Guidance

Fees applied to animal medicine authorisation applications

Definitive fees charged for applications under Schedule 7 of the Great Britain Veterinary Medicines Regulations 2013 (as amended).

Definitive fees charged for applications are set out in Schedule 7 of the GB Veterinary Medicines Regulations 2013 (as amended) and are reproduced here for reference.

The fees listed below applies in Great Britain from [effective date for GB VMR].

The fees applicable in Northern Ireland are set out in [Schedule 7 of the Veterinary Medicines Regulations 2013]

Fees relating to Marketing Authorisations (MA)

MA for specific applications

The fee for an application for a marketing authorisation relating to:

- Any biotechnical process involving recombinant DNA or the controlled expression of genes;
- A veterinary medicinal product containing a novel active ingredient;
- A biopharmaceutical product.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-SABAS	Full complex application: Novel/Recombinant DNA/Biopharm	7	£45,000

MA for pharmaceutical or immunological veterinary medicinal product

Fees relating to a full dossier, pharmaceutical, immunological or biological that is not immunological application under Part 1 of Schedule 1 or a bibliographic application for a pharmaceutical veterinary medicinal product; where all or parts of the data dossier are addressed using published data.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-PIBFA	Full application: Basic	7(a)	£27,995

V23-PIB1A	1st additional strength Full Simultaneous Application	7(a)	£4,590
V23-PIBSA	Each subsequent additional strength	7(a)	£1,465

Fee for a generic MA - generic application

Fees for a generic marketing authorisation; by referring to the safety and efficacy aspects of a data package submitted in support of an already authorised veterinary medicinal product, which is referred to as the reference product.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-GNABH	Generic Hybrid Base fee	15A	£13,950
V23-GNABN	Generic Normal Base fee	15A	£12,390
V23-GNA1A	1st additional strength Simultaneous Application	15A	£4,590
V23-GNASA	Each subsequent additional strength	15A	£1,465

MA based on informed consent

The fee for applications using identical data submitted simultaneously or on the basis of informed consent; where you cross refer to safety and efficacy parts of the data package for an identical, already authorised product, which is referred to as the parent.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**

V23-ICID	Informed Consent Application	11	£1,465

Fees for exceptional MA for a pharmaceutical product

Fees for an exceptional provisional or limited pharmaceutical MA, where there is no other product with a full UK marketing authorisation, and it is based on provisional or limited data.

Pharmaceutical Provisional Marketing Authorisation

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-J1130	Exceptional Provisional Pharmaceutical: -Base Fee	12	£12,015
V23-K1080	Exceptional Provisional Pharmaceutical: For A Food Producing Animal	12	£3,905
V23-K1090	Additional fee for each active ingredient not previously authorised for Food Producing Animals in UK	12	£5,850
V23-K1100	Additional fee for each active ingredient not previously authorised for Non-Food Producing Animals in UK	12	£4,910
V23-K1150	Fee for each additional pack type	12	£710

V23-K1160	Additional fee for each active ingredient (Food Producing Animal Application)	12	£5,955
V23-K1170	Additional fee for each active ingredient (Non-food producing animal Application)	12	£3,800
V23-K1180	Additional fee for each additional food producing species	12	£2,965
V23-K1190	Additional fee for each additional non-food-producing species	12	£1,485
V23-K1210	Additional fee for each additional recommended route of administration (food producing animal)	12	£2,185
V23-K1220	Additional fee for each additional recommended route of administration (non-food producing animal)	12	£710
V23-K1110	Simultaneous applications - fee for each additional product in the application	12	£2,895

V23-K2090	Additional fee for each active ingredient not previously authorised for Food Producing Animals in UK	12	£3,732
V23-K2100	Additional fee for each active ingredient not previously authorised for Non-Food Producing Animals in UK	12	£3,262
V23-K2150	Fee for each additional pack type	12	£370
V23-K2160	Additional fee for each active ingredient (Food Producing Animal Application)	12	£3,232
V23-K2170	Additional fee for each active ingredient (Non-food producing animal Application)	12	£2,155
V23-K2180	Additional fee for each additional food producing species	12	£1,985
V23-K2190	Additional fee for each additional non-food-producing species	12	£1,247
V23-K2210	Additional fee for each additional recommended route of	12	£1,347

	administration (food producing animal)		
V23-K2220	Additional fee for each additional recommended route of administration (non-food producing animal)	12	£608
V23-K2110	Simultaneous applications - fee for each additional product in the application	12	£1,447

Fee for Pharmaceutical Limited MA

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-J1150	Exceptional Limited Pharmaceutical: Base Fee	12	£6,765
V23-K2080	Exceptional Limited Pharmaceutical: For A Food Producing Animal	12	£1,952

Fee for exceptional MA for an Immunological or Biological Non-immunological product

Fees for an exceptional immunological or biological non-immunological Marketing Authorisation, where there is no other product with a full UK marketing authorisation, and it is based on provisional or limited data.

Immunological or Biological Non-immunological Provisional Marketing Authorisation

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR

			2013 (as amended)]
V23-J3040	Exceptional Provisional Immunological/Biological Non-immunological: Base Fee	13	£10,810
V23-K304-110	Additional fee for each and/or combination of active ingredients not previously authorised in the UK	13	£5,650
V23-K304-120	Additional fee for each and/or combination of adjuvants/preservatives not previously authorised in the UK.	13	£1,350
V23-K304-140	Additional fee for each antigenic component.	13	£1,190
V23-K304-200	Additional fee for each additional species (first species included in base fee).	13	£4,060
V23-K304-230	Additional fee for each additional route of administration (first route of administration included in base fee).	13	£4,060
V23-K304-304	Simultaneous applications - fee for	13	£2,895

	each additional product in the application		
V23-K305-110	Additional fee for each and/or combination of active ingredients not previously authorised in the UK	13	£3,702
V23-K305-120	Additional fee for each and/or combination of adjuvants/preservatives not previously authorised in the UK.	13	£672
V23-K305-140	Additional fee for each antigenic component.	13	£675
V23-K305-200	Additional fee for each additional species (first species included in base fee).	13	£2,690
V23-K305-230	Additional fee for each additional route of administration (first route of administration included in base fee).	13	£2,690
V23-K305-304	Simultaneous applications - fee for each additional product in the application	13	£1,447

Fee for Immunological and Biological Non-immunological Limited MA

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR**

			2013 (as amended)]
V23-J3050	Exceptional Limited Immunological/Biological Non-immunological: Base Fee	13	£5,887

Fee for the conversion from an exceptional MA to a full MA

[Explanatory notes to help customers]

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-K115-311	Fee to convert an Exceptional Marketing Authorisation to a full Marketing Authorisation	14	£3,000

Application fee for reassessment of an exceptional MA

[Explanatory notes to help customers]

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-REMA	Exceptional Marketing Authorisation: First reassessment	22	£305
V23-REMAS	Exceptional Marketing Authorisation: Repeated reassessment	22	£1,360

Fee payable by manufacturers

Fee for variation to a MA

Fees to apply for a variation to one or more marketing authorisation.

- Variations to remove animal testing or to reduce the numbers of animals used in testing, will incur no fee.
- A simultaneous application for the same change(s) to multiple products, and those based on identical data, will be charged as a grouped variation.
- Grouped variation fees will be 'led' by the most complex variation type contained within the application.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-VSIP	Standard Variation Requiring Assessment (VRA-S)	17	£2,895
V23-VRIP	Reduced Variation Requiring Assessment (VRA-R)	17	£885
V23-VANFP	Extension Variation Requiring Assessment (VRA-E) – New route of administration (Non-Food Species)	17	£5,390
V23-VAFPA	Extension Variation Requiring Assessment (VRA-E) – New route of administration (Food Species)	17	£7,135
V23-VCB	Extension Variation Requiring Assessment (VRA-E)	17	£8,415

	– Change of bioavailability.		
V23-VCBMS	Extension Variation Requiring Assessment (VRA-E) – Change of biological active substance.	17	£8,415
V23-VCBMC	Extension Variation Requiring Assessment (VRA-E) – Change to the antigen vector or the source material.	17	£8,415
V23-VCP	Extension Variation Requiring Assessment (VRA-E) – Change of Pharmacokinetics.	17	£8,415
V23-VSA1A	Extension Variation Requiring Assessment (VRA-E) – Simultaneous application.	17	£1,465
V23-VNA	Variations not requiring assessment (VNRA)	17	£455
V23-VGS19	Grouped Variation: Standard led for the first 9 changes/products	17	£6,280

V23-VGSS5	Each subsequent group of up to 5 changes/products	17	£2,250
V23-VGR19	Grouped Variation: Reduced led for the first 9 changes/products	17	£1,770
V23-VGRS5	Each subsequent group of up to 5 changes/products	17	£2,250

Registration of a Veterinary Homeopathic Remedy

Fee for a veterinary homeopathic remedy registration prepared from homeopathic stocks using a homeopathic manufacturing procedure.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-HA10	Homeopathic r-emedy; formulation and stocks not assessed before, up to 5 stocks	24	£760
V23-HA20	Homeopathic remedy; formulation and stocks not assessed before, > 5 stocks	24	£985
V23-HA30	Homeopathic remedy; either formulation or stocks not assessed	24	£455

	before, up to 5 stocks		
V23-HA40	Homeopathic remedy; either formulation or stocks not assessed before, > 5 stocks	24	£665
V23-HA50	Homeopathic remedy; formulation and stocks assessed before, up to 5 stocks	24	£160
V23-HA60	Homeopathic remedy; formulation and stocks assessed before, > 5 stocks	24	£375
V23-HE10	Homeopathic remedy; already authorised for humans in UK, – up to 5 stocks	24	£160
V23-HE20	Homeopathic remedy; already authorised for humans in UK, > 5 stocks	24	£375

Annual fees for MA

The holders of UK marketing authorisations (MA) are required under the veterinary medicines regulations to pay annual fees to cover ongoing service costs.

There are two elements to the charge:

- Graded annual fee charged at 0.67% of your declared turnover
- Fixed annual fee; a fixed amount for each active marketing authorisation held

Guidance on how to complete and submit the turnover declaration form as the holder of a UK marketing authorisation can be found [here]

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-YFAF1	Fixed Annual Fee for each GB MA, NI MA and UK wide MA – turnover in the UK of authorised products equal to or greater than £230,000	26(2)	£ (0.67T / 100) + £230n Where "T" is the annual turnover and "n" is the number of active marketing authorisations
V23-YFAF2	Fixed Annual Fee for each GB MA, NI MA and UK wide MA – turnover in the UK of authorised products less than £230,000	26(3)	£ (0.67T / 100) + £200n Where "T" is the annual turnover and "n" is the number of active marketing authorisations
V23-YGAF1	Graded Annual Fee - % on turnover in the UK	26(2)	0.67%
	Failure to provide an audit certificate: Base fee	27(2)	£11,300
	Failure to provide an audit certificate: Fee for each MA held	27(2)	£2,245

Fees payable by manufacturers

Application for a manufacturing authorisation

A fee is payable in respect of each application for an authorisation to manufacture: an authorised veterinary medicine, a product marketed under Schedule 6 of the Regulations (Exemptions for small pet animals), an extemporaneous preparation for treating an animal under the cascade, or a blood product or stem cell product for non-food animals. Your manufacturing site will be inspected before authorisation is granted and the applicable inspection fee will apply.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-MANA1	Manufacturing Authorisation – New application (all types)	28	£762

Application for a variation of manufacturing authorisation

A fee is payable in respect of an application to vary a manufacturing authorisation relating to: an authorised veterinary medicine, a product marketed under Schedule 6 of the Regulations (Exemptions for small pet animals), an extemporaneous preparation for treating an animal under the cascade, or a blood product or stem cell product for non-food animals. There are two variation fees – one for simple administration only variations and another that requires scientific/pharmaceutical assessment by a GMP inspector (which may also require an inspection, for which the relevant inspection fee will apply).

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-MANV1	Manufacturing Authorisation – Variation Scientific or pharmaceutical assessment	29(a)	£684
V23-MANV2	Manufacturing Authorisation Variation Administration only	29(b)	£105

Annual fee (manufacturing authorisations)

Holders of a manufacturing authorisation relating to an authorised veterinary medicine, a product marketed under Schedule 6 of the Regulations (Exemptions for small pet animals), an extemporaneous preparation for treating an animal under the cascade, an autogenous vaccine or a blood product or stem cell product for non-food animals, are required to pay an annual fee to cover ongoing service costs.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-MAAF1	Annual fee for each manufacturing authorisation held	31	£575

Inspection of a site where an extemporaneous preparation for administration under the cascade is manufactured

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-ICS1A	Inspection fee for cascade Super Site – UK Site	30(2)	£21,416
V23-ICS1B	Inspection fee for cascade Super Site – Non-UK Site	30(2)	£22,710
V23-ICM1A	Inspection fee for cascade Major Site – UK Site	30(2)	£12,850
V23-ICM1B	Inspection fee for cascade Major Site – Non-UK Site	30(2)	£14,144

V23-ICT1A	Inspection fee for cascade Standard Site – UK Site	30(2)	£6,425
V23-ICT1B	Inspection fee for cascade Standard Site – Non-UK Site	30(2)	£7,719
V23-ICN1A	Inspection fee for cascade Minor Site – UK Site	30(2)	£4,283
V23-ICN1B	Inspection fee for cascade Minor Site – Non-UK Site	30(2)	£5,577

Application and Assessment for an authorisation to manufacture an autogenous vaccine

A fee is payable in respect of each application for an authorisation to manufacture an autogenous vaccine. Your application will be scientifically assessed, and your manufacturing site will be inspected before the authorisation is granted. The applicable inspection fee will apply

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-AASA	Initial Scientific assessment of Autogenous Vaccine	30A(1)	£6,962

Inspection of a site where an autogenous vaccine is manufactured

AVA manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-IVS1A	Inspection fee for Autogenous Vaccine for Super site UK	30A(2)	£21,416
V23-IVS1B	Inspection fee for Autogenous Vaccine for Super site – Non-UK Site	30A(2)	£22,710
V23-IVM1A	Inspection fee for Autogenous Vaccine for Major site UK	30A(2)	£12,850
V23-IVM1B	Inspection fee for Autogenous Vaccine for Major site – Non-UK site	30A(2)	£14,144
V23-IVT1A	Inspection fee for Autogenous Vaccine for Std site UK	30A(2)	£6,425
V23-IVT1B	Inspection fee for Autogenous Vaccine for Std Site – Non-UK site	30A(2)	£7,719
V23-IVN1A	Inspection fee for Autogenous Vaccine for Minor site UK	30A(2)	£4,283
V23-IVN1B	Inspection fee for Autogenous Vaccine	30A(2)	£5,577

	for Minor site – Non-UK site		

Assessment of a variation of an authorisation to manufacture an autogenous vaccine

A fee is payable in respect of an application to vary an autogenous vaccine. There are three fees – one for simple administration only variations and two that require scientific/pharmaceutical assessment (depending on the nature of the changes being made, an inspection may also be required. The relevant inspection fee will apply).**Fee Code**	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-AVCV1	Variation Complex Scientific or Pharmaceutical Assessment	30B(a)	£2,895
V23-AVSV2	Variation Simple Scientific or Pharmaceutical Assessment	30B(b)	£885
V23-AVAV3	Variation Administrative Scientific	30B(c)	£455

Inspection of a site where an immunological veterinary medicine is manufactured

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-IIS1A	Inspection fee for Immunological Super site UK	33	£32,124
V23-IIS1B	Inspection fee for Immunological Super site non-UK	33	£33,418
V23-IIM1A	Inspection fee for Immunological Major site UK	33	£21,416
V23-IIM1B	Inspection fee for Immunological Major site Non-UK	33	£22,710
V23-IIT1A	Inspection fee for Immunological Standard site UK	33	£10,708
V23-IIT1B	Inspection fee for Immunological Standard site Non-UK	33	£12,002
V23-IIN1A	Inspection fee for Immunological Minor site UK	33	£6,425

V23-IIN1B	Inspection fee for Immunological Minor site Non-UK	33	£7,719

Inspection of site where a sterile veterinary medicine is manufactured

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-ISS1A	Inspection fee for Sterile Super site UK	34	£27,841
V23-ISS1B	Inspection fee for Sterile Super site UK	34	£29,135
V23-ISM1A	Inspection fee for Sterile Major site UK	34	£19,274
V23-ISM1B	Inspection fee for Sterile Major site Non-UK	33	£20,569
V23-IST1A	Inspection fee for Sterile Standard site UK	34	£10,708
V23-IST1B	Inspection fee for Sterile Standard site Non-UK	34	£12,002
V23-ISN1A	Inspection fee for Sterile Minor site UK	34	£6,425

V23-ISN1B	Inspection fee for Sterile Minor site Non-UK	34	£7,719

Inspection of site where no Immunological or Sterile veterinary medicines are manufactured

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-INS1A	Inspection fee for-non-Immunological/non-Sterile Super site UK	35	£21,416
V23-INS1B	Inspection fee for-non-Immunological/non-Sterile Super site Non-UK	35	£22,710
V23-INM1A	Inspection fee for-non-Immunological/non-Sterile Major site UK	35	£12,850
V23-INM1B	Inspection fee for-non-Immunological/non-Sterile Major site Non-UK	35	£14,144
V23-INT1A	Inspection fee for-non-Immunological/non-	35	£8,566

	Sterile Standard site UK		
V23-INT1B	Inspection fee for-non-Immunological/non-Sterile Standard site Non-UK	35	£9,861
V23-INN1A	Inspection fee for-non-Immunological/non-Sterile Minor site UK	35	£4,283
V23-INN1B	Inspection fee for-non-Immunological/non-Sterile Minor site Non-UK	35	£5,577
V23-INT6A	Inspection fee for Sch 6 products Standard site UK	35	£3,212
V23-INT6B	Inspection fee for Sch 6 products Standard site Non-UK	35	£4,507
V23-INN6A	Inspection fee for Sch 6 products Minor site Non-UK	35	£2,142
V23-INN6B	Inspection fee for Sch 6 products Minor site Non-UK	35	£3,436

Inspection of a site where a veterinary medicine is assembled

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-IAS1A	Inspection fee for Assembly only Super site UK	36	£17,133
V23-IAS1B	Inspection fee for Assembly only Super site Non-UK	36	£18,427
V23-IAM1A	Inspection fee for Assembly only Major site UK	36	£10,708
V23-IAM1B	Inspection fee for Assembly only Major site Non-UK	36	£12,002
V23-IAT1A	Inspection fee for Assembly only Standard site UK	36	£6,425
V23-IAT1B	Inspection fee for Assembly only Standard site Non-UK	36	£7,719
V23-IAN1A	Inspection fee for Assembly only Minor site UK	36	£4,283

V23-IAN1B	Inspection fee for Assembly only Minor site Non-UK	36	£5,577

Inspection of a site where a veterinary medicine is tested

Manufacturing test sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-IT1A	Inspection fee for Test site UK	37	£3,212
V23-IT1B	Inspection fee for Test site Non-UK	37	£4,507

Inspection of an authorised non-food animal blood bank or non-food animal stem cell centre

Manufacturing sites are subject to a pre-authorisation inspection and thereafter regular risk-based inspections, for which a fee is payable.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-IBT1A	Inspection fee for Blood Bank site UK	38(1)a	£3,212
V23-IBT1B	Inspection fee for Blood Bank site Non-UK	38(1)b	£4,507

V23-IXT1A	Inspection fee for Stem cell product site UK	38(2)a	£2,142
V23-IXT1B	Inspection fee for Stem cell product site Non-UK	38(2)b	£3,436

Fees relating to a Wholesale Dealer's Authorisation (WDA)

Application for a WDA

In order to wholesale veterinary medicines you must have a valid wholesaler dealer's authorisation covering the types of products you wish to wholesale. If you don't have the appropriate authorisation you will need to submit an application and below is the fee you will be charged.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-WDA1	Wholesale Dealers application for authorisation	39(1)	£344

Annual Fees for a WDA

In order to maintain your authorisation you must pay an annual fee as set out below.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-WAN1	WDA Annual Fee	41	£427

Variation of a WDA

A fee is payable in respect of an application to vary a wholesale dealer's authorisation. There are two variation fees – one for simple administration only variations and another that requires scientific/pharmaceutical assessment by an inspector (which may also require an inspection, for which the relevant inspection fee will also apply)

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-WDAV1	WDA Variation scientific pharmaceutical assessment	40(a)	£265
V23-WDAV2	WDA Variation admin only	40(b)	£105

Inspection of WDA holder's site

Your WDA premises will need to be inspected before you receive your authorisation. A scientific variation may also require an inspection depending on the change you are making. We will also inspect each premises named on your authorisation on an ongoing risk basis. The inspection fees are listed below depending on the authorisation you hold. A reduced fee is applied if the authorisation for that premises only relates to products classified as AVM-GSL or homeopathic remedies, or products marketed under Schedule 6.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-IWDS1	Inspection fee WDA GDP (standard)	42(a)	£1,177
V23-IWDR1	Inspection fee WDA GDP (reduced)	42(b)	£877

Fees relating to Feedingstuffs

Fees for applications for authorisation and annual fees relating to feedingstuffs in GB

To manufacture or distribute feedingstuffs containing veterinary medicines or specified feed additives you must have an appropriate authorisation. If you don't have the appropriate authorisation you will need to submit an application and below is the fee you will be charged as well as the ongoing annual fees.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-FAPF1	Feed business application for authorisation	43(1)	£105
V23-FANF1	Feed business annual fee	43(2)	£122

Inspection fees relating to feedingstuffs in GB

Fees for the inspection of establishments manufacturing or distributing feedingstuffs in Great Britain are in accordance with the following table. Your premises will be inspected before your authorisation can be granted and will be inspected on an ongoing risk basis following authorisation.

Where more than one manufacturing activity is carried out at one premises by the same legal entity only one fee (the highest) is payable.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-IFSFA	Inspection Fee – Specified Feed Additive (SFA) manufacturer	44	£1,610
V23-IFIF	Inspection Fee – Intermediate feed manufacturer	44	£976

V23-IFCM	Inspection Fee – Commercial Feed manufacturer	44	£841
V23-IFFM	Inspection Fee – Farm-mixer	44	£476
V23-IFDT	Inspection Fee – Distributor or trader of Schedule 5 Products	44	£350

Fees relating to premises for retail supply by Suitably Qualified Persons (SQP)

If you want to hold an SQP retailer authorisation you must submit the relevant application, the fee associated is listed below. You will also be required to pay an annual fee as listed. We will inspect your premises on a risk basis, the inspection fees are listed below for each different type of premises.

The fee for an application for the authorisation of premises for the retail supply of veterinary medicinal products by SQPs is listed below, along with the annual fees for these premises. The fees for the inspection of sites authorised for the retail supply of veterinary medicinal products by SQPs is also listed.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-SQPAP	SQP retailer application for authorisation	46(1)a	£105
V23-SQPAN	SQP retailer annual fee	46(2)a	£57
V23-ISQPC	Inspection fee for SQP retailer-Companion animal medicine site	46(1A)	£285

V23-ISQPE	Inspection fee for SQP retailer - Equine medicine site	46(1A)	£285
V23-ISQPL	Inspection fee for SQP retailer - Livestock site	46(1A)	£338
V23-ISQPA	Inspection fee for SQP retailer – Avian site	46(1A)	£285

General

Testing samples

[Explanatory notes to help customers]

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-ATC1	Animal Test Certificate Fee	48(1)	£1,170
V23-ATCS	Animal Test Certificate – small scale trial	48(2)	£40
V23-ATCSV	Variation of the Animal Test Certificate - small scale trial	48(4)a	£40
V23-ATCOV	Variation of the Animal Test Certificate any other trial	48(4)b	£390

V23-ATCSR	Application renewal of Animal Test Certificate small scale	48(5)a	£40
V23-ATCOR	Application renewal of Animal Test Certificate any other trial	48(5)b	£190

Wholesale Dealer Import Certificate

If you are a wholesale dealer and want to hold and supply imported medicines on request of a valid Special Import Certificate (SIC) holder, you will need a Wholesale Dealer Import Certificate. A fee applies if 100 or more SICs naming the importing wholesale dealer were issued in the last 12 months.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-WDAIC	WDA Import Certificate Non-UK	50(1)	£760

Specific batch control

[Explanatory notes to help customers]

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-BC10	Specific Batch Control release fee	51(a)	£560
V23-BC15	Specific Batch Control each additional batch affected	51(b)	£100

Control tests of an immunological product

[Explanatory notes to help customers]

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-BC81A	Submission fee – control tests	7	£80

Export certificates

Export certificates are issued upon request to certify that the product you are exporting was manufactured in accordance with the UK marketing authorisation (MA), if there is one, or if not, that the manufacturer holds a certificate of good manufacturing practice, or manufacturing authorisation (ManA) in the UK for that type of product. Different certificate types are available depending on the requirement of the exporter.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-ECA1	Export certificate	53	£54

Provision of advice

[Explanatory notes to help customers]

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-ADV1	Application for written advice	54	£885
V23-ADVS1	Written advice – scientific	54A	£4,487

Appeals to the VPC

[Explanatory notes to help customers]

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-VA30	Appeal veterinary products committee	55	£1,500
V23-VA99	Referral to appointed person	56	£5,000

Fees for Veterinary Surgeon's Practice Premises (VPP)

If you have registered a VPP you must pay an annual fee to the RCVS as below and we will inspect your premises on a risk basis. The inspection fees are detailed below. Please note that a mixed practice is a premises supplying medicines to livestock in addition to any other category listed.

Fee Code	Description	GB VMR 2013 (as amended) Schedule 7 Para	Fee from [effective date for GB VMR 2013 (as amended)]
V23-VPRCV	Initial registration & fee (payable to the RCVS)	57(2)	£38
V23-IVPPC	Inspection fee for Companion animal VPP	57(1)	£536
V23-IVPPE	Inspection fee for Equine VPP	57(1)	£536
V23-IVPPL	Inspection fee for Livestock VPP	57(1)	£536

V23-IVPPM	Inspection fee for mixed practice VPP	57(1)	£698
V23-IVPPO	Inspection fee for any other type of VPP	57(1)	£451
V23-DCDV1	Fee for witnessing controlled drug destruction (special visit)	57A(a)	£142
V23-DCDI1	Fee for witnessing controlled drug destruction during an inspection	57A(b)	£31

Pharmacovigilance Inspections

MAHs are subject to regular risk-based inspections of their pharmacovigilance systems, in this respect:

"Large marketing authorisation holder" means a marketing authorisation holder who holds 30 or more marketing authorisations;

"Small marketing authorisation holder" means a marketing authorisation holder who holds fewer than 30 marketing authorisations.

Fee Code	**Description**	**GB VMR 2013 (as amended) Schedule 7 Para**	**Fee from [effective date for GB VMR 2013 (as amended)]**
V23-PILMA	Pharmacovigilance inspection fee large Marketing Authorisation holder	57B(1)a	£3,600
V23-PISMA	Pharmacovigilance Inspection fee small Marketing Authorisation holder	57B(1)b	£1,650