SCHEDULE 7 Regulation 16

Fees

# CONTENTS

PART 3

Fees payable by manufacturers



PART 4

Fees relating to a wholesale dealer's authorisation



PART 5

Fees relating to feedingstuffs



PART 6

General

# PART 1

## Introduction

**Interpretation**

**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.

| *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:** | 950 | 1,885 | 1,885 | 2,410 | 470 |
| The following fees are in addition to the base fee: | | | | | |
| **Quality assessment** (if | 3,970 | 3,365 | 2, 825 | 3,620 | 1, 880 |

| *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 (£)* | |
| quality data are assessed): | | | | | |
| **Safety assessment** (if safety data are assessed): | 3,970 | 3, 165 | 1,075 | 1,380 | 1,880 |
| **Efficacy assessment** (if efficacy data are assessed): | 3,970 | 3,165 | 1,075 | 1,380 | 1,880 |
| **Ecotoxicology assessment**: (if ecotoxicology data are assessed): | 670 | 535 | 335 | 430 | 405 |
| **Additional fee if any of the target species is a food-producing animal** (not payable if neither safety data nor ecotoxicology data are assessed): | 3,905 | 3,585 | 2,155 | 2,760 | 1,415 |
| Reduced by— | | | | | |
| if no safety data are assessed: | 2,190 | 2,190 | 1,340 | 1,715 | 670 |
| if no ecotoxicology | 1,035 | 790 | 305 | 390 | 305 |

| *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: | 7,465 | 6,595 | 5,855 | 7,495 | 2,630 |
| non-food-producing animal: | 6,525 | 5,855 | 5,590 | 7,155 | 2,295 |
| **Additional fee for each additional pack type:** | 740 | 740 | 605 | 775 | 330 |
| Reduced by— | | | | | |
| if no quality data are assessed: | 365 | 365 | 365 | 465 | 120 |
| if no safety data are assessed: | 185 | 185 | 120 | 155 | 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 (£)* | |
| if no efficacy data are assessed: | 60 | 60 | 60 | 80 | 60 |
| if no ecotoxicity data are assessed: | 60 | 60 | | | 60 |
| **Additional fee for each additional active ingredient (food-producing animal):** | 6,465 | 6,125 | 4,040 | 5,165 | 2,085 |
| Reduced by— | | | | | |
| if no quality data are assessed: | 1,460 | 1,460 | 1,460 | 1,870 | 485 |
| if no safety data are assessed: | 2,740 | 2,740 | 1,645 | 2,100 | 850 |
| if no efficacy data are assessed: | 915 | 730 | 550 | 700 | 305 |
| if no ecotoxicity data are assessed: | 730 | 610 | | | 245 |
| **Additional fee for each** | 4,310 | 4,105 | 3,235 | 4,135 | 1,475 |

| *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 active ingredient (non-food-producing animal):** | | | | | |
| Reduced by— | | | | | |
| if no quality data are assessed: | 1,460 | 1,460 | 1,460 | 1,870 | 485 |
| if no safety data are assessed: | 1,460 | 1,460 | 915 | 1,170 | 485 |
| if no efficacy data are assessed: | 915 | 730 | 550 | 700 | 305 |
| 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):** | 3,970 | 3,565 | 2,425 | 3,100 | 1,280 |
| Reduced by— | | | | | |
| if no quality | 185 | 185 | 185 | 235 | 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 safety data are assessed: | 1,460 | 1,460 | 915 | 1,170 | 485 |
| if no efficacy data are assessed: | 1,825 | 1,460 | 1,095 | 1,400 | 550 |
| 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):** | 2,495 | 2,090 | 1,550 | 1,980 | 805 |
| Reduced by— | | | | | |
| if no quality data are assessed: | 185 | 185 | 185 | 235 | 60 |
| if no safety data are assessed: | 185 | 185 | 120 | 155 | 60 |
| if no efficacy | 1,825 | 1,460 | 1,095 | 1,400 | 550 |

| *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 (food-producing animal):** | 2,695 | 2,490 | 1,620 | 2,070 | 940 |
| Reduced by— | | | | | |
| if no safety data are assessed: | 1,460 | 1,460 | 915 | 1,170 | 485 |
| if no efficacy data are assessed: | 915 | 730 | 550 | 700 | 305 |
| if no ecotoxicity data are assessed: | 60 | 60 | | | 60 |
| **Additional fee for each additional recommended route of administration (non- food-** | 1,215 | 1,010 | 740 | 945 | 405 |

| *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):** | | | | | |
| Reduced by— | | | | | |
| if no safety data are assessed: | 185 | 185 | 120 | 155 | 60 |
| if no efficacy data are assessed: | 915 | 730 | 550 | 700 | 305 |
| **Simultaneous applications**: fee for each additional product in the application: | 2,895 | 2,895 | 2,895 | 3,705 | 1,685 |

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

**8.** 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 for a pharmacologically equivalent product (£)* | *Additional fee otherwise (£)* |
|---|---|---|
| Food-producing animal: one member State: | 5,230 | 3,705 |
| Non-food-producing animal: one member State: | 3,985 | 3,220 |
| Each additional member State: | 530 | 530 |

| *Application* | *Additional fee for a pharmacologically equivalent product (£)* | *Additional fee otherwise (£)* |
|---|---|---|
| Simultaneous application: fee for each additional product in the application: | | |
| one member State | 6,670 | 6,670 |
| each additional member State | 120 | 120 |

**Application for a marketing authorisation for an immunological product**

**9.** 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 (£)* |
|---|---|---|
| **1. Immunological product other than in paragraph 2:** | | |
| **Base fee**: | 11,775 | 5,785 |
| 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: | 7,405 | 2,490 |
| 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: | 1,345 | 675 |

| *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 (£)* |
|---|---|---|
| More than one antigenic component – fee for each additional component: | 1,350 | 405 |
| More than one species – fee for each additional species | 5,380 | 1,615 |
| More than one route of administration – fee for each additional route of administration | 5,380 | 1,615 |
| Simultaneous application - fee for each additional product in the application | 2,895 | 1,685 |
| **2. Immunological product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and that only contains antigens contained in that product** | 10,430 | 5,380 |

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

**10.** 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 set out in the previous table, with the addition of the fees in the following table—

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

| *Application* | *Additional fee (£)* |
|---|---|
| One member State | 3,470 |
| Each additional member State | 530 |
| Simultaneous applications: fee for each additional product in the application | |
| one member State | 6,670 |
| each additional member State | 120 |

**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 (£)* |
|---|---|
| Decentralised application where the United Kingdom is the reference member State— | |
| one member State: | 4,165 |
| each additional member State: | 530 |
| Any other application | 945 |

**Application for an exceptional marketing authorisation (pharmaceutical)**

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

***Fees for an exceptional marketing authorisation for a pharmaceutical product***

| *Menu* | *Fee (£)* |
|---|---|
| Base Fee: | 950 |
| The following fees are in addition to the base fee: | |
| Quality assessment (if quality data are assessed): | 3,970 |
| Safety assessment (if safety data are assessed): | 3,970 |
| Efficacy assessment (if efficacy data are assessed): | 2,455 |
| Ecotoxicology assessment (if ecotoxicology data are assessed): | 670 |
| Additional fee if any of the target species is a food-producing animal (not payable if neither safety data nor ecotoxicology data are assessed): | 3,905 |
| Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom— | |
| food-producing animal: | 5,850 |
| non-food-producing animal: | 4,910 |
| Additional fee for each additional pack type: | 710 |
| Additional fee for each additional active ingredient (food-producing animal): | 5,955 |

| *Menu* | *Fee (£)* |
|---|---|
| Additional fee for each additional active ingredient (non-food-producing animal): | 3,800 |
| Additional fee if there is more than one target species, for each additional species (food-producing animal): | 2,965 |
| Additional fee if there is more than one target species, for each additional species (non- food-producing animal): | 1,485 |
| Additional fee for each additional recommended route of administration (food-producing animal): | 2,185 |
| Additional fee for each additional recommended route of administration (non-food-producing animal): | 710 |
| Simultaneous applications— fee for each additional product in the application: | 2,895 |

**Fees for an application for an exceptional marketing authorisation (immunological)**

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

***Fees for an exceptional marketing authorisation for an immunological product***

| *Menu* | *Fee (£)* |
|---|---|
| Base fee: | 10,810 |
| 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: | 5,650 |
| 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: | 1,350 |
| More than one antigenic component – fee for each additional component: | 1,190 |
| More than one species – fee for each additional species: | 4,060 |
| More than one route of administration – fee for each additional route of administration: | 4,060 |

| *Menu* | *Fee (£)* |
|---|---|
| Simultaneous application - fee for each additional product in the application | 2,895 |

**Fee for the conversion from an exceptional to a full marketing authorisation**

**14.** The fee for the conversion of an exceptional 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 exceptional marketing authorisation, the fee is £5,865.

**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: | 1,775 |
| each additional member State: | 355 |
| Application to add an additional member State after the marketing authorisation has been granted—fee for each member State | 455 |
| Any other application—fee for each member State from which the product is imported: | 2,130 |

**Application for a variation obtained under a national procedure**

**16.**—(1) — This paragraph applies in relation to an application for a variation to a marketing authorisation obtained under a national procedure.

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

(3) As an exception from sub-paragraph (1), an applicant who applies for more than one variation to the quality data in a marketing authorisation on the same application form may elect to pay a total fee of £4,620; 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.

(4) If the variation is one specified as Type 1A in Commission Regulation (EC) No 1084/2003(**1**), the fee is £455.

(5) If the variation is specified as Type 1B in those Regulations, the fee is £885 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<br><br>Supporting data are identical<br><br>All applications are submitted at the same time | First product | 885 |
| | | Each subsequent product | 455 |

(6) The fee for a variation classified as Type II in Commission Regulation (EC) No 1084/2003 is £2,310 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<br><br>Supporting data are identical<br><br>All applications are submitted at the same time | First product | 2,310 |
| | | Each subsequent product | 455 |
| b) Change of distributor | No other aspect of the dossier is changed and the marketing authorisation holder remains the same | 885 | |
| c) Change of legal entity of marketing authorisation holder | No other aspect of the dossier is changed | 885 | |
| d) Simple dosage instruction changes intended to remove ambiguity | The change is not as a result of safety concerns<br><br>No new studies are required to support the change<br><br>The dosage regime remains the same | 885 | |
| e) Addition or change to safety warnings | No other aspects of the dossier are changed | 885 | |

(**1**) On 1st January 2010 this Regulation is superseded by Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ No L 334, 12.12.2008, p. 7) but for the purposes of variations to marketing authorisations granted under the national procedure the classifications in Commission Regulation (EC) No 1084/2003 continue to be used.

| Change | Conditions | Fee (£) |
|---|---|---|
| | No safety warnings are removed<br><br>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 | |
| 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<br><br>No new studies are required to support the change and no other aspect of the dossier is changed<br><br>The legibility of the current English labelling is not compromised<br><br>The indications and warnings are the same in all languages | 885 |
| 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<br><br>The application has been resubmitted within 3 months of the date the refusal advice was issued | 885 |
| 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<br><br>The change is not required as a result of the holder failing to keep the Part II (quality) data in accord with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**2**) | 885 |
| i) Approval of a mock-up for an authorised pack size | The pack size is already authorised | 885 |

(**2**) 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 (£) |
|---|---|---|
| | No new studies are required to support the change and no other aspect of the dossier is changed | |
| 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 | 885 |
| k) Changes to details of the marketing authorisation holder's pharmacovigilance system | No other changes to the dossier | 885 |

**Application for a variation to a marketing authorisation obtained through mutual recognition or decentralised procedures: fees until 1st January 2010**

**17.**—(1) This paragraph applies until 1st January 2010.

(2) It applies in relation to an application for a variation to a marketing authorisation obtained through mutual recognition or decentralised procedures.

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

(4) 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).

(5) 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:** | 5,200 | 3,120 |
| If a marketing authorisation holder applies for a Type II variation for a number of marketing authorisations, and—<br>— all the applications have identical supporting data<br>— all the changes are identical<br>— all the applications are submitted at the same time<br>the fee payable is— | | |
| — for the first variation: | 5,200 | 3,120 |

| *Type of variation* | *UK is the reference member State (£)* | *UK is a concerned member State (£)* |
|---|---|---|
| — for each subsequent variation: | 685 | 455 |
| 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: | 1,325 | 885 |
| Changes to details of the marketing authorisation holder's pharmacovigilance system (no other changes to the dossier) | 1,325 | 885 |
| **Type 1A variation:** | 685 | 455 |
| **Type 1B variation:** | 1,325 | 885 |
| 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 | 1,325 | 885 |
| — for each subsequent variation | 685 | 455 |

**Application for a variation to a marketing authorisation obtained through mutual recognition or decentralised procedures: fees from 1st January 2010**

**18.**—(1) This paragraph applies from 1st January 2010.

(2) It applies in relation to an application for a variation to a marketing authorisation obtained through mutual recognition or decentralised procedures.

(3) In this paragraph the types of variation are those specified in Commission Regulation (EC) 1234/2008 (concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products(**3**)).

(4) 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) except where the variations are grouped in accordance with Article 7 of Commission Regulation (EC) No 1234/2008 ("grouped variations").

(5) In this paragraph "worksharing" means the procedure set out in Article 20 of Commission Regulation (EC) No 1234/2008.

(6) The fee for any kind of variation where the Agency co-ordinates worksharing is £455 for each marketing authorisation.

(7) In any other case 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** | | |
| Application for a grouped variation: | 12,060 | 6,240 |
| Any other application: | 6,030 | 3,120 |
| **Type II variation using the worksharing procedure** | | |
| Application for a grouped variation— | | |
| Base fee (including the first nine changes): | 13,265 | 5,620 (6,745 where the United Kingdom is co-reference member State[(a)]) |
| For the tenth and each subsequent ten changes: | 4,500 | 4,500 |
| Any other application: | 6,630 | 2,810 |
| **Type IB variations** | | |
| Application for a grouped variation: | 2,650 | 1,770 |
| Any other application: | 1,325 | 885 |

**(a)** A co-reference member State is a member State appointed to assist the reference member State in the assessment of specific marketing authorisations.

(**3**) OJ No L334, 12.12.2008, p. 7. This Regulation supersedes Regulation (EC) No 1084/2003 on 1st January 2010.

| *Type of variation* | *UK is the reference member State (£)* | *UK is a concerned member State (£)* |
|---|---|---|
| **Type IB variations using the worksharing procedure** | | |
| Application for a grouped variation— | | |
| Base fee (including the first nine changes): | 2,915 | 1,590 (1,910 where the United Kingdom is co-reference member State[a]) |
| For the tenth and each subsequent ten changes: | 4,500 | 4,500 |
| Any other application: | 1,325 | 885 |
| **Type IA variation** | | |
| Application for a grouped variation— | | |
| Base fee (including the first nine changes): | 1,325 | 885 |
| For the tenth and each subsequent ten changes: | 4,500 | 4,500 |
| Notification under Article 8 of Commission Regulation (EC) No 1234/2008: | 1,325 | 885 |
| Any other application | 685 | 455 |
| **Type 1A variation using the worksharing procedure** | | |
| Application for a grouped variation— | | |
| Base fee (including the first nine changes): | 1,460 | 820 |
| For the tenth and each subsequent ten changes: | 4,500 | 4,500 |

**(a)** A co-reference member State is a member State appointed to assist the reference member State in the assessment of specific marketing authorisations.

### Application for an extension to a marketing authorisation

**19.** 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 was obtained using a national procedure (£)* | *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 | 6,670 | 3,300 |
| Change of pharmaceutical form or the addition of a new pharmaceutical form | 8,415 | 3,835 |
| 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: | 5,390 | 2,895 |
| a pharmaceutical product for a food-producing animal: | 7,135 | 3,430 |
| Change or addition of target species | 9,620 | 4,245 |
| Change of active substance | 8,415 | 3,835 |
| Other | 8,415 | 3,835 |
| Simultaneous application: fee for each additional product in the application | 2,895 | 1,685 |

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

**20.** 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 19, with the addition 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: | 3,705 |

| *Application* | *Additional fee (£)* |
|---|---|
| Pharmaceutical product for a non-food-producing animal – one member State: | 3,220 |
| Immunological product – one member State: | 3,460 |
| Each additional member State: | 530 |
| Simultaneous application: fee for each additional product in the application: | |
| one member State | 6,670 |
| each additional member State | 115 |

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

**21.**—(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 to provide the information to an additional member State within six months of the date the last information was provided, the fees are—

| *Type of application* | *Fee for a pharmacologically equivalent product (£)*[a] | *Fee (other products) (£)* |
|---|---|---|
| Pharmaceutical product for a food-producing animal – one member State: | 3,940 | 2,440 |
| Pharmaceutical product for a non-food-producing animal – one member State: | 2,645 | 1,895 |
| Immunological product – one member State: | 2,130 | 2,130 |
| Each additional member State: | 535 | 535 |

**(a)** This fee is payable if the application for the marketing authorisation was on the basis that the product was pharmacologically equivalent to another veterinary medicinal product.

(3) In any other case the fees are—

| *Type of application* | *Fee for a pharmacologically equivalent product (£)*[a] | *Fee (other products) (£)* |
|---|---|---|
| Pharmaceutical product for a food-producing animal – one member State: | 12,015 | 10,515 |

**(a)** See footnote for previous table.

| *Type of application* | *Fee for a pharmacologically equivalent product (£)*[a] | *Fee (other products) (£)* |
|---|---|---|
| Pharmaceutical product for a non-food-producing animal – one member State: | 8,115 | 7,365 |
| Immunological product – one member State: | 8,940 | 8,940 |
| Each additional member State: | 535 | 535 |

**(a)** See footnote for previous table.

(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**

**22.**—(1) The fee for an application for the renewal of a marketing authorisation originally granted on or after 30th October 2005 is £1,360.

(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 £1,360 and otherwise £305;

(b) if further assessment of post authorisation commitments is required the fee is £660.

(3) The fee for the first reassessment of an exceptional marketing authorisation is £305, and the fee for each subsequent reassessment is £1,360.

**Application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure**

**23.** The fee for an application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure is —

(a) £1,835 if the United Kingdom is the reference member State, and

(b) £1,225 if the United Kingdom is a concerned member State.

**Registration of a homeopathic remedy**

**24.** 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: | 375 |
| If either all the stocks have already been assessed by the Secretary of State but there is | |

| *Type of application* | *Fee(£)* |
|---|---|
| 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: | 455 |
| more than five stocks: | 665 |
| 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: | 760 |
| more than five stocks: | 985 |
| 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: | 375 |

**Annual fees for marketing authorisations**

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

(2) When providing the statement of turnover the holder must pay an annual fee, rounded up to the next £10, of—

$$£\frac{0.67T}{100} + £230n$$

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 £230,000, the amount, rounded up to the next £10, is—

$$£\frac{0.67T}{100} + £200n$$

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 sales value at manufacturers' prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom;

"manufacturers' prices" means the prices charged (excluding value added tax) 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 the marketing authorisation holder has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by the marketing authorisation holder for those products.

**Auditor's certificate**

**26.**—(1) If the Secretary of State required an audit certificate when the demand for the statement of turnover was sent out, and the holder of the marketing authorisation has not provided it within 30 days, an additional fee is payable for that year of £11,200 plus an additional £2,245 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, the Secretary of State may require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances are needed; 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**

**27.**—(1) Any person who fails to pay the annual fee for a marketing authorisation within 30 days from and including the date of the demand 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 annual turnover so that the annual fee cannot be determined before the due date, the holder 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**

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

(a) £3,010; or

(b) £525 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**

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

(a) £540 if the variation requires scientific or pharmaceutical assessment;

(b) £375 if the variation only involves a change of ownership;

(c) £180 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and

(d) otherwise £295.

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

**30.**—(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 £3,240 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 £1,620.

(3) The fee to vary an authorisation is £300 if no further inspection is required, and otherwise is the full application fee.

**Annual fees**

**31.**—(1) An annual fee of £490 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 sales value at manufacturers' prices net of value added tax of all authorised veterinary medicinal products sold or supplied in the United Kingdom.

**Site inspections – type of site**

**32.** 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**

**33.** 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**

**34.** 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 | 24,680 |
| Major site | 13,635 |
| Standard site | 8,725 |
| Minor site | 4,305 |

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

**35.** 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 | 14,865 |
| Major site | 8,725 |
| Standard site | 7,250 |
| Minor site | 3,970 |
| If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals— | |
| Standard site | 4,335 |
| Minor site | 2,340 |

**Inspection of a site where veterinary medicinal products are assembled**

**36.** 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 | 11,665 |
| Major site | 6,295 |
| Standard site | 4,255 |
| Minor site | 1,745 |

**Test sites**

**37.** The fee for the inspection of a test site is £2,870.

**Animal blood bank or equine stem cell centre authorisations**

**38.**—(1) The fee for an authorisation to operate a blood bank is £2,800, with the same fee for each subsequent inspection.

(2) The fee for an authorisation to operate an equine stem cell centre is £3,240, with the same fee for each subsequent inspection.

(3) The fee for a variation to an authorisation to operate a blood-bank or equine stem cell centre is £300.

# PART 4

## Fees relating to a wholesale dealer's authorisation

**Application for a wholesale dealer's authorisation**

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

(a) £1,745, or;

(b) £775 if the application is accompanied by an estimate that the first year's turnover will be less than £35,000.

(2) An applicant who has paid a fee of £775 must send a declaration of turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £35,000 must pay the balance of £980 within 30 days.

(3) If the applicant paid £1,745 but the turnover for the first year of trading was lower than £35,000, if the applicant 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 sales value net of value added tax 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**

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

(a) £510 if the variation requires scientific or pharmaceutical assessment;

(b) £425 if the variation only involves a change of ownership; and

(c) otherwise £295.

**Annual fee for a wholesale dealer's authorisation**

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

(a) £325; or

(b) £215 if the holder certifies when making the payment that the turnover during the previous year was less than £35,000.

(2) In this paragraph "turnover" means the sales value net of value added tax 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**

**42.** The fee for the inspection of a wholesale dealer's premises is £1,745, or £820 if—

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

(b) the turnover relating to all veterinary medicinal products in the calendar year preceding the inspection was less than £35,000.

# PART 5

## Fees relating to feedingstuffs

**Fees relating to feedingstuffs**

**43.**—(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)]** |
| 1 | Application for the approval of an establishment to manufacture a specified feed | 965 | 1,150 | 515 | 620 |

**(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)]** |
| | additive, and the subsequent annual fee [(b)]: | | | | |
| 2 | Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee: | 610 | 735 | 410 | 490 |
| 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: | 610 | 735 | 410 | 490 |
| 4 | Application for the approval of an establishment to manufacture feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more, and | 410 | 485 | 300 | 360 |

**(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: | | | | |
| 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: | 205 | 250 | 160 | 195 |
| 6 | Application for the approval of an establishment to manufacture feedingstuffs for the manufacturers own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more, and the subsequent annual fee: | 150 | 180 | 125 | 150 |
| 7 | Application for the approval of an establishment to manufacture feedingstuffs | 130 | 155 | 105 | 125 |

**(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)]** |
| | using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee: | | | | |
| 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: | 145 | 170 | 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**

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

(a) £260; or

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

(i) horses (or horses and companion animals) £145; or

(ii) companion animals, £110.

(2) The subsequent annual fee is—

(a) £185, or £215 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) £95, or £120 if the fee is not paid within 60 days of the invoice,

(ii) companion animals, £70, or £90 if the fee is not paid within 60 days of the invoice.

**Reduced fees**

**45.** 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**

**46.** 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**

**47.**—(1) The fee for an animal test certificate is £345 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) The fee for an animal test certificate to administer medicinal products in a small scale trial to test them for clinical safety or efficacy is £30.

(3) In any other case the fee is £815.

(4) The fee for an application for a variation of the certificate is £265 for each change.

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

(6) The Secretary of State may waive the fee if satisfied that the application is in relation to developing a veterinary medicinal product for a limited market (for example, for a minor species, a minor use, or for a disease with restricted regional distribution).

**Importation of a veterinary medicinal product for treatment under the cascade**

**48.**—(1) The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product under the cascade is—

(a) £15 if the veterinary medicinal product is authorised in another member State;

(b) £30 if the veterinary medicinal product is authorised in a third country.

(2) The fee is payable in respect of each animal treated, but 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.

(3) There is no fee if the application is made using the website of the Veterinary Medicines Directorate.

**Importation of a veterinary medicinal product for administration under the Animals (Scientific Procedures) Act 1986**

**49.**—(1) 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.

(2) There is no fee if the application is made using the website of the Veterinary Medicines Directorate.

**Wholesale dealer's import certificate**

**50.**—(1) The fee payable by the holder of a wholesale dealer's authorisation for a certificate to import and store a veterinary medicinal product not authorised in the United Kingdom to enable it to be supplied for administration under Schedule 4 is £750.

(2) The fee is only payable if, in the twelve month period immediately before the application, the applicant has supplied the veterinary medicinal product to which the certificate relates in accordance with at least 100 certificates.

**Specific batch control**

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

(a) £560; or

(b) £455 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**

**52.** 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**

**53.** 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 animal test certificates**

**54.** 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 | 1,940 |
| Standard application | 515 |
| Application for a pharmacologically equivalent product | 515 |
| Application using identical data | 205 |
| Application for an animal test certificate | 675 |

**Appeals to the Veterinary Products Committee: variations**

**55.** 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 | 205 |
| Type 1B variation | 205 |
| Type II variation | 270 |

**Appeal to the Veterinary Products Committee: suspensions**

**56.** The fee for an appeal to the Veterinary Products Committee following the suspension of a marketing authorisation or animal test certificate is £675.

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

**57.** 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 £675.

**Fee relating to an appointed person**

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

**Fees relating to a veterinary surgeon's practice premises**

**59.**—(1) The fee for the inspection of a veterinary surgeon's practice premises is £250.

(2) The annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is £40.

(3) Notwithstanding paragraph 2 of this Schedule, this is payable to the Royal College of Veterinary Surgeons.

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

**60.** 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, the Secretary of State changes the decision that was the subject of the appeal.

**Fees relating to an improvement notice**

**61.** 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**

**62.** 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**

**63.**—(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 the Secretary of State 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**

**64.**—(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.