HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Fees for Veterinary Products

FIN-G0003-20
04 JANUARY 2021
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

ABBREVIATIONS

CMS	Concerned Member State
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
EDQM	European Directorate for the Quality of Medicines & HealthCare
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
HPRA	Health Products Regulatory Authority
MA	Marketing Authorisation
MR	Mutual Recognition
MRA	Mutual Recognition Agreement
PVPA	Parallel Veterinary Product Authorisation
RMS	Reference Member State
QP	Qualified Person
SPC	Summary of Product Characteristics
VPA	Veterinary Product Authorisation

INTRODUCTION

The Health Products Regulatory Authority is the competent authority for the authorisation of medicinal products for veterinary use. This guide is intended to assist applicants in identifying the correct category of fee to accompany applications for authorisation. It follows the order of the fees in the 'Fee Application Form (Veterinary)' and uses the fee code numbers in that form.

In this document, the term 'VPA range' means that the veterinary product authorisations belong to the same VPA company and have the same product trade name and active substance(s).

1 AUTHORISATION OF MEDICINES

1.1 New applications

1.1.1 Reduced dossier – standard

Fee codes **551-558, 561-565, 567** and **568** apply to applications for veterinary medicinal products containing established active substances which are already licensed in Ireland and which are submitted under the following articles of Directive 2001/82/EC:

- Article 13.1 (generics, including generics referring to an EU reference product)
- Article 13c (informed consent)

Codes **551-553** apply to national applications and the initial 120-day 'assessment step 1' of applications in the decentralised procedure where Ireland is the reference Member State (RMS).

Codes **555-557** apply to mutual recognition applications made to the HPRA where Ireland is a concerned Member State (CMS).

Within these two fee code groups, the fee categories are structured as follows. The basic fee codes apply to the initial application for the first form, strength and target species in a range. The codes for 'each additional form at the same time' apply to each application for an additional pharmaceutical form submitted at the same time as the initial application. The codes for 'each additional strength at the same time' apply to each application for an additional strength submitted at the same time as the initial application.

Where a National or outgoing MRP/Decentralised application has different target species, each additional species is charged fee code **562.** This fee is charged per product range included within an application and will be capped at €7,650. No additional target species fee is charged for minor species. For the classification of a species as major or minor, see Appendix II.

Code **558** applies to mutual recognition (MR) applications where Ireland is the RMS. This supplement is for the production and release of the assessment report and the handling and administration of the procedure. It is payable in addition to the appropriate national fee. Code **558** applies to the entire VPA range in the first MR procedure. National variation fees apply to any updating of the dossier prior to the MR procedure (see section 1.5.1) but no fees are charged for any updating of the dossier at the end of the MR procedure. For repeat use procedures, the fee code **558** supplement applies.

Code **554** applies to mutual recognition (MR) applications where Ireland is the RMS and where the MR application is made within 12 months of the national procedure ending.

Codes **563-565, 567** and **568** apply to applications in the decentralised procedure (DCP) where Ireland is either the RMS or a CMS.

Code **568** applies to mutual recognition and decentralised applications where Ireland is the RMS. This fee is applied per CMS per product range included in the same application. It also applies to repeat use procedures for each new CMS included. This fee is capped at €7,650.

Code **561** applies to each additional drug master file or plasma master file submitted with the application. There is no charge for the first master file for each active substance in an application. As an alternative to drug master files, companies may submit certificates of suitability from EDQM. Submission of these certificates does not attract any fee.

Reduced dossier standard fees also apply to duplicate applications.

Example 1, an application for an outgoing DCP for one pharmaceutical form in two strengths attracts a fee of:

€23,460	(Product X, 10 mg tablets) (fee code **567**)
€ 775	(Product X, 20 mg tablets) (fee code **564**)
€24,235	

Example 2, an application for an outgoing DCP with two pharmaceutical forms, each form having two strengths attracts a fee of:

€23,460	(Product X, 10 mg tablets) (fee code **567**)
€ 6,020	(Product X, 10 mg/5 ml oral solution) (fee code **563**)
€ 775	(Product X, 20 mg tablets) (fee code **564**)
€ 775	(Product X, 20 mg/5 ml oral solution) (fee code **564**)
€31,030	

Example 3, an application for an outgoing DCP with one pharmaceutical form, five strengths, and a total of three target species (cats, dogs, rabbits) attracts a fee of:

€23,460	(Product X, 40 mg spot-on) (fee code **567**)
€ 775	(Product X, 80 mg spot-on) (fee code **564**)
€ 775	(Product X, 100 mg spot-on) (fee code **564**)

€ 775	(Product X, 250 mg spot-on) (fee code **564**)
€ 775	(Product X, 400 mg spot-on) (fee code **564**)
€ 2,550	(second target species) (fee code **562**)
€29,110	

Example 4, an application for an outgoing DCP with one pharmaceutical form, three strengths, two target species, and 10 CMS attracts a fee of :

€23,460	(Product X, 10 mg tablets) (fee code **567**)
€ 775	(Product X, 20 mg tablets) (fee code **564**)
€ 775	(Product X, 40 mg tablets) (fee code **564**)
€ 2,550	(second target species) (fee code **562**)
€ 5,100	(10 CMS) (fee code **568** x10)
€32,660	

1.1.2 Reduced dossier – complex

Codes **531–538, 541-545, 547** and **548** apply to applications for veterinary medicinal products containing known active substances which have already been authorised in Ireland, and which are submitted under the following articles of Directive 2001/82/EC:

- Article 12.3 (full)
- Article 13.3 ('hybrid')
- Article 13.4 (similar biological)
- Article 13a (well-established use/bibliographical), and Article 13b (fixed combination)

The structure of the fee codes is the same as that described in section 1.1.1.

For MR applications where Ireland is the RMS, national variation fees apply to any updating of the dossier prior to the MR procedure (see section 1.5.1) but no fees are charged for any updating of the dossier at the end of the MR procedure.

For repeat use procedures, the fee code **558** supplement applies.

Hybrid and generic applications for a single product range where the hybrid relates to a new strength will be charged one single hybrid fee with the appropriate additional strength fees.

1.1.3 Complex dossier, new active substance

Codes **511-518 and 520-527**, apply to applications for medicinal products containing a new active substance not previously licensed in Ireland, and submitted under Article 12.3 of Directive 2001/82/EC.

The structure of the fee codes is the same as that described in section 1.1.1.

For MR applications where Ireland is the RMS, national variation fees apply to any updating of the dossier prior to the MR procedure (see section 1.5.1) but no fees are charged for any updating of the dossier at the end of the MR procedure. For repeat use procedures, the fee code **558** supplement applies.

1.2 Subsequent extension applications

Codes **529**, **530**, **571-575**, **577** and **614-620** refer to extension applications for additional pharmaceutical forms and strengths made subsequent to the first application. The extension fee codes do not differ between applications made under different legal bases. The structure of the fee codes is the same as those described in section 1.1.1.

1.3 Addition of a food-producing animal

Code **579** refers to National, MR and DCP applications to add a food producing animal to an existing authorisation. This fee applies to each target species added to the authorisation.

1.4 Switching applications

Code **578** applies to an application for changes to the legal supply classification of a veterinary medicinal product.

1.5 Variations

Variation fees are charged for each VPA which is varied (i.e. per VPA number), and for each change applied for. No fees are charged for Type IA (immediate notification) or Type IA (annual report) variations. An outgoing supplement fee is charged for MRP/DCP Type IA variations. Fees are charged for all other variations, including safety variations, whether requested by the HPRA or not.

Grouped and work-sharing applications which include multiple variations will be charged in accordance with the relevant fee for each variation included in the group or work-sharing application, up to a maximum of €5,055 (fee code **626**) per VPA range, €3,370 (fee code **630**) per VPA and €5,055 (fee code **613**) for work-sharing applications. The bulk fees (fee codes **626, 630** and **613**) do not apply to complex Type II group or work-sharing applications.

Reduced rates apply to bulk variations where the same change is made to three or more VPAs (within a VPA range). For changes to only one or two VPAs, each change for each VPA attracts the full-rate fee. 'VPA range' means that the veterinary product authorisations belong to the same VPA company and have the same product trade name and active substance.

Applications for variations to authorisations that are withdrawn by the applicant, will incur an administrative fee of up to 10% of the variation fee.

The variation procedure is not applicable to the transfer of an authorisation to another VPA holder, for which a transfer of ownership application must be made (see section 1.6).

1.5.1 National variations

Variations to national product authorisations are classified according to the Commission Regulations (EC) No. 1234/2008, as minor variations Type IA and IB and major variations Type II.

Fee code **591** and the reduced rate code **592** apply to Type IB variations, i.e. those changes which are not defined as Type IA or Type II.

When the supporting data is identical to the originator and the variations are submitted at the same time, no fees are charged for variations to informed consent applications.

Code **596** is the full-rate code for complex Type II variations, which are listed in Appendix I. This code is also applicable to any update to a dossier prior to an MR procedure where Ireland is the RMS and updating involves changes to the expert reports, Parts II, III or IV. The code also applies to certain 'extensions' as defined in Annex I of Commission Regulation (EC) No. 1234/2008, and listed in the appendix to this guideline. Code **606** is the reduced-rate fee which applies to bulk variations for the same change to three or more VPAs (within a VPA range).

For applications relating to the assessment of the same active substance master file for a number of products with the same company number, and where the applications have been submitted at the same time, the reduced rate fee will apply to the third and subsequent products.

Codes **597** and **601** are the full and reduced-rate codes for standard Type II variations, i.e. those changes which are classified as Type II but are not listed as complex in the appendix to this guide.

Code **597** also applies to any update to a dossier prior to an MR procedure where Ireland is the RMS and the updating involves only changes to Part IB (e.g. to bring the SPC and/or labelling into line with current guideline requirements).

Code **626** applies when the cost of multiple variations exceeds €5,055 per VPA range. This fee covers both national and MR Type IB and Type II applications.

Code **630** applies when the cost of multiple variations (submitted at the same time) to one VPA exceeds €3,370. This fee covers both national and MR Type IB and Type II applications.

Code **613** applies when the cost of a Type IB or a Type II work-sharing application exceeds €5,055. The bulk fees (fee codes **626, 630** and **613**) do not apply to group or work-sharing applications that include complex Type II variations (complex Type II variations are listed in the appendix).

1.5.2 Mutual recognition variations

The fees for mutual recognition (MR) variations apply to veterinary marketing authorisations granted following a mutual recognition or decentralised procedure.

1.5.2.1 MR variations where Ireland is the CMS

The mutual recognition fee codes apply to MR variations where Ireland is a CMS.

Fee code **594** and the reduced rate code **595** apply to Type IB variations, i.e. those changes which are not defined as Type IA or Type II.

Code **599** is the full-rate code for incoming complex Type II variations, which are listed in the appendix to this guide. The code also applies to certain 'extensions' as defined in Annex I of Commission Regulation (EC) No. 1234/2008, and listed in the appendix to this guideline. Code **600** is the reduced-rate fee which applies to bulk variations of the same change to three or more VPAs.

For applications relating to the assessment of the same active substance master file for a number of products with the same company number and where the applications have been submitted at the same time, the reduced rate fee will apply to the third and subsequent products.

Codes **602** and **603** are the full and reduced-rate codes for incoming standard Type II variations, i.e. those changes which are classified as Type II but are not listed in the appendix to this guide.

1.5.2.2 MR variations where Ireland is the RMS

Fee code **588** is an outgoing supplement and applies to Type IA MR/DCP variations where Ireland is the RMS. This fee covers the VPA range.

The mutual recognition fee codes **593**, **598** and **621** apply to mutual recognition variations where Ireland is the RMS. These fees are a supplement, paid in addition to the appropriate national variation fee(s) (see section 1.5.1 above), and cover the VPA range.

1.6 Transfer of ownership

These fee codes refer to the transfer of ownership of VPAs from one VPA holder to another VPA holder with a different legal entity.

Fee code **611** refers to the transfer of ownership of a VPA to a company which is related, i.e. a 'sister', 'mother' or 'daughter' company or a common corporate body formed from a takeover or merger. This fee is applied to the first marketing authorisation within the range. Fee code **652** applies to each additional marketing authorisation within the range. Codes **653** and **612** refer to the transfer between companies which are not related. These fees are applied as above.

Where bulk transfers are notified in advance, the first 10 VPAs are charged at the normal rate and thereafter are charged at €345 (fee code **612** or **652**) per transfer.

For transfer of ownership before the VPA has been granted, see section 3.1.

1.7 Renewals

There is no fee for renewal applications, however a supplement is payable for MR/decentralised applications where Ireland is the RMS. The fee code is **632** and a single supplement covers the VPA range.

1.8 Parallel imports

Code **607** applies to the first pharmaceutical form and strength of a product to be parallel-imported into Ireland. A separate fee is charged for each source country applied for, whether included in the initial application or applied for subsequently.

Code **609** applies to each additional strength per country, and code **610** applies to each additional pharmaceutical form per country, whether submitted at the same time or subsequently.
Example:

€ 3,590	(Product X, 10 mg tablets, from Greece and Portugal)
€ 1,070	(Product X, 20 mg tablets, from Greece and Portugal)
€ 1,070	(Product X, cream, from Greece and Portugal)
€ 5,730	

Code **654** applies to applications for parallel imports where the originator is not on the Irish market.

Code **608** refers to the transfer of ownership of parallel import licences. This fee covers the PVPA range.

Parallel import variations are charged the VPA variation fees where appropriate. See application form for a variation to a PVPA authorisation.

1.9 Homeopathic product registration

1.9.1 New applications

Codes **641** and **642** are for applications for certificate of registration for homeopathic medicinal products under the simplified registration scheme. The codes apply to national applications and decentralised applications where Ireland is CMS.

Codes **643** and **644** apply to incoming MR applications where Ireland is a CMS.

Each pharmaceutical dosage form of a product requires a separate application form and a separate fee, irrespective of the stock or potency used. An application for a series of dilutions (potencies) derived from the same stock or stocks is treated as a single application, provided all dilutions are mentioned in the same application.

1.9.2 Variations

Code **646** is for national variation applications. For bulk variations for the same change to two or more certificates, code **647** is the reduced rate fee which applies to the third and subsequent certificate.

Codes **648** and **649** apply to incoming MR variation applications where Ireland is a CMS.

1.10 Maintenance of authorisations or registrations

Codes **631, 639** and **640** are yearly fees for each VPA, which cover all aspects of routine dossier management and maintenance, including the work associated with on-going pharmacovigilance activities.

A reduced fee (code **631)** is applied to the first 10 VPAs and fee code **639** is applied to the subsequent VPAs. Fee code **640** applies to VPAs which are deemed to be dormant.

Dormant authorisations are defined as VPAs where the product is not marketed (excluding temporary cessation) as notified to the HPRA by 01 January of each year. Notification can be made by submitting a Marketing Status Notification form.

Where a VPA holder has less than 10 dormant authorisations, these will be charged at the dormant rate, the balance up to 10 at the reduced rate and all other authorisations charged at the standard rate.

Where a VPA holder has more than 10 dormant authorisations, these will be charged at the dormant rate, and all other authorisations charged at the standard rate.

VPAs that are withdrawn before 01 May will not be charged a maintenance fee for that year. VPAs withdrawn on 01 May and after that date will be charged a full year's fee.

Maintenance fees are payable annually and are invoiced to VPA holders during the course of the year.

A reduced maintenance fee (code **634**) applies to parallel import authorisations (PVPA).

A reduced annual maintenance fee (code **633**) applies to homeopathic products.

1.11 Batch-specific requests

The fee for batch-specific requests (code **721**) is payable per VPA. Where the change is identical across a number of VPAs held by the same MAH, only one batch-specific request fee will apply.

1.12 Classification

Code **582** relates to classification requests for a determination of the veterinary medicinal product status of a product. This fee will apply per product. Where an appeal on a determination is made, code **584** applies.

1.13 Service items

Code **580** applies to 'service items', i.e. applications for radiopharmaceuticals and veterinary medicinal products with severely limited but important uses for which no alternative authorised product exists. The designation of a product as a service item must be agreed with the HPRA in advance of the submission. A turnover cut-off is also considered and companies should be prepared to divulge their expected turnover when discussing the application for service item status with the HPRA. The designation of a medicinal product as a service item is subject to review at any time.

1.14 Clinical field trials

Clinical field trial applications are made under Animal Remedies legislation, Directive 2001/82/EU and S.I. No. 786 of 2007. *These are known as "research licences" under the applicable national legislation.*

Code **904** applies to a research trial for an investigational veterinary product unauthorised in the EU for use in a major species.

Code **905** applies to a research trial for an investigational veterinary product unauthorised in the EU for use in a minor species.

Code **906** applies to a research trial for a veterinary medicine product authorised in the EU for use in a major species.

Code **907** applies to a research trial for a veterinary medicine product authorised in the EU for use in a minor species.

Code **903** applies to variations to a current research trial licence.

For more information on the classification of a species as major or minor, see Appendix II.

2 MANUFACTURER'S LICENCE, INSPECTION AND CERTIFICATION

2.1 Manufacturer's licence

Code **670** applies to each application for a manufacturer's licence. There is no fee charged for the once-off renewal of an existing licence.

Codes **671, 673, 675** and **677** are annual fees payable in respect of each licence and are related to the size of the facility based on the numbers of 'relevant employees', defined as those involved directly in the manufacture of medicines, i.e. in production, quality control/assurance and engineering. In cases in which a manufacturer holds manufacturers' licences for medicinal products for both human and veterinary use, the total number of relevant employees will determine the site size and the fee per annum is 1.5 times the single authorisation fee.

A company is assigned a size category at the application stage. The company must notify the HPRA of a change in size classification. The new classification will be assigned to the company from the date of notification. The HPRA may also notify the company if our records show that there has been a change in size.

Code **679** applies to variations to licences in cases where the only change is an administrative change to the licence document. A single administrative fee will also apply to a variation to remove one or more contract manufacturers/laboratories regardless of the number of licences involved. Code **680** applies to variations involving technical assessment, e.g. requiring inspection or review of supplementary data. Where the same technical variation applies to two or more licences, the second and subsequent applications are charged at the fee code **679** rate.

Fee codes **679** and **680** also apply to variations to a GMP certificate issued to manufacturers of active substances.

When adding and removing a QP or the same key personnel, code **680** applies for both changes as they are subsequent to each other. This only applies when they are being added and removed in the same application. Any other removal will be charged the administrative fee code **679**.

Applications for manufacturers' licences and variations to authorisations that are incorrect or incomplete may incur a fee of up to 10% of the application/variation fee.

An inspection fee per day/hour per member of the inspection team is payable in relation to each inspection (see section 2.3 below).

2.2 Transfer of manufacturers' licences

Code **681** applies to the transfer of a manufacturer's licence to a company which is related, i.e. a 'sister', 'mother' or 'daughter' company or a common corporate body formed from a takeover or merger. Code **682** refers to transfers between unrelated companies.

2.3 Inspections

Codes **711** and **712** apply to:
- inspections that form part of the evaluation of an application for a new manufacturer's licence
- inspections of licensed manufacturers
- inspections of contract laboratories named in manufacturers' licences
- inspections of marketing authorisation holders and firms involved in pharmacovigilance activities
- inspections of manufacturers of active substances
- remote inspections / distant assessments

An inspection fee per day/hour per member of the inspection team is payable in relation to each inspection of each site.

In addition to the fees for each day of the inspection, travel time (max of five hours per inspector for travel within Ireland) will be charged together with the cost of expenses, including travel costs and subsistence for the following inspections:

Inspections of sites in a country that is not part of the European Economic Area. Accommodation costs will also be charged with the expenses listed above for these inspections.
- Inspections of sites not subject to licence under the European Communities (Animal Remedies) Regulations, e.g. manufacturers of active substances, marketing authorisation holders, firms involved in pharmacovigilance activities.
- Inspections of contract laboratories.
- Inspections conducted in response to suspected non-compliance with the principles of GMP, e.g. follow-up inspections, for-cause inspections.
- Inspections performed as a result of an application to vary a licence/authorisation.
- Inspections to review engineering installations.

2.3.1 Booking fees for Inspections

Fee code **713** is applicable to non-routine inspections requested by a MIA holder. This fee is non-refundable and will be credited against the inspection fee provided the inspection takes place on the pre agreed dates. If the dates are changed at the request of the authorisation holder the booking fee will be forfeited.

2.4 Export and other certificates

Code **691** is for export and other certificates, including Certificate of a Pharmaceutical Product, Free Sale Certificates, GMP Certificates for finished products and for active pharmaceutical ingredients, certificates of analysis and TSE declarations. There is no charge for certificates provided in relation to mutual recognition agreements (MRAs) on GMP inspection.

Code **692** is for urgent supply of the above certificates.

There is no fee charged for GMP certificates that are issued on satisfactory conclusion of an inspection. Fee codes **691** or **692** apply to requests for the reissue of a post-inspection GMP certificate.

Note: certificates for feed supplements must be obtained from the Department of Agriculture, Food and the Marine.

3 MISCELLANEOUS

3.1 Technical and administrative services

Codes **731** and **732** are daily and hourly charge-out rates which apply when the services of technical staff are sought, for example, assessments outside the authorisation process, IT consultancy. These fee codes may also apply to advice provided by the HPRA to professional advisors. These will be considered on a case-by-case basis.

Code **733** is a charge for non-routine administrative work, e.g. photocopying requested by companies, corrections required to the authorisation documents, etc. This code is also used for the transfer of an application for a VPA before the VPA has been granted. Where there are two or more VPAs in the product range, twice the code **733** fee is charged for the entire VPA range.

3.2 Requests for information

Code **581** relates to requests to the HPRA for information from the veterinary medicinal products' database. The fee is payable per request.

3.3 Appeals

Code **734** is the fee for a formal appeal to a decision of the Authority of the HPRA; it is refundable to the applicant if the appeal is successful.

APPENDIX I LIST OF TYPE II COMPLEX VARIATIONS

The following are classified as complex variations. Note that the variation numbers below relate to the numbers used in the European Commission Guideline on variation categories (2010/C 17/01).

Quality Changes – I Active Substance

B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier

b) Introduction of a new manufacturer of the active substance that is supported by an ASMF.
c) The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions, which may have a potential to change important quality characteristics of the active substance, such as qualitative and/or quantitative impurity profile requiring qualification, or physico-chemical properties impacting on bioavailability.
d) New manufacturer of material for which an assessment is required of viral safety and/or TSE risk.

B.I.a.2 Changes in the manufacturing process of the active substance

b) Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product.

B.I.e.1 Introduction of a new design space or extension of an approved design space for the active substance, concerning:

a) One unit operation in the manufacturing process of the active substance including the resulting in-process controls and/or test procedures.
b) Test procedures for starting materials/reagents/intermediates and/or the active substance.

B.I.e.2 Introduction of a post approval change management protocol related to the active substance

Quality Changes – II Finished Product

B.II.a.3 Changes in the composition (excipients) of the finished product

b) Other excipients.
2. Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the medicinal product.
4. Any new excipient that includes the use of materials of human or animal origin for which assessment is required of viral safety data or TSE risk.
5. Change that is supported by a bioequivalence study.

B.II.a.5 Change in concentration of a single-dose, total use parenteral product, where the amount of active substance per unit dose (i.e. the strength) remains the same.

B.II.b.3 Change in the manufacturing process of the finished product

b) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product.

B.II.c.3 Change in source of an excipient or reagent with TSE risk

b) Change or introduction of a TSE risk material or replacement of a TSE risk material from a different TSE risk material, not covered by a TSE certificate of suitability.

B.II.d.3 Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product

B.II.e.1 Change in immediate packaging of the finished product

b) Type of container.
2. Sterile medicinal products and biological/ immunological medicinal products.

B.II.g.1 Introduction of a new design space or extension of an approved design space for the finished product, excluding biologicals, concerning:

a) One or more unit operations in the manufacturing process of the finished product including the resulting in-process controls and/or test procedures
b) Test procedures for excipients/intermediates and/or the finished product.

B.II.g.2 Introduction of a post approval change management protocol related to the finished product

Safety, Efficacy and Pharmacovigilance changes - I Veterinary medicinal products

C.I.4 Variations related to significant modifications of the Summary of Product Characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance data – SPC sections 4.3, 4.9 and 5.1.
Only one complex fee will be charged for C.I.4 variations if the additional changes applied for are consequential to the main change.

C.I.6 Change(s) to therapeutic indication(s)

a) Addition of a new therapeutic indication or modification of an approved one.
(Note: complex fee not charged for a modification)

Safety, Efficacy and Pharmacovigilance changes - II Veterinary medicinal product – specific changes

C.II.1 Variations concerning a change to or addition of a non-food producing target species.

C.II.3 Changes to the withdrawal period for a veterinary medicinal product

C.II.4 Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue

C.II.5 Variations concerning the replacement of a strain for a veterinary vaccine against equine influenza.

Other categories of variations where there are substantial changes may be complex and will be considered on a case by case basis.

APPENDIX II CLASSIFICATION OF SPECIES AS MAJOR OR MINOR

The classification of species as major or minor is based on European Medicines Agency policy on minor use minor species (MUMS)/limited market.

Major species: Major species is defined by the Committee for Medicinal Products for Veterinary Use (CVMP). Major species have been defined for the purposes of this policy as follows:

Major food-producing animal species:

- cattle (dairy and meat animals)
- sheep (meat animals)
- pigs
- chickens (including laying hens)
- salmon (Salmon should be considered a major species, however other species of the *Salmonidae* family such as rainbow trout should be considered minor species)

Major companion animal species:

- cats
- dogs

Minor species: All other animal species, which are not considered major, are as a consequence, classed as minor species.