SCHEDULE 7 Regulation 16

Fees

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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.

Expenses for inspections

5. Whenever premises are inspected, the travel and subsistence costs of the inspectors and, in the case of an inspection outside the United Kingdom, interpreters' fees are payable in addition to the inspection fee specified.

Translation

6. All translation costs are charged additionally.

PART 2

Fees relating to marketing authorisations

Fees for specified pharmaceutical applications

7. 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* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
Base Fee:	930	1,860	1,860	2,380	460
The following fees are in addition to the base fee:					
Quality assessment (if quality data are assessed):	3,900	3,320	2,790	3,560	1,860

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 (£)*	
Safety assessment (if safety data are assessed):	3,900	3,120	1,060	1,360	1,860
Efficacy assessment (if efficacy data are assessed):	3,900	3,120	1,060	1,360	1,860
Ecotoxicology assessment:(if ecotoxicology data are assessed):	660	530	330	420	400
Additional fee if any of the target species is a food-producing animal (not payable if neither safety data nor ecotoxicology data are assessed):	3,850	3,520	2,120	2,710	1,390
Reduced by— if no safety data are assessed:	2,160	2,160	1,320	1,690	660
if no ecotoxicology data are assessed:	1,020	780	300	380	300

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically Equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—					
food-producing animal:	7,350	6,500	5,770	7,370	2,590
non-food-producing animal:	6,430	5,770	5,510	7,030	2,260
Additional fee for each additional pack type:	730	730	600	760	330
Reduced by— if no quality data are assessed:	360	360	360	460	120
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	60	60	60	80	60

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically Equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
if no ecotoxicity data are assessed:	60	60	–	–	60
Additional fee for each additional active ingredient(food-producing animal):	6,360	6,030	3,980	5,090	2,060
Reduced by— if no quality data are assessed:	1,440	1,440	1,440	1,840	480
if no safety data are assessed:	2,690	2,690	1,620	2,070	840
if no efficacy data are assessed:	900	720	540	690	300
if no ecotoxicity data are assessed:	720	600	–	–	240
Additional fee for each additional active ingredient(non-food-producing animal):	4,250	4,050	3,180	4,070	1,460

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:	1,440	1,440	1,440	1,840	480
if no safety data are assessed:	1,440	1,440	900	1,150	480
if no efficacy data are assessed:	900	720	540	690	300
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):	3,910	3,520	2,390	3,050	1,260
Reduced by— if no quality data are assessed:	180	180	180	230	60
if no safety data are assessed:	1,440	1,440	900	1,150	480

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 efficacy data are assessed:	1,800	1,440	1,080	1,380	540
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):	2,460	2,060	1,530	1,950	800
Reduced by— if no quality data are assessed:	180	180	180	230	60
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	1,800	1,440	1,080	1,380	540
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):	2,650	2,460	1,590	2,040	930
Reduced by— if no safety data are assessed:	1,440	1,440	900	1,150	480
if no efficacy data are assessed:	900	720	540	690	300
if no ecotoxicity data are assessed:	60	60	–	–	60
Additional fee for each additional recommended route of administration(non-food-producing animal):	1,190	1,000	730	930	400
Reduced by— if no safety data are assessed:	180	180	120	150	60

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically Equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
if no efficacy data are assessed:	900	720	540	690	300
Simultaneous applications: fee for each additional product in the application:	2,850	2,850	2,850	3,640	1,660

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

8.—(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 7, 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 member State:	3,650
Non-food-producing animal: one member State:	3,170
Each additional member State:	520

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,570 for one member State and £120 for each additional member State.

Application for a marketing authorisation for an immunological product

9.—(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:	11,600	5,700
The following fees are in addition to the base fee.		
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:	7,290	2,450
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:	1,330	660
More than one antigenic component—fee for each additional component:	1,330	400
More than one species—fee for each additional species:	5,300	1,590
More than one route of administration—fee for each additional route of administration:	5,300	1,590
Simultaneous application—feefor each additional product in the application:	2,850	1,660

(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 £10,270 (United Kingdom only) or £5,300 (decentralised application where the United Kingdom is the concerned member State).

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

10.—(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, with the additions of £3,420 for the first member State involved in the application and £520 for each additional member State.

(2) In the case of a simultaneous application the fee for each additional product in the application is £6,570 for one member State and £120 for each additional member State.

Application for a marketing authorisation using identical data

11. 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:	930
Decentralised application where the United Kingdom isthe reference member State—	
one member State:	4,105
each additional member State:	520

Application for a provisional marketing authorisation (pharmaceutical)

12. The fee for an application for a provisional marketing authorisation for a pharmaceutical product is in accordance with the following table.

Fees for a provisional marketing authorisation for a pharmaceutical product

Menu	*Fee (£)*
Base Fee:	930
The following fees are in addition to the base fee:	
Quality assessment (if quality data are assessed):	3,900
Safety assessment (if safety data are assessed):	3,900
Efficacy assessment (if efficacy data are assessed):	2,420
Ecotoxicology assessment (if ecotoxicology data are assessed):	660
Additional fee if any of the target species is a food-producing animal (not payable if neither safety data nor ecotoxicology data are assessed):	3,850
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—	
food-producing animal:	5,770
non-food-producing animal:	4,840

Menu	*Fee (£)*
Additional fee for each additional pack type:	700
Additional fee for each additional active ingredient (food-producing animal):	5,860
Additional fee for each additional active ingredient (non-food-producing animal):	3,750
Additional fee if there is more than one target species, for each additional species (food-producing animal):	2,920
Additional fee if there is more than one target species, for each additional species (non- food-producing animal):	1,460
Additional fee for each additional recommended route of administration (food-producing animal):	2,160
Additional fee for each additional recommended route of administration (non-food-producing animal):	700
Simultaneous applications—fee for each additional product in the application:	2,850

Fees for an application for a provisional marketing authorisation (immunological)

13. The fee for an application for a provisional marketing authorisation for an immunological product is in accordance with the following table.

Fees for a provisional marketing authorisation for an immunological product

Menu	*Fee (£)*
Base fee:	10,650
The following fees are in addition to the base fee.	
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:	5,560
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:	1,330
More than one antigenic component—fee for each additional component:	1,170
More than one species—fee for each additional species:	3,990

Menu	*Fee (£)*
More than one route of administration—fee for each additional route of administration:	3,990
Simultaneous application—fee for each additional product in the application:	2,850

Fee for the conversion from a provisional to a full marketing authorisation

14. The fee for the conversion of a provisional marketing authorisation to a full marketing authorisation is the same as the fee for an application for a full marketing authorisation except that, if the application for conversion is made within two years of the grant of the provisional marketing authorisation—

(a) if the application for the provisional marketing authorisation was made before 1st October 2006 the fee is £10,995; and

(b) if the application for the provisional marketing authorisation was made on or after 1st October 2006 the fee is £5,780.

Application for a marketing authorisation relating to a parallel import

15. 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 procedure, and the United Kingdom is included in these procedures—	
import from one member State:	1,730
each additional member State:	350
Application to add an additional member State after the marketing authorisation has been granted—fee for each member State:	450
Any other application—fee for each member State from which the product is imported:	2,100

Application for a variation

16.—(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 £4,550; 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 £450 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 £870 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 Each subsequent product	870 450

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No. 1084/2003 is £2,275 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	First product 2,275 Each subsequent product 450
b) Change of distributor	No other aspect of the dossier is changed and the marketing authorisation holder remains the same	870
c) Change of legal entity of marketing authorisation holder	No other aspect of the dossier is changed	870
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	870

Change	*Conditions*	*Fee (£)*
	The dosage regime remains the same	
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	870
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	870
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	870
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 accord with current practice or inline with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**1**)	870

(**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. L136, 30.4.2004, p. 1.

Change	*Conditions*	*Fee (£)*
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	870
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	870
k) Changes to details of the marketing authorisation holder's pharmacovigilance system	No other changes to the dossier	870

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

17.—(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.

Variations

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
Type II variation:	5,125	3,075
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:	5,125	3,075
– for each subsequent variation:	675	450

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
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:	1,305	870
Changes to details of the marketing authorisation holder's pharmacovigilance system (no other changes to the dossier):	1,305	870
Type 1A variation:	675	450
Type 1B variation:	1,305	870
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	1,305	675
– for each subsequent variation	870	450

Application for an extension to a marketing authorisation

18. 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	6,570	3,250
Change of pharmaceutical form or the addition of a new pharmaceutical form	8,290	3,780
Change of route of administration, or the addition of a new one, of — an immunological product, or a pharmaceutical product for a non food-producing animal:	5,310	7,030
– a pharmaceutical product for a food-producing animal:	2,850	3,380
Change or addition of target species	9,480	4,180
Change of active substance	8,290	3,780
Other	8,290	3,780
Simultaneous application: fee for each additional product in the application	2,850	1,660

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

19.—(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 18, 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 member State:	3,650
Pharmaceutical product for a non-food-producing animal—one member State:	3,170

Application	*Additional fee (£)*
Immunological product—one member State:	3,410
Each additional member State:	520

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,570 for one member State and £115 for each additional member State.

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

20.—(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:	2,405
Pharmaceutical product for a non-food-producing animal—one member State:	1,865
Immunological product—one member State:	2,100
Each additional member State:	525

(3) In any other case the fees are—

Type of application	*Fee (£)*
Pharmaceutical product for a food-producing animal —one member State:	10,360
Pharmaceutical product for a non-food-producing animal—one member State:	7,255
Immunological product—one member State:	8,810
Each additional member State:	525

(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 £115 for each additional product for each additional member State.

Application for the renewal of a national marketing authorisation

21.—(1) The fee for an application for the renewal of a marketing authorisation originally granted on or after 30th October 2005 is £1,340.

(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 the fee is £1,340, and otherwise £300;

(b) if further assessment of post authorisation commitments is required the fee is £650.

(3) The fee for the first reassessment of a provisional marketing authorisation is £300, and the fee for each subsequent reassessment is £1,340.

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

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

(a) £1,810 if the United Kingdom is the reference member State, and

(b) £1,205 where the United Kingdom is a concerned member State.

Registration of a homeopathic remedy

23. 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:	160
more than five stocks:	370
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 five stocks:	450
more than five stocks:	655
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	
not more than five stocks:	750
more than five stocks:	970
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:	160
more than five stocks:	370

Annual fees for marketing authorisations

24.—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation must 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 must pay an annual fee, rounded up to the next £10, of—

£0.67T100+£225n

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—

£0.67T100+£170n

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 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 that 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

25.—(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 £11,035 plus an additional £2,210 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 may 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

26.—(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

27. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is—

(a) £2,740; or

(b) £500 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals).

Application for a variation of a manufacturing authorisation

28. The fee for an application to vary a manufacturing authorisation is—

(a) £490 if the variation requires scientific or pharmaceutical assessment,

(b) £345 if the variation only involves a change of ownership;

(c) £170 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and

(d) otherwise £270.

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

29.—(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 £3,110 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 £1,555.

(3) The fee to vary an authorisation is £290 if no further inspection is required, and otherwise is the full application fee.

Annual fees

30.—(1) An annual fee of £435 is payable in respect of each manufacturing authorisation held (other than as specified in this paragraph).

(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.

(3) There is no annual fee for a manufacturing authorisation for a veterinary medicinal product manufactured in accordance with Schedule 6 for small pet animals.

(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.

Site inspections—type of site

31. 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

32. 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	25,230
Major site	17,760
Standard site	5,710
Minor site	4,985

Inspection of a site where sterile veterinary medicinal products are manufactured

33. 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	23,905
Major site	13,205
Standard site	8,450
Minor site	4,170

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

34. 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	14,395
Major site	8,450
Standard site	7,020
Minor site	3,845

Inspection of a site where veterinary medicinal products are assembled

35. 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	11,300
Major site	6,095
Standard site	4,120
Minor site	1,690

Test sites

36. The fee for the inspection of a test site is £2,800.

Animal blood bank authorisations

37.—(1) The fee for an authorisation to operate a blood bank is £3,110, with the same fee for each subsequent inspection.

(2) The fee for a variation is £290.

PART 4

Fees relating to a wholesale dealer's authorisation

Application for a wholesale dealer's authorisation

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

(a) £1,590, or;

(b) £710 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 £710, he must 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 must pay the balance of £880 within 30 days.

(3) If the applicant paid £1,590 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 must refund the excess.

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

(5) In 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.

Variation of a wholesale dealer's authorisation

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

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

(b) £390 if the variation only involves a change of ownership; and

(c) otherwise £270.

Annual fee for a wholesale dealer's authorisation

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

(a) £285, or

(b) £190 if the holder certifies when making the payment that his turnover during the previous year was less than £40,000.

(2) In 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.

Inspection of a wholesale dealer's premises

41. The fee for the inspection of a wholesale dealer's premises is £1,690, or £795 if—

(a) the authorisation only relates to products classified as AVM-GSL; or

(b) his turnover relating to all veterinary medicinal products in the calendar year preceding the inspection was less than £40,000.

PART 5

Fees relating to feedingstuffs

Fees relating to feedingstuffs

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

(2) Where more than one manufacturing 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[(b)]**
1	Application for the approval of an establishment to manufacture a specified feed additive, and the subsequent annual fee (b):	935	1,115	500	600
2	Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee:	590	710	395	475
3	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:	590	710	395	475
4	Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2	395	470	290	350

(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[(b)]**
	kg per tonne or more when the feedingstuffs are to be placed on the market, and the subsequent annual fee:				
5	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:	200	240	155	190
6	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:	145	175	120	145

(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[(b)]
7	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:	125	150	100	120
8	Application for approval as a distributor of specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products, and the subsequent annual fee:	140	165	65	75

(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 premises for supply by suitably qualified persons

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

(a) £250, or

(b) if the premises are only authorised to supply veterinary medicinal products for the treatment of—

(i) horses (or horses and companion animals) £140; or

(ii) companion animals, £105.

(2) The subsequent annual fee is—

(a) £180, or £210 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—

(i) horses (or horses and companion animals) £90, or £115 if the fee is not paid within 60 days of the invoice.

(ii) companion animals, £70, or £85 if the fee is not paid within 60 days of the invoice.

Reduced fees

44. In the case of premises approved as both—

(a) premises for the manufacture of feedingstuffs and for a distributor, or

(b) premises for the supply by a suitably qualified person and for a distributor,

the subsequent annual fee payable is the higher fee plus 75% of the lower fee.

PART 6

General

Testing samples

45. 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

46.—(1) The fee for an animal test certificate is £340 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 that 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 companion animals only.

(2) In any other case the fee is £805.

(3) The fee for an application for a variation of the certificate is £260 for each change.

(4) The fee for an application to renew a certificate is £130.

Treatment under the cascade

47. 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 under the Animals (Scientific Procedures) Act 1986

48. The fee for a certificate to import a product or substance for administration under a licence granted under the Animals (Scientific Procedure) Act 1986 is £15.

Treatment in exceptional circumstances

49.—(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

50. The fee for an authorisation to release a veterinary medicinal product under specific batch control is—

(a) £550; or

(b) £450 for each batch if a number of specific batch control applications are made at the same time and all the batches are affected by the same issue.

Submission of control tests of an immunological product

51. 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

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

Appeals to the Veterinary Products Committee: marketing authorisations and ATCs

53. 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 an appeal 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	1,910
Standard application	505
Application for a pharmacologically equivalent product	505
Application using identical data	200

Type of application	*Fee(£)*
Application for an animal test certificate	665

Appeals to the Veterinary Products Committee: variations

54. If the holder of a marketing authorisation applies for a variation and the Secretary of State refuses it, the fee for an appeal to the Veterinary Products Committee is in accordance with the following table.

Appeal to the Veterinary Products Committee: variations

Type of application	*Fee(£)*
Type 1A variation	200
Type 1B variation	200
Type II variation	265

Appeal to the Veterinary Products Committee: suspensions

55. The fee for an appeal to the Veterinary Products Committee following the suspension of a marketing authorisation or animal test certificate is £665.

Appeal to the Veterinary Products Committee: active substance under Schedule 6

56. The fee for an appeal to the Veterinary Products Committee against the refusal or suspension of an approval of an active substance under Schedule 6 is £665.

Fees relating to an appointed person

57. The appellant is liable for the full economic cost of a referral to an appointed person subject to a maximum of £5,000.

Refund of fees relating to the Veterinary Products Committee or appointed persons

58. The Secretary of State must refund the fee payable in relation to an appeal to the Veterinary Products Committee or to an appointed person if, as a result of the appeal, he changes the decision that was the subject of the appeal.

Fees relating to an improvement notice

59. If an improvement notice is served under these Regulations, the fee for any subsequent inspection necessary as a result of the notice is the full economic cost of the inspection, payable by the person on whom the notice was served.

Non-payment of fees

60. 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

61.—(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 fees when an application is withdrawn

62.—(1) Where an application for a marketing authorisation, a Type II variation or a variation referred to in paragraph 16(2) is withdrawn before determination, the fee is reduced in accordance with this paragraph.

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

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

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

(5) 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 reduction is 10%.

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