SCHEDULE 7 Regulation 16

Fees

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Explanatory Note

PART 1

Introduction

Payment of fees

1. All fees under this Schedule are payable to the Secretary of State.

Time of payment

2. All fees are payable on invoice unless otherwise specified.

Multiple inspections

3. If a site is inspected for more than one type of authorisation, only one fee (the highest) is payable.

PART 2

Fees relating to national marketing authorisations

Scope of Part 2

4. This Part has effect in relation to marketing authorisations which are confined to the United Kingdom and where there is not, or has not been, an application using the decentralised or mutual recognition procedures.

Standard application for a marketing authorisation

5. The fee for an application (referred to in this Schedule as a "standard application") for a marketing authorisation that does not fall into any of the following categories in this Part is £6,390.

Application for a marketing authorisation for a product with an active substance not contained in a veterinary medicinal product previously authorised in the United Kingdom

6.—(1) The fee for an application for a marketing authorisation for a veterinary medicinal product that contains an active substance which has not previously been included in an authorised veterinary medicinal product in the United Kingdom is £25,500.

(2) This is referred to in this Schedule as an "application for a new active substance".

(3) If additional applications are submitted at the same time for different strengths of the same active substance in the same dosage form, the fee for each additional strength is £6,390.

(4) If an additional application is submitted at the same time for another dosage form the fee for that additional dosage form is £14,795 and the fee for additional applications for the same dosage form is £ 6,390.

(5) The fee for immunological products submitted at the same time with lesser combination of antigens is £6,390 for each application.

Application for a marketing authorisation involving other aspects not previously authorised in a veterinary medicinal product in the UK

7.—(1) The fee for an application for a marketing authorisation where all the active substances of the veterinary medicinal product have previously been included in a veterinary medicinal product authorised in the United Kingdom but which has an element within the application and supporting data that has not previously been successfully assessed in relation to any of the active substances is £14,795.

(2) This is referred to in this Schedule as a "complex application".

(3) Examples of applications covered by sub-paragraph (1) are the following relating to any of the active substances—

(a) a different target species;

(b) a different indication for the target species;

(c) a different route of administration;

(d) a different adjuvant or excipient;

(e) a different method of sterilisation, synthesis or manufacture;

(f) the product has a controlled release preparation which is new for that active substance;

(g) in the case of an immunological product, the product uses a different growth medium;

(h) the active substance in the product is manufactured by a different manufacturer;

(i) the active substance is in a different dosage form.

(4) If additional applications are submitted at the same time for different strengths of the same active ingredient in the same dosage form, the fee for each additional strength is £6,390.

Pharmacologically equivalent products

8.—(1) The fee for an application for a marketing authorisation for a product that is pharmacologically equivalent to a product authorised in the United Kingdom is £4,995.

(2) This is referred to in this Schedule as an "application for a pharmacologically equivalent product".

(3) The fee for such an application where the reference product is authorised within the European Union but not within the United Kingdom is £6,390 plus any translation costs.

Application for a marketing authorisation using identical data

9. The fee for an application for a marketing authorisation that uses existing data relating to an authorised product and where the new product is identical in all respects (other than the name) to an existing product (referred to in this Schedule as an "application using identical data") is £1,785.

Application for a provisional marketing authorisation

10.—(1) The fee for an application for a provisional marketing authorisation for a new active substance is £14,795, and the fee for its conversion into a full marketing authorisation is—

(a) £10,705 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or

(b) in any other case £25,500.

(2) The fee for a complex application for a provisional marketing authorisation is £6,390, and the fee for its conversion into a full marketing authorisation is—

(a) £8,405 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or

(b) in any other case £14,795.

Application for a marketing authorisation relating to a parallel import

11.—(1) The fee for a marketing authorisation for a product imported in accordance with paragraph 13 of Schedule 1 (parallel imports) is £2000 for each member State from which a product is to be imported plus any translation costs.

(2) If the imported product has been authorised in accordance with the Mutual Recognition Procedure or Decentralised Procedure, and the United Kingdom is included within these procedures, the fee is £1650 for one member State on the application plus £330 for each additional member State on the application.

Application for a variation

12.—(1) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change) and the appropriate fee is payable for each application.

(2) The fee for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003 is the same as the fee for an application for a marketing authorisation for that product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £330 for a variation specified as Type 1A in that Annex.

(4) If the variation is specified as Type 1B in that Annex, the fee is £770 except in the following case—

Reductions to Type 1B fees

Variation	*Conditions*	*Fee*
Identical changes to a number of products	All the products are from the same marketing authorisation holder Supporting data are identical All applications are submitted at the same time	The fee for the first product is £770 and the fee for each subsequent product is £330

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No. 1084/2003 is £2,540 except in the following cases, where the fee is as specified:

Reductions to Type II fees

Change	*Conditions*	*Fee*
a) Identical changes to a number of products.	— All the products are from the same Marketing Authorisation holder. — Supporting data are identical. — All applications are submitted at the same time	The fee for the first product is £2540, and the fee for each subsequent product is £330

Change	*Conditions*	*Fee*
b) Change of Distributor.	– No other aspect of the dossier is changed and the marketing authorisation holder remains the same.	£770
c) Change of legal entity of marketing authorisation holder.	– No other aspect of the dossier is changed.	£770
d) Simple dosage instruction changes intended to remove ambiguity.	— The change is not as a result of safety concerns. — No new studies are required to support the change. — The dosage regime remains the same.	£770
e) Addition or change to safety warnings.	— No other aspects of the dossier are changed. — No safety warnings are removed. — No new studies are required to support the change and the proposed warnings serve to increase the protection of the user/ environment /target species as appropriate.	£770
f) Corrections or simple text lay out changes to Summary of Product Characteristics and/or product literature. Included in this is the introduction of multilingual labelling.	— The changes are not a result of safety concerns. — No new studies are required to support the change and no other aspect of the dossier is changed. — The legibility of the current English labelling is not compromised. — The indications and warnings are the same in all languages	£770
g) Abbreviated resubmission of a previously refused Type II variation	— At the time of refusal of a Type II variation, the Secretary of State has given written permission for resubmission under this category. — The application has been resubmitted within 3 months of the date the refusal advice was issued	£770
h) Submission made following the formal advice of the Secretary of State	— The Secretary of State has already assessed the relevant data and formed an opinion on these.	£770

Change	*Conditions*	*Fee*
	— The change is not required as a result of the holder failing to keep the Part II (quality) data in accord with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**1**).	
i) Approval of a mock-up for an authorised pack size.	— The pack size is already authorised. — No new studies are required to support the change and no other aspect of the dossier is changed.	£770
j) Changes to the Summary of Product Characteristics and product literature of a Marketing Authorisation for Parallel Import as a direct consequence of the approval of a variation to the Summary of Product Characteristics and product literature for the UK authorised product.	– The only changes to the Summary of Product Characteristics and product literature are those required to bring the Marketing Authorisation for Parallel Import back in direct line with those of the UK authorised product.	£770

Application for the renewal of a marketing authorisation

13.—(1) The fee for the renewal of a marketing authorisation issued after these Regulations come into force is £1,275.

(2) In the case of a marketing authorisation issued before these Regulations come into force—

(a) if it is the first time the marketing authorisation has been renewed the fee is £1,275; and otherwise £290;

(b) if further assessment of post authorisation commitments is required the fee is £1,275.

(3) The fee for the first reassessment of a provisional marketing authorisation is £290, and the fee for each subsequent reassessment is £1,275.

Registration of a homoeopathic veterinary medicinal product

14. The fee for an application for the registration of a homoeopathic veterinary medicinal product is in accordance with the following table:

(**1**) The Committee was established by Article 30 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L136, 30.4.2004, p. 1.

Fee for the registration of a homoeopathic veterinary medicinal product

Type of application	*Fee(£)*
If all stocks and the formulation have already been assessed by the Secretary of State—	
– not more than 5 stocks	150
– more than 5 stocks	350
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed—	
– not more than 5 stocks	430
– more than 5 stocks	625
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	
– not more than 5 stocks	710
– more than 5 stocks	920
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom or in another member State—	
– not more than five stocks	150
– more than five stocks	350

PART 3

Fees relating to decentralised and mutual recognition procedures

Scope of Part 3

15. This Part has effect in relation to marketing authorisations applied for or obtained using the decentralised procedure or the mutual recognition procedure.

Provision of information relating to the recognition of United Kingdom marketing authorisation

16.—(1) Where an application is made for the Secretary of State to provide information to other member States to enable them to recognise a marketing authorisation already granted by the United Kingdom the following fees are payable.

(2) Where the application to provide information to another member State is received within six months of the original grant of the marketing authorisation, or where the Secretary of State has already provided the information to a member State, and a further application is made for her to

provide the information to an additional member State within six months of the date she last provided the information—

(a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £2,290;

(b) if the product is an immunological veterinary medicinal product the fee is £2,000;

(c) in any other case the fee is £1,775.

(3) In any other case —

(a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £9,860;

(b) if the product is an immunological veterinary medicinal product the fee is £8,385;

(c) in any other case the fee is £6,905.

(4) The fees include the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

Mutual recognition of a marketing authorisation already granted in another member State

17.—(1) A fee for the recognition by the Secretary of State of a marketing authorisation already granted in another member State is as follows—

Fee for mutual recognition

Type of application	*Fee(£)*
Standard application	4,225
Application for a new active substance	14,070
Complex application	8,445
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	3,305
Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom	4,225 plus any translation costs
Application using identical data	1,120

Decentralised procedure where the United Kingdom is the reference member State

18.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is the reference member State—

Fee for the decentralised procedure where the United Kingdom is the reference member State

Type of application	*Fee(£)*
Standard application	10,400
Application for a new active substance	29,510
Complex application	18,800

Type of application	*Fee(£)*
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	9,000
Application for a pharmacologically equivalent product where reference product is not authorised in the United Kingdom	10,400 plus any translation costs
Application using identical data	4,075

(2) In each case the fee includes the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

Decentralised procedure where the United Kingdom is not the reference member State

19.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is not the reference member State—

Fee for the decentralised procedure where the United Kingdom is not the reference member State

Type of application	*Fee(£)*
Standard application	4,225
Application for a new active substance	14,070
Complex application	8,445
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	3,305
Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom	4,225 plus any translation costs
Application using identical data	1,680

Application for a variation

20.—(1) In this paragraph the types of variation are those specified in Commission Regulation (EC) 1084/2003.

(2) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change) and the appropriate fee is payable for each application.

(3) If an applicant applies for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003—

(a) if the applicant applies for a United Kingdom marketing authorisation the fee is the same as the fee for the application for a national marketing authorisation, plus any fees payable for any mutual recognition procedure; or

(b) if the applicant uses the decentralised procedure, the fee is the same as the fee for a marketing authorisation using the decentralised procedure.

(4) Other fees are in accordance with the following table—

Variations

Type of variation	*RMS Fee(£)*	*CMS Fee(£)*
Type II variation	10,125	2,540
If a marketing authorisation holder applies for a Type II variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time		
the fee payable is		
— for the first variation	10,125	2,540
— for each subsequent variation	1,675	330
If a marketing authorisation holder— — applies for a Type II variation to correct the Summary of Product Characteristics or product literature or where variations are required for simple text lay out changes — the change is not a result of safety concerns — no new studies are required to support the change — no other aspects of the dossier are changed.		
the fee payable is	2,705	355
Type 1A variation	1,675	330
Type 1B variation	2,705	355
If a marketing authorisation holder applies for a Type 1B variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time		
the fee payable is		
— for the first variation	2,705	355

Type of variation	*RMS Fee(£)*	*CMS Fee(£)*
— for each subsequent variation	1,675	330

Note: the RMS fee is payable when the United Kingdom acts as the reference member State and the CMS fee is payable when the United Kingdom acts as the concerned member State.

Application for the renewal of a marketing authorisation

21.—(1) The fee for the renewal of a marketing authorisation granted in more than one member State is —

(a) £1,720 if the United Kingdom is the reference member State, and

(b) £1,145 where the United Kingdom is a concerned member State.

PART 4

Fees payable by manufacturers

Application for a manufacturing authorisation

22. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is £2,595.

Application for a variation of a manufacturing authorisation

23. The fee for an application to vary a manufacturing authorisation is £465 where the variation requires scientific or pharmaceutical assessment, and £160 where it does not.

Application for an authorisation to manufacture an autogenous vaccine

24.—(1) An application for a standard authorisation to manufacture an autogenous vaccine is £2,960 for each manufacturing site, with the same fee for each subsequent inspection.

(2) In the case of an application for an individual authorisation to manufacture a single batch of autogenous vaccine, the fee is £1,480.

(3) The fee to vary an authorisation is £280 if no further inspection is required, and otherwise is the full application fee.

Annual fees

25.—(1) An annual fee of £240 is payable in respect of each manufacturing authorisation (other than a manufacturing authorisation in relation to an autogenous vaccine) held.

(2) The annual fee for a manufacturing authorisation for an autogenous vaccine is 0.67% of the turnover in the previous calendar year rounded up to the next £1, with a minimum fee of £10, and in this paragraph "turnover" has the meaning assigned in paragraph 39.

Site inspections – type of site

26. For the purposes of deciding the fee for a site inspection—

"super site" is a site at which 250 or more relevant persons are employed;

"major site" is a site at which 60 or more, but fewer than 250, relevant persons are employed;

"standard site" is a site at which 10 or more, but fewer than 60 relevant persons are employed;

"minor site" is a site at which fewer than 10 relevant persons are employed;

"relevant person" means a person employed on the premises and systems inspected.

Inspection of a site where immunological veterinary medicinal products are manufactured

27. The following fees are payable for the inspection of a site where immunological veterinary medicinal products are manufactured—

Sites where immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site	24,015
Major site	16,900
Standard site	5,435
Minor site	4,745

Inspection of a site where sterile veterinary medicinal products are manufactured

28. The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured—

Sites where sterile veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site	17,685
Major site	9,775
Standard site	4,805
Minor site	3,215

Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured

29. The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured—

Site where no immunological or sterile veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site	10,660
Major site	5,610
Standard site	4,025
Minor site	2,170

Inspection of a site where veterinary medicinal products are assembled

30. The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container—

Site where medicinal products are assembled

Type of site	*Fee (£)*
Super site	7,750
Major site	5,235
Standard site	2,570
Minor site	1,325

Test sites

31. The fee for the inspection of a test site is £2,665.

Animal blood bank authorisations

32.—(1) The fee for an authorisation to operate a blood bank is £2,960, with the same fee for each subsequent inspection.

(2) The fee for a variation is £280.

Expenses

33. In addition the travel and subsistence costs of the inspectors, and any additional costs reasonably incurred by them (including, in the case of an inspection outside the United Kingdom, interpreters' fees) are payable.

PART 5

Fees relating to a wholesale dealer's authorisation

Application for a wholesale dealer's authorisation

34.—(1) The fee for an application for a wholesale dealer's authorisation is —

(a) £1,510, or;

(b) £620 if the application is accompanied by an estimate that the first year's turnover will be less than £40,000.

(2) If the applicant paid a fee of £620, he shall send a declaration of his turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £40,000 he shall pay the balance of £890 within 30 days.

(3) If the applicant paid £1,510 but his turnover for the first year of trading was lower than £40,000, if he sends a declaration certifying the turnover, the Secretary of State shall refund the excess.

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

(5) For the purposes of this paragraph, "turnover" has the same meaning as paragraph 36.

Variation of a wholesale dealer's authorisation

35. The fee for an application to vary a wholesale dealer's authorisation is—

(a) £465 if the variation requires scientific or pharmaceutical assessment;

(b) otherwise £160.

Annual fee for a wholesale dealer's authorisation

36.—(1) The annual fee for a wholesale dealer's authorisation is—

(a) £485, or,

(b) £240 if the holder certifies when making the payment that his turnover for that year was less than £40,000.

payable on the anniversary of the grant of the authorisation.

(2) For the purposes of this regulation, "turnover" means the gross value of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom during the previous year.

PART 6

Fees relating to feedingstuffs

Fees relating to feedingstuffs

37.—(1) The following fees are payable in relation to feedingstuffs—

Fees relating to feedingstuffs

Application and inspection	*Fee payable in Great Britain* £	*Fee payable in Northern Ireland* £
Application for the approval of an establishment to manufacture a specified feed additive or a premixture using a specified feed additive, and the subsequent annual fee (in the case of premises that only manufacture specified feed additives and already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs, no fee is payable).	866	466
Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives directly, premixtures using veterinary medicinal product or feedingstuffs using veterinary medicinal product	546	368

Application and inspection	*Fee payable in Great Britain* £	*Fee payable in Northern Ireland* £
at any concentration, and the subsequent annual fee.		
Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be placed on the market, and the subsequent annual fee.	365	271
Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market, and the subsequent annual fee.	188	145
Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee.	135	111
Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee.	115	93

(2) Where more than one of the above activities is carried out at one premises, only one fee (the highest) is payable.

(3) This paragraph has effect on 1st January 2006.

Fees relating to distributors

38.—(1) The fee for an application or annual renewal to be a distributor of specified feed additives, veterinary medicinal products for incorporating into feedingstuffs, premixtures or feedingstuffs containing them is £128 in Great Britain and £59 in Northern Ireland.

(2) This paragraph has effect on 1st January 2006.

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.

(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

Type of application	*Fee(£)*
Application for a new active substance	1,820
Complex application	1,050
Standard application	485
Application for a pharmacologically equivalent product	485
Application using identical data	190

Type of application	*Fee(£)*
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.