SCHEDULE 7 Regulation 16

FEES

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PART 1

Introduction

Interpretation of Schedule 7

1. In this Schedule—

"national application" means an application for a marketing authorisation that does not involve another member State;

"pharmaceutical product" means any veterinary medicinal product other than an immunological product;

"simultaneous application" is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that—

(a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and

(b) in the case of a pharmaceutical product, they have different strengths of the active substance, and, in the case of an application involving more than one member State, the additional applications do not include a member State that was not included in the first application.

Payment of fees

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

Time of payment

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

Multiple inspections

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

Translation

5. All translation costs are charged additionally.

PART 2

Fees relating to marketing authorisations

Fees for specified pharmaceutical applications

6. The following table sets out the fees relating to a pharmaceutical veterinary medicinal product for—

(a) a national application for a marketing authorisation that is—

(i) a full application under Part 1 of Schedule 1;

(ii) a bibliographic application; or

(iii) an application based on pharmacological equivalence;

(b) an application for a marketing authorisation using the decentralised procedure where the United Kingdom is a concerned member State;

(c) an application for the mutual recognition of a product authorised in another member State.

Fees for specified pharmaceutical applications

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Base Fee: The following fees are in addition to the base fee—	910	1,800	1,800	2,320	460
Quality assessment (if quality data are assessed):	3,810	3,230	2,710	3,470	1,810
Safety assessment (if safety data are assessed):	3,810	3,030	1,030	1,330	1,810
Efficacy assessment (if efficacy data are assessed):	3,810	3,030	1,030	1,330	1,810
Ecotoxicology assessment (if ecotoxicology data are assessed):	640	520	320	410	390
Additional fee if any of the target species is a food-	3,740	3,420	2,070	2,650	1,350

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
producing animal (not payable if neither safety data nor ecotoxicology data are assessed):					
Reduced by—					
if no safety data are assessed:	2,100	2,100	1,290	1,650	640
if no ecotoxicology data are assessed:	990	760	290	370	290
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—					
food-producing animal:	7,170	6,330	5,610	7,200	2,520

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
non-food-producing animal:	6,260	5,620	5,360	6,870	2,200
Additional fee for each additional pack type:	720	720	590	740	330
Reduced by—					
if no quality data are assessed:	350	350	350	450	120
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	60	60	60	70	60
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee for each additional active ingredient (food-producing animal):	6,210	5,870	3,880	4,960	2,000

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Reduced by—					
if no quality data are assessed:	1,400	1,400	1,400	1,790	470
if no safety data are assessed:	2,630	2,630	1,580	2,020	820
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	700	580	—	—	230
Additional fee for each additional active ingredient (non-food-producing animal):	4,140	3,940	3,110	3,960	1,430
Reduced by—					
if no quality data are assessed:	1,400	1,400	1,400	1,790	470
if no safety	1,400	1,400	880	1,120	470

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
data are assessed:					
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee if there is more than one target species, for each additional species (food-producing animal):	3,820	3,430	2,330	2,980	1,240
Reduced by—					
if no quality data are assessed:	180	180	180	220	60
if no safety data are assessed:	1,400	1,400	880	1,120	470
if no efficacy data are assessed:	1,750	1,400	1,050	1,350	530

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
if no ecotoxicity data are assessed:	120	120	—	—	60
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	2,400	2,010	1,490	1,900	780
Reduced by—					
if no quality data are assessed:	180	180	180	220	60
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	1,750	1,400	1,050	1,350	530
if no ecotoxicity data are assessed:	60	60	—	—	60

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Additional fee for each additional recommended route of administration (food-producing animal):	2,590	2,390	1,560	1,980	910
Reduced by—					
if no safety data are assessed:	1,400	1,400	880	1,120	470
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee for each additional recommended route of administration (non- food-producing animal):	1,170	970	720	910	390
Reduced by—					

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	880	700	530	670	290
Simultaneous applications: fee for each additional product in the application:	2,780	2,780	2,780	3,560	1,610

Decentralised pharmaceutical application where the United Kingdom is the reference member State

7.—(1) The fee for a decentralised application for a pharmaceutical product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 6, with the addition of the fees in the following table.

Decentralised pharmaceutical application where the United Kingdom is the reference member State

Application	*Additional fee (£)*
Food-producing animal: one concerned member State:	3,560
Non-food-producing animal: one concerned member State:	3,100
Each additional concerned member State:	510

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

Application for a marketing authorisation for an immunological product

8.—(1) The fee for a national application for a marketing authorisation relating to an immunological product, a decentralised application where the United Kingdom is the concerned member State or the mutual recognition of a product authorised in another member State is in accordance with the following table.

Fees for specified immunological applications

Menu	*National application for a marketing authorisation (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
Base fee:	11,310	5,560
The following fees are in addition to the base fee—	7,100	2,390
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:		
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,300	640
More than one antigenic component—fee for each additional component:	1,290	390
More than one species—fee for each additional species:	5,170	1,550
More than one route of administration—fee for each additional route of administration:	5,170	1,550
Simultaneous application—fee for each additional product in the application:	2,780	1,610

(2) The fee for an application for a marketing authorisation for an immunological product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and which only contains antigens contained in the product already authorised is £10,020 (United Kingdom only) or £5,170 (decentralised application where the United Kingdom is a concerned member State).

Decentralised immunological application where the United Kingdom is the reference member State

9.—(1) The fee for a decentralised application for a marketing authorisation for an immunological product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 8(1), with the additions of £3,330 for one concerned member State and £510 for each additional concerned member State.

(2) In the case of a simultaneous application the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

Application for a marketing authorisation using identical data

10. The fee for an application for a marketing authorisation using identical data is in accordance with the following table.

Identical data

Application	*Fee (£)*
Any application other than decentralised where the United Kingdom is the reference member State:	910
Decentralised application where the United Kingdom is the reference member State—	
one concerned member State:	4,000
each additional concerned member State:	510

Application for a provisional marketing authorisation

11. The fee for an application for a provisional marketing authorisation is the same as that for a full national marketing authorisation in paragraph 6 (in the case of a pharmaceutical product) or the fee for a national application in paragraph 8 (in the case of an immunological product), and the fee for its conversion into a full marketing authorisation is—

(a) if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation—

(i) £8,130, or

(ii) if the application for the provisional marketing authorisation was made before 1st October 2006, £10,705; and

(b) in any other case the same fee as for the provisional marketing authorisation.

Application for a marketing authorisation relating to a parallel import

12. The fee for a marketing authorisation for a parallel import is in accordance with the following table.

Parallel imports

Application	*Fee (£)*
Application where the imported product has been authorised in accordance with the mutual recognition procedure or decentralised	

Application	*Fee (£)*
procedure, and the United Kingdom is included in these procedures—	
import from one member State:	1,690
each additional member State:	340
Any other application—fee for each member State from which the product is imported:	2,050

Application for a variation

13.—(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) As an exception from sub-paragraph (1), if an applicant applies for more than one variation to the quality data in a marketing authorisation on the same application form, he may elect to pay a total fee of £4,440; but this sub-paragraph does not apply—

(a) if one or more of the variations relates to a new source of an active substance and the applicant does not submit a Certificate of Suitability issued by the European Pharmacopeia relating to the new source, or

(b) if a significant formulation change is applied for that requires a new assessment of the safety or efficacy of the veterinary medicinal product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £440 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 £835 except in accordance with the following table.

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	First product 835 Each subsequent product 440

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No.1084/2003 is £2,220 except in the following cases, where the fee is as specified.

Reductions to Type II fees

Change	*Conditions*	*Fee (£)*
(a) (a) Identical changes to a number of products—	All the products are from the same marketing authorisation holder Supporting data are identical	First product 2,220 Each subsequent product 440

Change	*Conditions*	*Fee (£)*
	All applications are submitted at the same time	
(b) (b) Change of distributor—	No other aspect of the dossier is changed and the marketing authorisation holder remains the same	835
(c) (c) Change of legal entity of marketing authorisation holder—	No other aspect of the dossier is changed	835
(d) (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	835
(e) (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	835
(f) (f) Corrections or simple text layout 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	835
(g) (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	835

Change	*Conditions*	*Fee (£)*
	The application has been resubmitted within 3 months of the date the refusal advice was issued	
(h) (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 The change is not required as a result of the holder failing to keep the Part II (quality) data in accordance with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**1**)	835
(i) (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	835
(j) (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 United Kingdom 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 United Kingdom authorised product	835

Application for a variation to a marketing authorisation that has been issued in other member States

14.—(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).

(3) The fee is in accordance with the following table.

(**1**) The Committee was established by Article 30 of Regulation (EC) No. 762/2004 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. L 136, 30.4.2004, p. 1.

Variations

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
Type II variation:	8,990	2,220
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:	8,990	2,220
— for each subsequent variation:	1,555	440
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 layout 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:	2,455	475
Type 1A variation:	1,555	440
Type 1B variation:	2,455	475
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:	2,455	475

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
— for each subsequent variation:	1,555	440

Application for an extension to a marketing authorisation

15. The fee for an application for an extension to a marketing authorisation is in accordance with the following table.

Extension to a marketing authorisation

Extension	*Fee if the marketing authorisation is UK only (£)*	*Fee for a decentralised application where the United Kingdom is a concerned member State or the mutual recognition of an extension authorised in another member State (£)*
Change of strength or potency or the addition of a new strength or potency:	6,400	3,180
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,080	3,690
Change of route of administration, or the addition of a new one, of—	5,170	2,790
— an immunological product, or a pharmaceutical product for a non-food-producing animal:		
— a pharmaceutical product for a food-producing animal:	6,850	3,300
Change or addition of target species:	9,240	4,080
Change of active substance:	8,080	3,690
Other:	8,080	3,690
Simultaneous application —fee for each additional product in the application:	2,780	1,610

Decentralised application for an extension where the United Kingdom is the reference member State

16.—(1) The fee for a decentralised application for an extension where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 15, with the additions of the fees in the following table.

Decentralised application for an extension where the United Kingdom is the reference member State

Application	*Additional fee (£)*
Pharmaceutical product for a food-producing animal—one concerned member State:	3,560
Pharmaceutical product for a non-food-producing animal—one concerned member State:	3,100
Immunological product—one concerned member State:	3,300
Each additional concerned member State:	510

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

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

17.—(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 a valid 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 valid application is made for him to provide the information to an additional member State within six months of the date he last provided the information the fees are—

Type of application	*Fee (£)*
Pharmaceutical product for a food-producing animal—one member State:	2,345
Pharmaceutical product for a non-food-producing animal—one member State:	1,820
Immunological product—one member State:	2,050
Each additional member State:	510

(3) In any other case the fees are—

Type of application	*Fee (£)*
Pharmaceutical product for a food-producing animal—one member State:	10,105
Pharmaceutical product for a non-food-producing animal—one member State:	7,080

Type of application	*Fee (£)*
Immunological product—one member State:	8,595
Each additional member State:	510

(4) In the case of simultaneous applications, the above fees are payable for each additional product in the application for one member State, with a fee of £110 for each additional product for each additional member State.

Application for the renewal of a national marketing authorisation

18.—(1) The fee for the renewal of a national marketing authorisation originally granted on or after 30th October 2005 is £1,305.

(2) In the case of a marketing authorisation originally granted before 30th October 2005—

(a) if it is the first time the marketing authorisation has been renewed, or if the renewal entails assessment of post authorisation commitments the fee is £1,305, and

(b) otherwise £295.

(3) The fee for the first reassessment of a provisional marketing authorisation is £295, and the fee for each subsequent reassessment is £1,305.

Application for the renewal of a marketing authorisation granted in more than one member State

19. The fee for the renewal of a marketing authorisation granted in more than one member State is—

(a) £1,765 if the United Kingdom is the reference member State, and

(b) £1,175 where the United Kingdom is a concerned member State.

Registration of a homeopathic remedy

20. The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

Fee for the registration of a homeopathic remedy

Type of application	*Fee (£)*
If all stocks and the formulation have already been assessed by the Secretary of State— not more than five stocks:	155
more than five stocks:	360
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or 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 five stocks:	440
more than five stocks:	640

Type of application	*Fee (£)*
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	730
not more than five stocks:	
more than five stocks:	945
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—	155
not more than five stocks:	
more than five stocks:	360

Annual fees for marketing authorisations

21.—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation shall provide him 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—

$$£\frac{0.67T}{100} + £220n$$

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 £220,000, the amount, rounded up to the next £10, is—

$$£\frac{0.67T}{100} + £110n$$

where

T and *n* mean the same as in the preceding sub-paragraph.

(4) In this paragraph—

"turnover" means the gross value at manufacturers' 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

22.—(1) If the Secretary of State required an audit certificate when he 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 £10,765 plus an additional £2,155 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, he shall require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances he needs; and if these are 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

23.—(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, rounded up to the nearest £10, 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.

(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.

PART 3

Fees payable by manufacturers

Application for a manufacturing authorisation

24. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is £2,660.

Application for a variation of a manufacturing authorisation

25. The fee for an application to vary a manufacturing authorisation is £475 where the variation requires scientific or pharmaceutical assessment, and £165 where it does not.

Application for an authorisation to manufacture an autogenous vaccine or a product for administration under the cascade

26.—(1) The fee for an application for a standard authorisation to manufacture an autogenous vaccine or a veterinary medicinal product for administration under the cascade is £3,035 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, or a single batch of veterinary medicinal product for administration under the cascade the fee is £1,515.

(3) The fee to vary an authorisation is £285 if no further inspection is required, and otherwise is the full application fee.

Annual fees

27.—(1) An annual fee of £245 is payable in respect of each manufacturing authorisation held (other than a manufacturing authorisation in relation to an autogenous vaccine or a veterinary medicinal product for administration under the cascade).

(2) The annual fee for a manufacturing authorisation for an autogenous vaccine or a veterinary medicinal product for administration under the cascade 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 given in paragraph 21(4).

Site inspections—type of site

28. 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

29. The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

Sites where immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site:	24,615
Major site:	17,325
Standard site:	5,570
Minor site:	4,865

Inspection of a site where sterile veterinary medicinal products are manufactured

30. 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:	18,125
Major site:	10,020
Standard site:	4,925
Minor site:	3,295

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

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

Sites where no sterile or immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site:	10,925
Major site:	5,750
Standard site:	4,125
Minor site:	2,225

Inspection of a site where veterinary medicinal products are assembled

32. 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:	7,945
Major site:	5,365
Standard site:	2,635
Minor site:	1,360

Test sites

33. The fee for the inspection of a test site is £2,730.

Animal blood bank authorisations

34.—(1) The fee for an authorisation to operate a blood bank is £3,035, with the same fee for each subsequent inspection.

(2) The fee for a variation is £285.

Expenses

35. 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 4

Fees relating to a wholesale dealer's authorisation

Application for a wholesale dealer's authorisation

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

(a) £1,550; or

(b) £635 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 £635, 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 £915 within 30 days.

(3) If the applicant paid £1,550 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 in paragraph 38.

Variation of a wholesale dealer's authorisation

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

(a) £475 if the variation requires scientific or pharmaceutical assessment;

(b) otherwise £165.

Annual fee for a wholesale dealer's authorisation

38.—(1) The annual fee for a wholesale dealer's authorisation, payable on the anniversary of the grant of the authorisation, is—

(a) £495, or

(b) £245 if the holder certifies when making the payment that his turnover for that year was less than £40,000.

(2) For the purposes of this paragraph, "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 5

Fees relating to feedingstuffs

Fees relating to feedingstuffs

39.—(1) Fees relating to feedingstuffs are payable with the application, or on invoice for the subsequent annual fee.

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

(3) Fees are in accordance with the following table.

Fees relating to feedingstuffs

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late*[(a)]	*Standard*	*Late*[(a)]
Application for the approval of an establishment to manufacture a specified feed additive, and the subsequent annual fee[(b)]:	910	1,090	489	587
Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee:	575	690	386	463
Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures, and the subsequent annual fee:	575	690	386	463
Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2 kg per tonne or more when the feedingstuffs are to be placed on the market, and the	385	460	285	342

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late[(a)]*	*Standard*	*Late[(a)]*
subsequent annual fee:				
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:	195	235	152	182
Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2 kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee:	140	170	117	140
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	120	145	98	118

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late*[(a)]	*Standard*	*Late*[(a)]
the subsequent annual fee:				

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Fees relating to distributors

40. The fee for an application or subsequent annual fee to be a distributor of specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products is £135 in Great Britain (or £160 if the annual fee is not paid within 60 days of the invoice) and £62 in Northern Ireland (or £74 if the annual fee is not paid within 60 days of the invoice).

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.

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.

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.

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.

Specific batch control

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

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.

Export certificates

47. 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

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.

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

Type of application	*Fee (£)*
Application involving a new active substance:	1,865
Standard application:	495
Application for a pharmacologically equivalent product:	495
Application using identical data:	195

Type of application	*Fee (£)*
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

Type of application	*Fee (£)*
Type 1A variation:	195
Type 1B variation:	195
Type II variation:	260

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.

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.

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

Stage at which application is withdrawn	*Percentage reduction or refund*
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%

Stage at which application is withdrawn	*Percentage reduction or refund*
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%