SCHEDULE 7 Regulation 16

Fees

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PART 1

Introduction

Interpretation E+W+S

1. In this Schedule—

F1…

"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,

F2…

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F1 Words in Sch. 7 para. 1 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Sch. 7 para. 1 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Interpretation N.I.

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.

Extent Information

E19 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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, premises or establishment is inspected for more than one type of authorisation, approval or registration at the same time, the fee is the sum of —

(a) the highest fee payable; and

(b) 50% of each of the other fees.

Expenses for inspections outside the United Kingdom

5. Whenever premises outside the United Kingdom are inspected, the travel and subsistence costs of the inspectors and 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

[F3Application for a marketing authorisation for a pharmaceutical veterinary medicinal product] **E+W+S**

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

(a) **[**F4an 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;

F5(b) . . . . . .

(c) F6...

Application	*Full* F7 *...application under Part 1 of Schedule 1 (£)*	*Bibliographic* F8 *...application (£)*	*[F10Pharmacologically equivalent application]*	F9 ...	F9 ...
Base Fee:	13,530	12,115	7,195	F9	F9
Additional fee if any of the target species is a food-producing animal:	3,905	3,585	2,155	F9	F9
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	5,885	F9	F9
non-food-producing animal:	6,525	5,855	5,590	F9	F9
Additional fee for each additional pack type**:**	740	740	605	F9	F9
Additional fee for each additional active ingredient (food-producing animal):	6,465	6,125	4,040	F9	F9
Additional fee for each additional active ingredient (non-food-producing animal):	4,310	4,105	3,235	F9	F9
Additional fee if there is more than one target	3,970	3,565	2,425	F9	F9

Application	*Full* F7 *...application under Part 1 of Schedule 1 (£)*	*Bibliographic* F8 *...application (£)*	*[F10 Pharmacologically equivalent application]*	F9 *...*	F9 *...*
species, for each additional species (food-producing animal):					
Additional fee if there is more than one target species, for each additional species (non- food-producing animal):	2,495	2,090	1,550	F9	F9
Additional fee for each additional recommended route of administration (food-producing animal):	2,695	2,490	1,620	F9	F9
Additional fee for each additional recommended route of administration (non- food-producing animal):	1,215	1,010	740	F9	F9
Simultaneous applications: fee for each additional product in the application:	2,895	2,895	2,895	F9	F9

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F3 Sch. 7 para. 7 heading substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Sch. 7 para. 7(a) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Sch. 7 para. 7(b) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Sch. 7 para. 7(c) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in Sch. 7 para. 7 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iv)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Word in Sch. 7 para. 7 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iv)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in Sch. 7 para. 7 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iv)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Sch. 7 para. 7 Table substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iv)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

Specified pharmaceutical applications N.I.

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.

Application	*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:	13,530	12,115	7,195	9,220	6,515
Additional fee if any of the target species is a food-producing animal:	3,905	3,585	2,155	2,760	1,415
Additional fee for each active ingredient not					

Application	*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 (£)*	
previously included in a veterinary medicinal product authorised in the United Kingdom—					
food-producing animal:	7,465	6,595	5,885	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
Additional fee for each additional active ingredient (food-producing animal):	6,465	6,125	4,040	5,165	2,085
Additional fee for each additional active ingredient (non-food-producing animal):	4,310	4,105	3,235	4,135	1,475
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 Applies for a maximum of 2 additional species
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 Applies for a maximum of 2 additional species
Additional fee for each additional recommended route of administration	2,695	2,490	1,620	2,070	940

Application	*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 (£)*	
(food-producing animal):					
Additional fee for each additional recommended route of administration (non- food-producing animal):	1,215	1,010	740	945	405
Simultaneous applications: fee for each additional product in the application:	2,895	2,895	2,895	3,705	1,685

Extent Information

E20 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Decentralised pharmaceutical application where the United Kingdom is the reference member State E+W+S

[F11]8. . . . . . .

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F11 Sch. 7 para. 8 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Decentralised pharmaceutical application where the United Kingdom is the reference member State N.I.

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.

Fees for 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
Simultaneous application: fee for each additional product in the application:		
one member State:	6,670	6,670
each additional member State:	120	120

Extent Information

E21 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for a marketing authorisation for an immunological or biosimilar product E+W+S

9.—(1) The fee for **[**F12an application**]** for a marketing authorisation relating to an immunological or biosimilar product,F13... is in accordance with the following table.

(2) In this paragraph a biosimilar application means an application made in accordance with Article 13(4) of Directive 2001/82/EC and a biosimilar product means a product which is the subject of such an application.

Fees for specified immunological and biosimilar applications

Application	F14 *... application for a marketing authorisation(£)*	F15 ...
1. Immunological or biosimilar product other than in paragraph 2 below: Base fee:	11,775	F15 ...
The following fees are in addition to the base fee—		F15

Application	*F14* *... application for a marketing authorisation(£)*	*F15* *...*	
			...
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		F15 ...
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		F15 ...
More than one antigenic component – fee for each additional component:	1,350		F15 ...
More than one species – fee for each additional species:	5,380		F15 ...
More than one route of administration – fee for each additional route of administration:	5,380		F15 ...
Simultaneous application - fee for each additional product in the application:	2,895		F15 ...
2. Immunological or 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	F15 ...	

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F12 Words in Sch. 7 para. 9(1) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(d)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in Sch. 7 para. 9(1) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(d)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Word in Sch. 7 para. 9 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(d)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in Sch. 7 para. 9 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(d)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for a marketing authorisation for an immunological or biosimilar product **N.I.**

9.—(1) The fee for a national application for a marketing authorisation relating to an immunological or biosimilar 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.

(2) In this paragraph a biosimilar application means an application made in accordance with Article 13(4) of Directive 2001/82/EC and a biosimilar product means a product which is the subject of such an application.

Fees for specified immunological and biosimilar applications

Application	*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 or biosimilar product other than in paragraph 2 below: 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
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 Applies for a maximum of 2 additional species
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 or 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

Extent Information

E22 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Decentralised immunological application where the United Kingdom is the reference member State E+W+S

F16**10.** . . . . . .

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F16 Sch. 7 para. 10 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

Decentralised immunological application where the United Kingdom is the reference member State N.I.

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—

Fees for 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

Extent Information

E23 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F17Application for a marketing authorisation based on informed consent] E+W+S

11. The [F18fee] for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of Directive 2001/82/EC[F19is £945 per application.]

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F17 Sch. 7 para. 11 heading substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(f)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Word in Sch. 7 para. 11 substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(f)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in Sch. 7 para. 11 substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(f)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

Applications for a marketing authorisation using data already assessed N.I.

11. The fees for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of Directive 2001/82/EC are in accordance with the following table.

Fees for a marketing authorisation using data already assessed

Application	*Fee (£)per authorisation*
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

Extent Information

E24 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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

Application	*Provisional (£)*	*Limited (£)*
Base Fee:	12,015	6,765
The following fees are in addition to the base fee—		
Additional fee if any of the target species is a food-producing animal:	3,905	1,952
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—		
food-producing animal:	5,850	3,732
non-food-producing animal:	4,910	3,262
Additional fee for each additional pack type:	710	370
Additional fee for each additional active ingredient (food-producing animal):	5,955	3,232
Additional fee for each additional active ingredient (non-food-producing animal):	3,800	2,155
Additional fee if there is more than one target species, for each additional species (food-producing animal):	2,965	1,985
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	1,485	1,247
Additional fee for each additional recommended route of administration (food-producing animal):	2,185	1,347
Additional fee for each additional recommended route of administration (non-food-producing animal):	710	608
Simultaneous applications— fee for each additional product in the application:	2,895	1,447

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

Application	*Provisional (£)*	*Limited (£)*
Base fee:	10,810	5,887
The following fees are in addition to the base fee—		
Additional fee for each active ingredient not previously included in a veterinary medicinal	5,650	3,702

Application	*Provisional (£)*	*Limited (£)*
product authorised in the United Kingdom, and for each new combination of active ingredients:		
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,350	672
More than one antigenic component – fee for each additional component:	1,190	675
More than one species – fee for each additional species:	4,060	2,690
More than one route of administration – fee for each additional route of administration:	4,060	2,690
Simultaneous application - fee for each additional product in the application:	2,895	1,447

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 £3,000.

Application for a marketing authorisation relating to a parallel import **E+W+S**

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

[F20Parallel imports

Application	*Fee (£)*
Application where the imported product is identical to a product which is authorised for sale in the United Kingdom	2,130
Application where the imported product is therapeutically similar to a product which is authorised for sale in the United Kingdom (can only be applied to imported products for non-food producing species)	4,710**]**

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F20 Sch. 7 para. 15 Table substituted (E.W.S) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **Sch. 8 Pt. 2** (as amended by S.I. 2020/1461, regs. 1(2)(a), **2(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for a marketing authorisation relating to a parallel import N.I.

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 or more member States:	1,755
Application to add an additional member State after the marketing authorisation has been granted – fee for each member State:	455
Application where the imported product has not been authorised in accordance with the mutual recognition procedure or the decentralised procedure but where the imported product originates from the same manufacturing site as the product authorised in the United Kingdom to which the imported product is considered to be essentially similar:	2,130
Any other application – fee for each member State from which the product is imported:	4,710

Extent Information

E25 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application to change the distribution category of a product authorised through the centralised procedure E+W+S

F21 16. . . . . . .

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F21 Sch. 7 para. 16 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

Application to change the distribution category of a product authorised through the centralised procedure N.I.

16. The fee to change the distribution category of a product authorised through the centralised procedure is £3,135.

Extent Information

E26 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for a variation to a marketing authorisation F22.... E+W+S

17.—(1) This paragraph applies in relation to an application for a variation to one or more marketing authorisations except where paragraph 18, 19 or 21 applies.

(2) The fees for the variations to which this paragraph applies are set out in the following table.

(3) Where applications are made at the same time seeking an identical change to the terms of more than one marketing authorisation, and those applications are based on identical data, fees are payable as for a grouped variation.

(4) References in this paragraph to a grouped variation being "led" by a particular type of variation indicate that the principal variation in that group is a variation of that type.

Type of variation	F23 …	F24 …	F24 …
Single variations; one change for each product			
Extension:			
Change of strength or potency or the addition of a new strength or potency:	6,670	F24 …	F24 …
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,415	F24 …	F24 …
Change of route of administration, or the addition of a new one, of—			
(i) an immunological product, or a pharmaceutical product for a **[**F25non-food-producing**]** animal:	5,390	F24 …	F24 …
(ii) a pharmaceutical product for a food-producing animal:	7,135	F24 …	F24 …
Change or addition of a food producing target species:	9,620	F24 …	F24 …
Change of active substance, including:	8,415	F24 …	F24 …

Type of variation	*F23*	*F24*	*F24*
	…	…	…
use of a different salt, ester, complex or derivative of the same therapeutic moiety:			
use of a different biologically active substance with a slightly different molecular structure:			
modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source:			
use of a new ligand or coupling mechanism for a radiopharmaceutical:			
change of the extraction solvent or change of the ratio of herbal drug to herbal drug preparation:			
Change of bioavailability:	8,415	F24 …	F24 …
Change of pharmacokinetics:	8,415	… F24 …	F24 …
Simultaneous application: fee for each additional product in the application:	2,895	F24 …	F24 …
Type II:	2,895	F24 …	F24 …
Type IB:	885	F24 …	F24 …
Type IA:	455	F24 …	F24 …

Grouped variations

Extension-led:

The fee for an application for an extension-led grouped variation is the fee for that extension as specified above plus —

(a) if there is one variation in addition to the extension, the fee for that variation as specified above; or

(b) if there is more than one variation in addition to the extension, the fee that would be payable for a grouped variation of that type as specified below.

Type II led:

For the first nine changes:	6,280	F24 …	F24 …

Type of variation	*F23*	*F24*	*F24*
	…	…	…
For each subsequent group of up to ten changes:	4,500	F24 …	F24 …
Type IB led:			
For the first nine changes:	1,770	F24 …	F24 …
For each subsequent group of up to ten changes:	4,500	F24 …	F24 …
Type IA led:			
For the first nine changes:	885	F24 …	F24 …
For each subsequent group of up to ten changes:	4,500	F24 …	F24 …

Extent Information

E9 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F22 Words in Sch. 7 para. 17 heading omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in Sch. 7 para. 17 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(i)**(ii)(aa); 2020 c. 1, Sch. 5 para. 1(1)

F24 Words in Sch. 7 para. 17 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(i)**(ii)(bb); 2020 c. 1, Sch. 5 para. 1(1)

F25 Words in Sch. 7 para. 17 substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **4(2)**

Application for a variation to a marketing authorisation dealt with under national or mutual recognition variation procedures. **N.I.**

17.—(1) This paragraph applies in relation to an application for a variation to one or more marketing authorisations except where paragraph 18, 19 or 21 applies.

(2) The fees for the variations to which this paragraph applies are set out in the following table.

(3) Where applications are made at the same time seeking an identical change to the terms of more than one marketing authorisation, and those applications are based on identical data, fees are payable as for a grouped variation.

(4) References in this paragraph to a grouped variation being "led" by a particular type of variation indicate that the principal variation in that group is a variation of that type.

Type of variation	*National*	*UK is the reference member State*	*UK is a concerned member State*
Single variations; one change for each product			
Extension:			
Change of strength or potency or the addition of a new strength or potency:	6,670		1,998
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,415		2,301
Change of route of administration, or the addition of a new one, of—			
(i) an immunological product, or a pharmaceutical product for a **[**[F43]non-food-producing**]** animal:	5,390		1,737
(ii) a pharmaceutical product for a food-producing animal:	7,135		2,058
Change or addition of a food producing target species:	9,620		2,547
Change of active substance, including:	8,415		2,301
use of a different salt, ester, complex or derivative of the same therapeutic moiety:			
use of a different biologically active substance with a slightly different molecular structure:			
modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source:			
use of a new ligand or coupling mechanism for a radiopharmaceutical:			
change of the extraction solvent or change of the ratio of herbal drug to herbal drug preparation:			
Change of bioavailability:	8,415		2,301
Change of pharmacokinetics:	8,415		2,301
Simultaneous application: fee for each additional product in the application:	2,895		1,011

Type of variation	*National*	*UK is the reference member State*	*UK is a concerned member State*
Type II:	2,895	6,030	1,872
Type IB:	885	1,325	531
Type IA:	455	685	273

Grouped variations

Extension-led:

The fee for an application for an extension-led grouped variation is the fee for that extension as specified above plus —

(a) if there is one variation in addition to the extension, the fee for that variation as specified above; or

(b) if there is more than one variation in addition to the extension, the fee that would be payable for a grouped variation of that type as specified below.

Type II led:

For the first nine changes:	6,280	12,060	3,768
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Type IB led:

For the first nine changes:	1,770	2,650	1,062
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Type IA led:

For the first nine changes:	885	1,325	531
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Extent Information

E27 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F43 Words in Sch. 7 para. 17 substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **4(2)**

Application for a variation to a marketing authorisation dealt with under worksharing procedures E+W+S

18.—(1) This paragraph applies in relation to an application for a variation to a marketing authorisation dealt with in accordance with worksharing procedures as set out in Article 20 of Commission Regulation (EC) No 1234/.

[F26(2) The fees for a worksharing application are specified in the following table.**]**

F27(3) . . . . . .

F27(4) . . . . . .

F27(5) . . . . . .

Type of application	F28 …	F29 …			F29 …		
		F29 …	F29 …	F29 …	F29 …	F29 …	F29 …
Worksharing applications							
The following fees apply for each change to each product:							
Type II							
		F29	F29	F29	F29	F29	F29
For the first nine changes:	6,240	…	…	…	…	…	…
For each subsequent group of up to ten changes:	4,500	F29 …	F29 …	F29 …	F29 …	F29 …	F29 …
Type IB		…					
		F29	F29	F29	F29	F29	F29
For the first nine changes:	1,770	…	…	…	…	…	…
For each subsequent group of up to ten changes:	4,500	F29 …	F29 …	F29 …	F29 …	F29 …	F29 …

Textual Amendments

F26 Sch. 7 para. 18(2) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(j)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Sch. 7 para. 18(3)-(5) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(j)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Sch. 7 para. 18 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(j)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F29 Words in Sch. 7 para. 18 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(j)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for a variation to a marketing authorisation dealt with under worksharing procedures N.I.

18.—(1) This paragraph applies in relation to an application for a variation to a marketing authorisation dealt with in accordance with worksharing procedures as set out in Article 20 of Commission Regulation (EC) No 1234/.

(2) The fee for a worksharing application, involving marketing authorisations obtained by a national procedure in the United Kingdom only, is the fee specified in the following table in the column headed "UK Only".

(3) The fee for a worksharing application, involving marketing authorisations obtained through a national procedure in the United Kingdom and any other member State, is specified in the following table by reference to the United Kingdom's role in the procedure, as "UK Reference Authority", "UK Co-Reference Authority" or "Other".

(4) The fee for a worksharing application, involving at least one marketing authorisation obtained through the mutual recognition or decentralised procedure, is specified in the following table by reference to the United Kingdom's role in the procedure, as "UK Reference Authority", "UK Co-Reference Authority" or "UK Concerned member State".

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

Type of application	*UK Only*	*Where the application involves nationally authorised products in more than one member State*			*Application involves mutually recognised products*		
	UK Only	**UK Reference Authority**	**UK Co-Reference Authority**	**Other**	**UK Reference Authority**	**UK Co-Reference Authority**	**UK Concerned member State**
Worksharing applications							
The following fees apply for each change to each product:							
Type II							
For the first nine changes:	6,240	12,060	7,485	12,060	13,265	6,745	3,372
For each subsequent group of up to ten changes:	4,500	4,500	4,500	4,500	4,500	4,500	2,700
Type IB							
For the first nine changes:	1,770	2,650	2,120	2,650	2,915	1,905	954
For each subsequent group of up to ten changes:	4,500	4,500	4,500	4,500	4,500	4,500	2,700

Extent Information

E28 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for an extension dealt with under the decentralised procedure where the United Kingdom is the reference member State E+W+S

F30 19. . . . . . .

Extent Information

E10 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F30 Sch. 7 para. 19 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(k)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for an extension dealt with under the decentralised procedure where the United Kingdom is the reference member State **N.I.**

19. 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 17, with the addition of the supplementary fees in the following table (save that, where the application is for the addition of more than one species, only one supplementary fee applies).

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

Application	*Supplementary fee (£)*
Pharmaceutical product for a food-producing animal – one member State:	3,705
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:	120

Extent Information

E29 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Provision of information relating to the recognition of a United Kingdom marketing authorisation or an extension **E+W+S**

F31 20. . . . . . .

Extent Information

E11 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F31 Sch. 7 para. 20 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(k)**; 2020 c. 1, Sch. 5 para. 1(1)

Provision of information relating to the recognition of a United Kingdom marketing authorisation or an extension **N.I.**

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

(2) Those fees also apply where a marketing authorisation has been granted in more than one member State, the holder applies for an extension for that marketing authorisation and the United Kingdom acts as reference member State.

(3) 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.

(4) Where the information to be provided relates to a product granted a marketing authorisation using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of Directive 2001/82/EC the fees are—

Application	*Fee (£)*
Provision of information to—	
one member State:	4,165
each additional member State:	530

(5) 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
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) 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.

(6) 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.

Extent Information

E30 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Exception for a variation relating to animal testing **E+W+S**

21. If the only purpose of a variation is to remove animal testing or to reduce the numbers of animals used in testing, no fee is payable for the variation [F32]....

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F32 Words in Sch. 7 para. 21 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(l)**; 2020 c. 1, Sch. 5 para. 1(1)

Exception for a variation relating to animal testing **N.I.**

21. If the only purpose of a variation is to remove animal testing or to reduce the numbers of animals used in testing, no fee is payable for the variation in the case of a national authorisation, and the United Kingdom element of the fee for the variation is not payable for an authorisation obtained through the mutual recognition procedure or the decentralised procedure.

Extent Information

E31 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for the renewal of a [F33]... marketing authorisation E+W+S

22.—(1) The fee for an application for the renewal of a marketing authorisation is £1,360.

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

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F33 Word in Sch. 7 para. 22 heading omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(m)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for the renewal of a national marketing authorisation N.I.

22.—(1) The fee for an application for the renewal of a marketing authorisation is £1,360.

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

Extent Information

E32 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure E+W+S

[F34]**23.** . . . . . .

Extent Information

E14 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F34 Sch. 7 para. 23 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(n)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure N.I.

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.

Extent Information

E33 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Registration of a homeopathic remedy E+W+S

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	*Fees(£)*
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 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 F35	
...—	
not more than five stocks:	160
more than five stocks:	375

Extent Information

E15 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F35 Words in Sch. 7 para. 24 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(o)**; 2020 c. 1, Sch. 5 para. 1(1)

Registration of a homeopathic remedy N.I.

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	*Fees(£)*
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 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

Extent Information

E34 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Renewal of a homeopathic remedy

25. The fee for the renewal of a homeopathic remedy is £320.

Annual fees for marketing authorisations

26.—(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.

(2) The annual fee, rounded to the next £1, is—

$$£\frac{0.67T}{100} + £230n$$

where—

(a) T is the annual turnover in the previous calendar year;

(b) 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 annual fee, rounded to the next £1 is—

$$£\frac{0.67T}{100} + £200n$$

where—

(a) T is the annual turnover in the previous calendar year;

(b) 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

27.—(1) The Secretary of State may at any time require an audit certificate in support of a statement of turnover.

(2) If the holder of the marketing authorisation does not provide an audit certificate before the date stipulated in the demand, an additional fee is payable for that year of £11,300 plus an additional £2,245 in respect of each marketing authorisation held.

(3) 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 a further certificate and specify what further

assurances are needed; and if these are not provided by the required date, the additional fee specified in sub-paragraph (2) is payable.

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

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) £3,040; or

(b) £530 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 for the variation of a manufacturing authorisation is—

(a) £636 if the variation requires scientific or pharmaceutical assessment;

(b) £443 if the variation only involves a change of ownership;

(c) £210 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and

(d) otherwise £350.

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—

(a) £3,435 for a site in the United Kingdom;

(b) £3,270 for a site outside the United Kingdom.

(2) The fee for each inspection after a standard authorisation has been granted is (in each case) the same as the fee specified in paragraph (1).

(3) 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 £1,635.

(4) The fee to vary an authorisation is £305 if no further inspection is required, and otherwise is the full application fee.

Annual fees

31.—(1) An annual fee of £550 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 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 (£)*	
	United Kingdom site	*Site outside United Kingdom*
Super site	24,071	22,867
Major site	16,785	15,946
Standard site	6,661	6,327
Minor site	4,757	4,519

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 (£)*	
	United Kingdom site	*Site outside the United Kingdom*
Super site	23,324	22,157
Major site	13,010	12,359
Standard site	8,244	7,832
Minor site	5,022	4,770

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 (£)*	
	United Kingdom site	*Site outside the United Kingdom*
Super site	14,180	13,471
Major site	8,325	7,909
Standard site	6,854	6,511
Minor site	3,789	3,600
If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals—		
Standard site	5,055	4,802
Minor site	2,728	2,592

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 (£)*	
	United Kingdom site	*Site outside the United Kingdom*
Super site	11,025	10,474
Major site	5,949	5,652
Standard site	4,917	4,671
Minor site	2,035	1,933

Test sites

37. The fee for the inspection of a test site is £3,344, or £3,177 for a site outside the United Kingdom.

Animal blood bank or equine stem cell centre authorisations

38.—(1) The fee for an authorisation to operate a blood bank is—

(a) on a first inspection £3,113; and

(b) on each subsequent inspection—

(i) £3,113 for a site in the United Kingdom; and

(ii) £2,966 for a site outside the United Kingdom.

(2) The fee for an authorisation to operate an equine stem cell centre is £3,427, and £3,092 for each subsequent inspection.

(3) The fee for a variation to an authorisation to operate a blood-bank or equine stem cell centre is £320.

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;

(b) £785 if the application is accompanied by an estimate that the first year's turnover will be less than £35,000; or

(c) £785 if the authorisation only relates to products classified as AVM-GSL, homeopathic remedies, or products authorised under Schedule 6 (exemptions for small pet animals).

(2) An applicant who has paid a fee of £785 on the grounds of turnover 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 £960 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) £515 if the variation requires scientific or pharmaceutical assessment;

(b) £430 if the variation only involves a change of ownership; and

(c) otherwise £300.

Annual fee for a wholesale dealer's authorisation

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

(a) £483; or

(b) £315, if—

(i) the holder certifies when making the payment that the turnover during the previous year was less than £35,000; or

(ii) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies;

(c) £215 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

(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—

(a) £3,058; or

(b) £1,442 if—

(i) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies; or

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

(c) £830 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

PART 5

Fees relating to feedingstuffs

Fees for approvals and annual fees relating to feedingstuffs in Great Britain

43.—(1) Subject to sub-paragraph (3) the fee for the application for approval of establishments manufacturing feedingstuffs and approval of distributors of feedingstuffs in Great Britain is £70.

(2) An annual fee of £70 is payable in respect of any such approval.

(3) No fee is payable under sub-paragraph (1) in respect of an establishment where specified feed additives are manufactured if a veterinary medicinal product intended to be incorporated into feedingstuffs is manufactured at that establishment in accordance with a manufacturing authorisation.

(4) Fees relating to feedingstuffs are payable with the application or on invoice for the subsequent annual fee.

(5) Where more than one manufacturing activity is carried out at one establishment only one fee (the highest) is payable.

Inspection fees relating to feedingstuffs in Great Britain

44. Fees for the inspection of establishments manufacturing or distributing feedingstuffs in Great Britain are in accordance with the following table.

Inspection fees

	Type of establishment inspected	*Fee payable (£)*
1	Establishment manufacturing a specified feed additive:[(1)]	1,810

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

	Type of establishment inspected	*Fee payable (£)*
2	Establishment manufacturing a premixture:	1,090
3	Establishment manufacturing feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs:	1,090
4	Establishment manufacturing 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:	961
5	Establishment manufacturing feedingstuffs using premixtures or specified feed additive complementary feedingstuffs containing specified feed additives when the feedingstuffs are to be placed on the market:	405
6	Establishment manufacturing 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:	320
7	Establishment manufacturing feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs:	240
8	Establishment distributing specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or complementary feedingstuffs containing veterinary medicinal products:	227

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

Fees payable in relation to feedingstuffs in Northern Ireland E+W+S

F36 45. . . . . . .

Extent Information

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F36 Sch. 7 para. 45 omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(10)**

Fees payable in relation to feedingstuffs in Northern Ireland **N.I.**

45.—(1) The annual fees payable for the approval of establishments manufacturing and distributing feedingstuffs in Northern Ireland are in accordance with the following table.

(2) Fees are payable with the application or, for the subsequent annual fee, on invoice.

(3) Where more than one manufacturing activity is carried out at one establishment only the highest fee is payable.

Approval fees

	Type of establishment	*Fee payable (£)*
1	Establishment manufacturing a specified feed additive[(a)]:	545
2	Establishment manufacturing a premixture:	435
3	Establishment manufacturing feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs:	435
4	Establishment manufacturing 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:	320
5	Establishment manufacturing feedingstuffs using premixtures or specified feed additive complementary feedingstuffs containing specified feed additives when the feedingstuffs are to be placed on the market:	170
6	Establishment manufacturing 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:	131
7	Establishment manufacturing feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs:	110
8	Establishment distributing specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products:	70

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

Extent Information

E35 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Fees relating to premises for supply by suitably qualified persons

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

(a) £265; 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

(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

(ii) companion animals £70.

PART 6

General

Testing samples

47. 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 E+W+S

48.—(1) The fee for an animal test certificate is **[**[F37]£815**]**.

(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.

[F38](3) . . . . . .

(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).

Extent Information

E17 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F37 Sum in Sch. 7 para. 48(1) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(p)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F38 Sch. 7 para. 48(3) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(p)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Animal test certificates N.I.

48.—(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).

Extent Information

E36 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Importation of a veterinary medicinal product for treatment under the cascade E+W+S

49.—(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—

F39(a) . . . . . .

(b) £30 if the veterinary medicinal product is authorised in **[**F40another**]** 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.

Extent Information

E18 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F39 Sch. 7 para. 49(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(q)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F40 Word in Sch. 7 para. 49(1)(b) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(q)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Importation of a veterinary medicinal product for treatment under the cascade N.I.

49.—(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.

Extent Information

E37 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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 **[**[F41]£760**]** .

(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.

Textual Amendments

F41 Word in Sch. 7 para. 50 substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **4(3)**

Specific batch control

[[F42]**51.** The fee for an authorisation to release a veterinary medicinal product under specific batch control is—

(a) £560; and

(b) £100 for each additional batch affected by the same issue where the specific batch control application is made at the same time.**]**

Textual Amendments

F42 Sch. 7 para. 51 substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **4(4)**

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 other than autogenous vaccines 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.

Provision of advice

54. The fee for an application for written advice from the Secretary of State as to whether or not a product requires a marketing authorisation is £885.

Appeals to the Veterinary Products Committee

55. The fee for an appeal to the Veterinary Products Committee is £1,500.

Fee relating to an appointed person

56. 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

57.—(1) The fee for the inspection of a veterinary surgeon's practice premises is £350.

(2) The initial registration and annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is £34.

(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

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

Fees relating to an improvement notice

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

Non-payment of fees

60. Where any fee (other than any fee relating to a manufacturing authorisation or wholesale dealer's authorisation) is not paid, the Secretary of State may, after giving one month's written warning, suspend the processing of any application from the person who has not paid the fee.

Waiver or reduction of fees

61.—(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market 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

62.—(1) Where an application for a marketing authorisation, or any variation referred to in paragraph 17 or 18 as a Type II variation, an extension, an extension-led grouped variation or a Type II led grouped variation 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.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, SCHEDULE 7.