SCHEDULE 7

FEES

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* *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: 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

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):	3,810	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-producing animal (not payable if neither safety data nor ecotoxicology data are assessed):	3,740	3,420	2,070	2,650	1,350
Reduced by—					
if no safety data are assessed:	2,100	2,100	1,290	1,650	640
if no ecotoxicology	990	760	290	370	290

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:					
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
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	180	180	120	150	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 (£)*	
data are assessed:					
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
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	700	580	—	—	230

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:					
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 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 if there is more than one target species, for each	3,820	3,430	2,330	2,980	1,240

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 species (food-producing animal):					
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
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—					

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 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
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	880	700	530	670	290

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 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—					
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

Commencement Information
I1 Sch. 7 para. 6 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I2 Sch. 7 para. 7 in force at 1.10.2006, see **reg. 1**

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,		

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 (£)*
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).

Commencement Information

I3 Sch. 7 para. 8 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I4 Sch. 7 para. 9 in force at 1.10.2006, see **reg. 1**

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

Commencement Information
I5 Sch. 7 para. 10 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I6 Sch. 7 para. 11 in force at 1.10.2006, see **reg. 1**

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 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

Commencement Information

I7 Sch. 7 para. 12 in force at 1.10.2006, see **reg. 1**

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 All applications are submitted at the same time	First product 2,220 Each subsequent product 440
(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	835

Change	*Conditions*	*Fee (£)*
	The indications and warnings are the same in all languages	
(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 The application has been resubmitted within 3 months of the date the refusal advice was issued	835
(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

Commencement Information

I8 Sch. 7 para. 13 in force at 1.10.2006, see **reg. 1**

(**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.

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.

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—		

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

Commencement Information
I9 Sch. 7 para. 14 in force at 1.10.2006, see **reg. 1**

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— — an immunological product, or a pharmaceutical product for a non-food-producing animal:	5,170	2,790
— a pharmaceutical product for a food-producing animal:	6,850	3,300

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 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

Commencement Information
I10 Sch. 7 para. 15 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I11 Sch. 7 para. 16 in force at 1.10.2006, see **reg. 1**

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
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.

Commencement Information

I12 Sch. 7 para. 17 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I13 Sch. 7 para. 18 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I14 Sch. 7 para. 19 in force at 1.10.2006, see **reg. 1**

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
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:	730
more than five stocks:	945
If the product is already authorised for human use in the United Kingdom, or for human or	155

Type of application	*Fee (£)*
veterinary use in the United Kingdom or in another member State—	
not more than five stocks:	
more than five stocks:	360

Commencement Information

I15 Sch. 7 para. 20 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I16 Sch. 7 para. 21 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I17 Sch. 7 para. 22 in force at 1.10.2006, see **reg. 1**

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.

Commencement Information
I18 Sch. 7 para. 23 in force at 1.10.2006, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, PART 2.