(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 she 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.

Reduction of fees when an application is withdrawn

53.—(1) Where an application for a marketing authorisation is withdrawn before determination, the Secretary of State shall refund a proportion of the fee in accordance with this paragraph.

(2) Where no payment has been made, the applicant may apply reductions of the fee otherwise payable in connection with that application in accordance with this paragraph.

(3) The request for a reduced fee must be made in writing within two months of the withdrawal of the application, or a refusal of the application on the grounds that data that she has requested have not been supplied within the specified time limit.

(4) If no assessment (veterinary, scientific or pharmaceutical) has begun, the refund or reduction is 90%.

(5) If assessment has begun but the Secretary of State has not yet requested further data, the refund or reduction is 50%.

(6) If the Secretary of State has requested further information but it has not yet been provided, the refund or reduction is 25%.

(7) If the further information requested has been supplied but has not yet been fully assessed or the application has not been referred to the Veterinary Products Committee, the refund or reduction is 10%.

(8) Once the further information has been fully assessed, or the application has been referred to the Veterinary Products Committee, no reduction is made.