15 December 2011
EMA/283580/2011
Executive Director

Explanatory note on fees payable to the European Medicines Agency

Following the publication of the Rules for the implementation of Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures[1] as last adopted by the Agency's Management Board on 15 December 2011, the Agency applies the fees and definitions indicated in this document as of 1 January 2012.

Disclaimer:

This Explanatory Note is meant as a guidance note only. In case of discrepancies between the text and amounts of fees payable to the Agency quoted in the Explanatory Note and the provisions of the Fee Regulation (EC) No 297/95 and its Implementing Rules adopted by the Agency's Management Board, the latter documents prevail.

[1] Article 11(2) of Regulation (EC) No 297/95.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Changes introduced in this version (1 January 2012)

- Sections 1.1.7 and 2.1.7: inspection fees have been revised (9 700 EURO applies to consecutive distinct plasma master file inspections performed under specified conditions; 9 700 EURO no longer applies to medicinal products for veterinary use).
- Section 1.5.3: the conditions for fees for the re-certification of plasma master files have been revised (58 400 EURO applies when at least one of the variations that is included is a major variation; 12 900 EURO applies when no major variations are included but the fee is increased by the applicable fee for each type IA or type IB variation that is included, up to a maximum of EUR 58 400).
- Section 3.2: fees for certificates of medicinal product are explained in more detail and a new urgent procedure for fast tracking of certificates has been introduced.
- Sections 4.2.3 and 4.4.3: a clarification on a total fee exemption on scientific advice/protocol assistance on development of medicinal products for the paediatric population when the advice requested does not include the adult population.
- Section 4.5: an update of fee reductions for advanced therapy medicinal products (incentives during the first year from granting of a marketing authorisation apply to tissue-engineered products only until 30 December 2012; incentives for advanced therapy medicinal products other than tissue-engineered products ceased to apply after 30 December 2011).
- Section 4.6.2: a clarification that, in the case of core dossier medicinal products to be used in a human pandemic situation, a 100% fee reduction applies for the negative validation of a type-IB or type-II variation (but excluding the type-II pandemic variation).
- Section 4.7.2: a clarification that, in the case of medicinal products for minor uses and minor species/limited markets, a 50% fee reduction applies to extensions of marketing authorisation for products indicated for a food-producing species to add a minor species and to type-II variations to marketing authorisations for a non-food-producing species to add a minor species.
- Examples of the determination of fees are now presented in an annex. New examples have been added for: applications for marketing authorisation, renewals of marketing authorisation, fees for GMP inspections, and certificates of medicinal product.

Table of contents

1. Medicinal products for human use

Note: This section on fees for medicinal products for human use should be read in conjunction with the section on fee exemptions (Section 4) and the annex.

1.1. Centralised procedure

1.1.1. Definitions

Pharmaceutical form: According to terms in the 'Standard Terms' published by the Council of Europe.

Strength: See definition used in the pre-submission guidance.

Presentation: Each unit/entity of a certain strength and form of a pharmaceutical product which will be individually authorised and eventually marketed (= each individual sub-number).

1.1.2. Application for a marketing authorisation

1.1.2.1. Application for which a full dossier needs to be presented

Basic fee	259 400 EURO For a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 26 000 EURO For each additional strength or pharmaceutical form including one presentation, submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

1.1.2.2. Application for which a full dossier need not be presented

Basic fee	167 600 EURO For an application for a marketing authorisation pursuant to Article 10(4) of Directive 2001/83/EC. This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 10 000 EURO For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

Basic fee	100 700 EURO For applications for a marketing authorisation pursuant to Article 10(1), Article 10(3) and Article 10c of Directive 2001/83/EC. This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 10 000 EURO For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

Note: Refer to section A.1.1.2. in the annex for examples of the determination of fees for applications for marketing authorisation.

1.1.3. Extension of a marketing authorisation

1.1.3.1. Extension of a marketing authorisation under Annex I to Commission Regulation (EC) No 1234/2008

Basic fee (Level I)	77 900 EURO For each extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use. This fee is for a single strength/potency associated with one pharmaceutical form and one presentation.
Additional fee	+ 19 500 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the time of the extension application.

Basic fee (Level II)	58 400 EURO For all quality extensions (i.e. requiring chemical, pharmaceutical and biological documentation) for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the MAH. This fee is for a single strength/potency associated with one pharmaceutical form and one presentation. (Note: Bioequivalence data qualify as clinical data. Biowaiver dossiers are not considered as clinical data.)

Additional fee	+19 500 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the time of the initial extension application.

1.1.3.2. Extension of a marketing authorisation for use in the paediatric population under Article 29 of Regulation (EC) No 1901/2006

Basic fee (Level III)	77 900 EURO For each extension of a marketing authorisation made under Article 29 of Regulation (EC) No 1901/2006 on medicinal products for paediatric use. This fee is for a single strength/potency associated with one pharmaceutical form and one presentation.
Additional fee	+ 19 500 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the time of the initial extension application.

Note: Refer to section A.1.1.3. in the annex for examples of the determination of fees for extensions of marketing authorisation.

1.1.4. Variation to a marketing authorisation

The following fees apply to variations that are notified or applied for individually in a notification or application.

1.1.4.1. Type-IA variation

Basic fee	2 800 EURO For a minor variation to a marketing authorisation, as defined in Article 2(2) of Commission Regulation (EC) No 1234/2008.

1.1.4.2. Type-IB variation

Basic fee	6 500 EURO For a minor variation to a marketing authorisation, as defined in Article 2(5) of Commission Regulation (EC) No 1234/2008.

- In the event of the same variation being introduced, the fee will cover all authorised strengths, pharmaceutical forms and presentations of a given medicinal product (= per main authorisation number).

1.1.4.3. Type-II variation

Basic fee (Level I)	77 900 EURO For a major variation to a marketing authorisation, as defined in Article 2(3) of Commission Regulation (EC) No 1234/2008.
Basic fee (Level II)	58 400 EURO For a quality variation (i.e. amendments to the chemical, pharmaceutical and biological documentation) for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the MAH. (Note: Bioequivalence data qualify as clinical data. Biowaiver dossiers are not considered as clinical data.)
Basic fee (Level III)	19 500 EURO For each of the third and subsequent type II variations that are grouped in a single application made under the terms of Article 7(2) of Commission Regulation (EC) No 1234/2008. For each of the third and subsequent type II variations to the centralised marketing authorisation or to one of the centralised marketing authorisations, where there is more than one centralised marketing authorisation, in the case of a worksharing application made under the terms of Article 20 of Commission Regulation (EC) No 1234/2008.

1.1.5. Grouping and worksharing procedures

1.1.5.1. Grouping of extensions and/or variations notified or submitted under the terms of Article 7(2) of Commission Regulation (EC) No 1234/2008

- The applicable fee specified in sections 1.1.3 and 1.1.4 shall be payable for each individual extension and/or variation to a marketing authorisation that is grouped in a single notification or a single application.
- The applicable level I and level II basic fees specified in sub-section 1.1.4.3 above are payable for the first and second type II variation respectively when both levels of fees are applicable to variations in the same grouping.
- Consequential variations in a grouping shall be similarly charged the applicable fees as specified above.
- In the case of grouping of the same Type IA variations to the terms of several marketing authorisations owned by the same holder (as set out in Article 7(2)(a) of Commission Regulation

(EC) No 1234/2008), the applicable fee shall be payable for each individual Type IA variation and for each marketing authorisation in the grouping.

- The same marketing authorisation holder also means several marketing authorisation holders that are linked through a parent company. The fee for the grouping shall be payable by the marketing authorisation holder applying for the grouping procedure.
- Where any extensions/variations included in a grouping are found not to be valid and the remainder are validated positively, the applicable fees as specified above shall be payable for each of the positively validated extensions/variations.

1.1.5.2. Worksharing procedure under the terms of Article 20 of Commission Regulation (EC) No 1234/2008

- The applicable fee specified in section 1.1.4 is payable for each individual variation to one of the centralised marketing authorisations owned by the same holder, where more than one centralised marketing authorisation is included in the worksharing application, or to the single centralised marketing authorisation included in the worksharing application, as applicable.
- The applicable level I and level II basic fees specified in 1.1.4.3 above are payable for the first and second type II variation respectively when both levels of fees are applicable to variations in the same worksharing procedure.
- The administrative fee shown in the table below is additionally payable for each individual variation to each of the other centralised marketing authorisation(s) owned by the same holder included in the same worksharing application, if applicable.
- No fee is payable to the Agency for any national marketing authorisations included in the same worksharing application.
- The same marketing authorisation holder also means several marketing authorisation holders that are linked through a parent company. The fee for the worksharing procedure shall be payable by the marketing authorisation holder applying for the procedure.

Variation type	Worksharing fees for one centralised marketing authorisation	Worksharing administrative fees	
		Other centralised marketing authorisations (excluding multiple applications on usage patent grounds)	Other centralised marketing authorisations (multiple applications on usage patent grounds[2])
Type II (Level I)	77 900 EURO	6 500 EURO	3 720 EURO
Type II (Level II)	58 400 EURO		
Type II (Level III)	19 500 EURO		
Type IB	6 500 EURO	1 080 EURO	1 080 EURO
Type IA	2 800 EURO	540 EURO	540 EURO

- Where any variations included in a worksharing procedure are found not to be valid and the remainder are validated positively, the applicable fees as specified above shall be payable for each of the positively validated variations.

[2] These fees apply to generic medicinal product applications, hybrid applications and similar biological medicinal product applications and are applicable for as long as the concerned marketing authorisation is affected by usage patent(s) pertaining to indication(s) and/or dosage form(s). Refer to section 4.3 for further details on fee exemptions.

1.1.6. Renewal of a marketing authorisation

Basic fee	12 900 EURO For each strength associated with a pharmaceutical form for which renewal is sought.

Note: Refer to section A.1.1.6. in the annex for examples of the determination of fees for renewals of marketing authorisation.

1.1.7. Inspection

Basic fee (Level I)	19 500 EURO For each inspection inside or outside the European Union; for inspections outside the European Union, travel expenses shall be charged extra on the basis of actual cost.
Basic fee (Level II)	9 700 EURO For each consecutive distinct plasma master file (PMF) inspection performed in conjunction with an inspection that attracts the level I fee, provided that such consecutive inspection concerns the same PMF application, the same inspection team and is conducted in the same PMF inspection tour.

Note: Refer to section A.1.1.7. in the annex for examples of the determination of fees for good manufacturing practice (GMP) inspections.

1.1.8. Transfer of a marketing authorisation

Basic fee	6 500 EURO For all authorised presentations of the medicinal product.

1.1.9. Maintenance of a marketing authorisation – Annual fee

Basic fee (Level I)	93 000 EURO For each marketing authorisation of a medicinal product. This fee covers all authorised presentations of the medicinal product.
Basic fee (Level II)	46 600 EURO For each marketing authorisation of a biosimilar medicinal product (Article 10(4) of Directive 2001/83/EC). This fee covers all authorised presentations of the medicinal product.
Basic fee (Level III)	23 200 EURO For each marketing authorisation of a generic, hybrid or informed consent medicinal product (Articles 10(1), 10(3) and 10c of Directive 2001/83/EC). This fee covers all authorised presentations of the medicinal product.

1.1.10. Referral

Basic fee	64 700 EURO For procedures laid down in Article 30(1) and 31 of Directive 2001/83/EC that are initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Note: Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than 10 different applicants or holders, the fee will be charged by the application of the above mentioned referral fee.

1.2. Scientific advice

1.2.1. Definitions

Quality development: Chemical, pharmaceutical and biological testing.

Safety development: Toxicological and pharmacological tests.

Clinical development: Studies in human subjects in whether patients or non-patient volunteers, including clinical pharmacological trials designed to determine the efficacy and safety of the product.

Qualification advice: Advice on the acceptability of a specific use of the proposed method (e.g. use of a biomarker) in a research and development (R&D) context (non-clinical or clinical studies), based on the assessment of submitted data.

Initial request: First request for scientific advice or protocol assistance introduced in relation to the submission of an application for marketing authorisation or a variation, whatever the authorisation phase (pre- or post-authorisation).

Follow-up to initial request: Any subsequent request falling within the same therapeutic indication and initial area(s) as the initial request, (area means quality, preclinical and/or clinical development including pharmacovigilance/risk management aspects).

1.2.2. Initial request for scientific advice

Basic fee (Level III)	77 900 EURO For **initial** requests for scientific advice on: • quality and safety and clinical development, or • quality and clinical development, or • safety and clinical development, or • qualification advice.

Basic fee (Level II)	58 400 EURO For **initial** requests on: • clinical development, or • quality and safety development, or • quality and bioequivalence studies for generic medicinal products.
Basic fee (Level I)	38 900 EURO For **initial** requests on: • quality development or • safety development, or • bioequivalence studies for generic medicinal products.

1.2.3. Follow-up request for scientific advice

Basic fee (Level III)	38 900 EURO For **follow-up** to the initial request on: • quality and safety and clinical development, or • quality and clinical development, or • safety and clinical development, or • qualification advice.
Basic fee (Level II)	29 200 EURO For **follow-up** to the initial request on: • clinical development, or • quality and safety development, or • quality and bioequivalence studies for generic medicinal products.
Basic fee (Level I)	19 500 EURO For **follow-up** to the initial request on: • quality development, or • safety development, or • bioequivalence studies for generic medicinal products.

1.3. Scientific services

A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific Committee, which is not covered by Articles 3 to 7 or by Article 8(1).

1.3.1. Scientific opinions pursuant to Article 58 of Regulation (EC) No 726/2004

Basic fee	259 400 EURO For a scientific opinion for the evaluation of medicinal products for human use intended exclusively for markets outside the European Union. The fee is for a single strength associated with one pharmaceutical form and one presentation
Additional fee	+ 26 000 EURO For each additional strength or pharmaceutical form and one presentation
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation

- Fees for relevant post-authorisation applications and annual fees will be charged according to the corresponding fees for centrally authorised products.

1.3.2. Compassionate use

Basic fee	129 800 EURO For any opinion on medicinal products for compassionate use

1.3.3. Herbal medicinal products

Basic fee (Level I)	19 500 EURO For requests for scientific support and advice by the Committee on Herbal Medicinal Products (HMPC) on multiple areas related to traditional herbal medicinal products
Basic fee (Level II)	12 900 EURO For requests for scientific support and advice by the HMPC on single areas related to traditional herbal medicinal products, for example: • quality, or • safety, or • long-standing use.

1.3.4. Certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises

Basic fee (Level I)	58 400 EURO Evaluation of an application relating to quality and non-clinical data.
Basic fee (Level II)	38 900 EURO Evaluation of an application relating to quality data.

- The above fees are subject to the fee reduction for scientific services applicable to micro, small and medium-sized enterprises (SMEs) in accordance with section 4.1.2.

1.4. Consultation on ancillary substances including blood derivates incorporated in medical devices

1.4.1. Initial request

Basic fee (Level I)	77 900 EURO For consultation on an ancillary medicinal substance or blood derivative new to the centralised procedure. This applies where the substance/derivative from the specified manufacturer has not been evaluated by the Agency in connection with a previous marketing authorisation and/or a previous successful notified body consultation.
Basic fee (Level II)	58 400 EURO For consultation on a known ancillary blood derivative from a known source. This applies where the blood derivative from the specified manufacturer has been evaluated by the Agency in connection with a previous marketing authorisation and/or a previous successful notified body consultation.
Basic fee (Level III)	38 900 EURO For consultation on a known ancillary medicinal substance from a known source. This applies where the substance from the specified manufacturer has been evaluated by the Agency in connection with a previous marketing authorisation and/or a previous successful notified body consultation.

1.4.2. Follow-up to the initial request

Basic fee	19 500 EURO For consultation on a known ancillary medicinal substance from a known source. This applies where the substance from the specified manufacturer has been evaluated by the Agency in connection with a previous marketing authorisation and/or a previous successful notified body consultation. In this case a further consultation is requested by a notified body after a first consultation, i.e. when additional data are submitted to the Agency for evaluation in response to a list of deficiencies notified in an initial Agency report.

Basic fee	38 900 EURO For consultation on an amendment to the documentation on an ancillary medicinal substance or blood derivate already evaluated by the Agency (The amendments should be classified by analogy to Annex I of Commission Regulation (EC) No 1234/2008).
Basic fee	38 900 EURO For consultation on a major amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency (The amendment should be equivalent to a Type II variation as classified by analogy to Commission Regulation (EC) No 1234/2008).
Basic fee	6 500 EURO For consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency. (The amendment should be equivalent to a Type IB variation as classified by analogy to Commission Regulation (EC) No 1234/2008).
Basic fee	2 800 EURO For consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency. (The amendment should be equivalent to a Type IA variation as classified by analogy to Commission Regulation (EC) No 1234/2008).

1.5. Certification of compliance with European Union legislation for plasma master files (PMF) and vaccine antigen master files (VAMF)

1.5.1. Application for PMF certification (initial certification)

1.5.1.1. Not submitted simultaneously with a new application under the centralised procedure

Basic fee (Level I)	64 700 EURO For the review of the PMF and its initial certification where the data contained in the PMF have not been previously evaluated within the centralised procedure.
Basic fee (Level II)	58 400 EURO For the review of the PMF and its initial certification where the PMF applicant has included change(s) to the data previously evaluated within the centralised procedure and which are now part of the PMF application.
Basic fee (Level III)	19 500 EURO For the review of the PMF and its initial certification where the data contained in the PMF have been previously evaluated under the centralised procedure and no changes have been included.

1.5.1.2. Submitted simultaneously with a new application under the centralised procedure

Basic fee	6 500 EURO For the review of the PMF and its certification when it is submitted in parallel and within the submission of a new application within the centralised procedure. The PMF documentation will be evaluated by the Agency simultaneously with a centralised marketing authorisation application.

1.5.2. Variation to a certified PMF

Basic fee	58 400 EURO For the review and certification of a major variation to the PMF (in accordance with Commission Regulation (EC) No 1234/2008).
Basic fee	58 400 EURO For the review and certification of two or more variations that are grouped in a single application made under the terms of Article 7(2)(b) of Commission Regulation (EC) No 1234/2008 where at least one of the variations is a major variation.
Basic fee	6 500 EURO For the review and certification of a minor variation of type IB to the PMF (in accordance with Commission Regulation (EC) No 1234/2008).
Basic fee	2 800 EURO For the review and certification of a minor variation of type IA to the PMF (in accordance with Commission Regulation (EC) No 1234/2008).

1.5.3. Annual re-certification of PMF

Basic fee	58 400 EURO For the review and annual re-certification of the PMF under this scheme where one or more variations are included in the submitted documentation and at least one of the variations is a major variation.
Basic fee	12 900 EURO For the review and annual re-certification of the PMF under this scheme where no major variations are included in the submitted documentation. This fee is increased by the applicable fee for each minor variation of type IA or type IB included in the submitted documentation, up to a maximum of EUR 58 400.

1.5.4. Application for a VAMF certification (initial certification)

1.5.4.1. Not submitted simultaneously with a new application under the centralised procedure

Basic fee	64 700 EURO For the review of the VAMF and its certification where the data contained in the vaccine antigen master file have not been previously evaluated within the centralised procedure. In the case of a group of antigens aimed at preventing a single infectious disease, e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 64 700 EURO.
Additional fee	+ 6 500 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

Basic fee	58 400 EURO For the review of the VAMF and its certification where the initial data have been previously evaluated within the centralised procedure but where the VAMF applicant has included changes or harmonisation as part of the VAMF certification scheme. In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 58 400 EURO.
Additional fee	+ 6 500 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

Basic fee	19 500 EURO For the review of the VAMF and its initial certification where the data contained in the vaccine antigen master file have been previously evaluated under the centralised procedure and where no changes or harmonisation have been included. In the case of a group of antigens aimed at preventing a single infectious disease e.g. Inactivated Polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 19 500 EURO.
Additional fee	+ 6 500 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

1.5.4.2. Submitted simultaneously with a new application under the centralised procedure

Basic fee	6 500 EURO For the review of the VAMF and its certification when it is submitted in parallel and within the submission of a new application containing the named antigen within the centralised procedure. In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 6 500 EURO.
Additional fee	+ 6 500 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

1.5.5. Variation to a certified VAMF

Basic fee	58 400 EURO For the review and certification of a major variation to the VAMF (in accordance with Commission Regulation (EC) No 1234/2008). In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 58 400 EURO.
Additional fee	+ 6 500 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

Basic fee	58 400 EURO For the review and certification of two or more variations that are grouped in a single application made under the terms of Article 7(2)(b) of Commission Regulation (EC) No 1234/2008 where at least one of the variations is a major variation. In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the grouped variations application for one antigen will be charged at 58 400 EURO.
Additional fee	+ 6 500 EURO For each VAMF grouping application submitted simultaneously for antigens from the same group, up to a maximum of 77 900 EURO.

Basic fee	6 500 EURO For the review and certification of a minor variation of type IB to the VAMF (in accordance with Commission Regulation (EC) No 1234/2008). In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 6 500 EURO.
Additional fee	+ 6 500 EURO For each VAMF applications submitted simultaneously for antigens from the same group, up to a maximum of 38 900 EURO.

Basic fee	2 800 EURO For the review and certification of a minor variation of type IA to the VAMF (in accordance with Commission Regulation (EC) No 1234/2008). In the case of a group of antigens aimed at preventing a single infectious disease e.g. inactivated polio serotypes 1, 2 and 3, the VAMF application for one antigen will be charged at 2 800 EURO.
Additional fee	+ 2 800 EURO For each VAMF application submitted simultaneously for antigens from the same group, up to a maximum of 19 500 EURO.

2. Medicinal products for veterinary use

Note: This section on fees for veterinary medicinal products should be read in conjunction with the section on fee exemptions (Section 4) and the annex.

2.1. Centralised procedure

2.1.1. Definitions

Pharmaceutical form: According to terms in the 'Standard Terms' published by the Council of Europe.

Strength: See definition used in the pre-submission guidance.

Presentation: Each unit/entity of a certain strength and form of a pharmaceutical product which will be individually authorised and eventually marketed (= each individual sub-number).

2.1.2. Application for a marketing authorisation

2.1.2.1. Full fee

Basic fee	129 800 EURO For a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 12 900 EURO For each additional strength or pharmaceutical form including one presentation, submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

- Number of target species applied for does not impact on the fee.

2.1.2.2. Full fee – Immunologicals

Basic fee	64 700 EURO For a single strength associated with one pharmaceutical form and one presentation.
Additional fee (I)	+ 6 500 EURO For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

Additional fee (II)	+ 6 500 EURO For each multi-strain additional presentation of the same application submitted at the time of the initial application as described in the guideline on data requirements for multi-strain applications for inactivated vaccines against avian influenza, Bluetongue and Foot-and-Mouth Disease[3] up to a maximum of EUR 129 800. In this context, each combination of strain identified in the application represents a presentation.

- Number of target species applied for does not impact on the fee.

2.1.2.3. Reduced fee

Basic fee	64 700 EURO For applications for marketing authorisation pursuant to Article 13(1), Article 13(3) and Article 13c of Directive 2001/82/EC. That fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 12 900 EURO For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.
Basic fee	109 700 EURO For applications for a marketing authorisation pursuant to Article 13(4) of Directive 2001/82/EC. This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 12 900 EURO For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
	+ 6 500 EURO For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

- Number of target species applied for does not impact on the fee.

[3] Commission Directive 2009/9/EC amending Directive 2001/82 EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use introduces under Title IV B the concept of multi-strain veterinary immunological products for vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-mouth disease (FMD)

2.1.2.4. Reduced fee – Immunologicals

Basic fee	32 400 EURO For a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 6 500 EURO For each additional strength or pharmaceutical form and one presentation submitted at the same time as the initial application.

- Number of target species applied for does not impact on the fee.

Note: Refer to section A.2.1.2. in the annex for examples of the determination of fees for applications for marketing authorisation.

2.1.3. Extension of a marketing authorisation

2.1.3.1. Extension of a marketing authorisation under Annex I to Commission Regulation (EC) No 1234/2008

Basic fee (Level I)	32 400 EURO For each extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of a marketing authorisation for veterinary medicinal products. This fee is for a single strength/potency associated with one pharmaceutical form and one presentation. This fee shall also cover one or more target species associated with that pharmaceutical form.
Additional fee	+ 8 100 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application. This fee shall also cover one or more target species associated with that pharmaceutical form.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the same time of the extension application.

Basic fee (Level II)	29 200 EURO For all quality extensions (i.e. requiring chemical, pharmaceutical and biological documentation) for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the MAH. This fee is for a single strength associated with one pharmaceutical form and one presentation.

Additional fee	+ 8 100 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application. This fee shall also cover one or more target species associated with that pharmaceutical form.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the same time of the extension application.

Basic fee (Level III)	8 100 EURO For all quality extensions (i.e. requiring chemical, pharmaceutical and biological documentation) of an immunological veterinary medicinal product for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the MAH. This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	+ 8 100 EURO For each additional strength/potency of the same pharmaceutical form of the same extension including one presentation submitted at the time of the extension application. This fee shall also cover one or more target species associated with that pharmaceutical form.
Additional fee	+ 6 500 EURO For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension submitted at the same time of the extension application.

Note: Refer to section A.2.1.3. in the annex for examples of the determination of fees for extensions of marketing authorisation.

2.1.4. Variation to a marketing authorisation

The following fees apply to variations that are notified or applied for individually in a notification or application.

2.1.4.1. Type-IA variations

Basic fee	2 800 EURO For a minor variation to a marketing authorisation, as defined in Article 2(2) of Commission Regulation (EC) No 1234/2008.

2.1.4.2. Type-IB variations

Basic Fee	6 500 EURO For a minor variation to a marketing authorisation, as defined in Article 2(5) of Commission Regulation (EC) No 1234/2008.

- In the event of the same variation being introduced, the fee will cover all authorised strengths, pharmaceutical forms and presentations of a given medicinal product (= per main authorisation number).

2.1.4.3. Type-II variations

Basic fee (Level I)	38 900 EURO For a major variation to a marketing authorisation, as defined in Article 2(3) of Commission Regulation (EC) No 1234/2008.
Basic fee (Level II)	29 200 EURO For a quality variation (i.e. amendments to the chemical, pharmaceutical and biological documentation) for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the MAH. (Note: bioequivalence data qualifies as clinical data.)
Basic fee (Level III)	9 700 EURO For each of the third and subsequent type II variations that are grouped in a single application made under the terms of Article 7(2) of Commission Regulation (EC) No 1234/2008. For each of the third and subsequent type II variations to the centralised marketing authorisation or to one of the centralised marketing authorisations, where there is more than one centralised marketing authorisation, in the case of a worksharing application made under the terms of Article 20 of Commission Regulation (EC) No 1234/2008,
Basic fee (Level IV)	6 500 EURO For each variation to a marketing authorisation for an immunological veterinary medicinal product.

2.1.5. Grouping and worksharing procedures

2.1.5.1. Grouping of extensions and/or variations notified or submitted under the terms of Article 7(2) of Commission Regulation (EC) No 1234/2008

- The applicable fee specified in sections 2.1.3 and 2.1.4 shall be payable for each individual extension and/or variation to a marketing authorisation that is grouped in a single notification or a single application.
- The applicable level I and level II basic fees specified in sub-section 2.1.4.3 above are payable for the first and second type II variation respectively when both levels of fees are applicable to variations in the same grouping.
- Consequential variations in a grouping shall be similarly charged the applicable fees as specified above.
- In the case of grouping of the same Type IA variations to the terms of several marketing authorisations owned by the same holder (as set out in Article 7(2)(a) of Commission Regulation (EC) No 1234/2008), the applicable fee shall be payable for each individual Type IA variation and for each marketing authorisation in the grouping.
- The same marketing authorisation holder also means several marketing authorisation holders that are linked through a parent company. The fee for the grouping shall be payable by the marketing authorisation holder applying for the grouping procedure.
- Where any extensions/variations included in a grouping are found not to be valid and the remainder are validated positively, the applicable fees as specified above shall be payable for each of the positively validated extensions/variations.

2.1.5.2. Worksharing procedure under the terms of Article 20 of Commission Regulation (EC) No 1234/2008

- The applicable fee specified in section 2.1.4 is payable for each individual variation to one of the centralised marketing authorisations owned by the same holder, where more than one centralised marketing authorisation is included in the worksharing application, or to the single centralised marketing authorisation included in the worksharing application, as applicable.
- The applicable level I and level II basic fees specified in 2.1.4.3 above are payable for the first and second type II variation respectively when both levels of fees are applicable to variations in the same worksharing procedure.
- The administrative fee shown in the table below is additionally payable for each individual variation to each of the other centralised marketing authorisation(s) owned by the same holder included in the same worksharing application, if applicable.
- No fee is payable to the Agency for any national marketing authorisations included in the same worksharing application.
- The same marketing authorisation holder also means several marketing authorisation holders that are linked through a parent company. The fee for the worksharing procedure shall be payable by the marketing authorisation holder applying for the procedure.

Variation type	Worksharing fees for one centralised marketing authorisation	Worksharing administrative fees
Type II (Level I)	38 900 EURO	3 210 EURO
Type II (Level II)	29 200 EURO	
Type II (Level III)	9 700 EURO	
Type IB	6 500 EURO	1 080 EURO
Type IA	2 800 EURO	540 EURO

- Where any variations included in a worksharing procedure are found not to be valid and the remainder are validated positively, the applicable fees as specified above shall be payable for each of the positively validated variations.

2.1.6. Renewal of a marketing authorisation

Basic fee	6 500 EURO For each strength associated with a pharmaceutical form.

Note: Refer to section A.2.1.6. in the annex for examples of the determination of fees for renewals of marketing authorisation.

2.1.7. Inspection

Basic fee (Level I)	19 500 EURO For inspections outside the European Union, travel expenses shall be charged extra on the basis of actual cost.

Note: Refer to section A.1.1.7. in the annex for examples of the determination of fees for good manufacturing practice (GMP) inspections.

2.1.8. Transfer of a marketing authorisation

Basic fee	6 500 EURO For all authorised presentations of the medicinal product.

2.1.9. Maintenance of a marketing authorisation – Annual fee

Basic fee (Level I)	31 000 EURO For each marketing authorisation of a medicinal product. This fee covers all authorised presentations of the medicinal product.
Basic fee (Level II)	15 400 EURO For each marketing authorisation of a biosimilar medicinal product (Article 13(4) of Directive 2001/82/EC). This fee covers all authorised presentations of the medicinal product.

Basic fee (Level III)	7 800 EURO For each marketing authorisation of a generic, hybrid or informed consent medicinal product (Articles 13(1), 13(3) and 13c of Directive 2001/82/EC). This fee covers all authorised presentations of the medicinal product.

2.1.10. Referral

Basic fee	38 900 EURO For the procedures laid down in Article 34(1) and 35 of Directive 2001/83/EC initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Note: Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than 10 different applicants or holders, the fee will be charged by the application of the above mentioned referral fee.

2.2. Maximum residue limits (MRLs)

Basic fee	64 700 EURO For an application to set an initial MRL for a given substance intended to be used in veterinary medicinal products or in biocidal products used in animal husbandry.
	19 500 EURO For each application to modify or extend an existing MRL, as included in Table 1 of the Annex to Regulation (EEC) No 470/2009.

- MRL fees shall be deducted from the fee payable for an application for marketing authorisation or an application to extend a marketing authorisation for the medicinal product containing the substance for which an MRL has been set where such applications are submitted by the same applicant. However, this deduction may in total be no more than one half of the fee to which it applies.

2.3. Scientific advice

2.3.1. Definitions

The following definitions shall apply for the determination of fees for scientific advice requests.

Quality development: Chemical, pharmaceutical and biological testing.

Safety development: Toxicological and pharmacological tests.

Clinical development: Studies in animal patients, including clinical pharmacological trials designed to determine the efficacy and safety of the product.

Initial request: First request for scientific advice or protocol assistance introduced in relation to the submission of an application for marketing authorisation or a variation, whatever the authorisation phase (pre- or post-authorisation).

Follow-up to initial request: Any subsequent request falling within the same therapeutic indication and initial area(s) as the initial request, (area means quality, preclinical and/or clinical development including pharmacovigilance/risk management aspects).

2.3.2. Initial request for scientific advice

Basic fee (Level I)	38 900 EURO This corresponds to an **initial** request for scientific advice (SA) on: • quality and safety and clinical development, or • quality and clinical development, or • safety and clinical development.
Basic fee (Level II)	19 500 EURO For **initial** requests on: • clinical development, or • quality and safety development, or • quality and bioequivalence studies for generic medicinal products.
Basic fee (Level III)	12 900 EURO For **initial** requests on: • quality development, or • safety development, or • bioequivalence studies for generic medicinal products, or • new MRL.

2.3.3. Follow-up request for scientific advice

Basic fee (Level I)	19 500 EURO For **follow-up** to the initial request on: • quality and safety and clinical development, or • quality and clinical development, or • safety and clinical development.
Basic fee (Level II)	12 900 EURO For **follow-up** to the initial request on: • clinical development, or • quality and safety development, or • quality and bioequivalence studies for generic medicinal products.
Basic fee (Level III)	9 700 EURO For **follow-up** to the initial request on: • quality development, or • safety development • bioequivalence studies for generic medicinal products, or • new MRL.

2.3.4. Scientific advice in relation to products classified by the CVMP

Basic fee	9 700 EURO For assessing compliance of a proposed data package with relevant Guidelines on data requirements for veterinary medicinal products intended for minor uses or minor species.

2.4. Fee for scientific services

A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific committee, which is not covered by Articles 3 to 7 or by Article 8(1).

Basic fee (Level I)	129 800 EURO When it concerns veterinary medicinal products.
Basic fee (Level II)	32 400 EURO E.g. vaccine antigen master file.
Basic fee (Level III)	6 500 EURO Variations to a VAMF.

3. Administrative fees

3.1. Negative validation

Basic fee	2 800 EURO For an application that has been found not to be valid, an administrative fee for the validation of the application shall be charged. This fee is for all negative validations except for grouping or worksharing applications.
Basic fee	2 800 EURO For a grouping or worksharing application where all extensions/variations in the application have been found not to be valid. If individual extensions/variations in an application are found not to be valid but the remainder are validated positively, no administrative fee shall be charged for the invalid extensions/variations.

3.2. Certificate of a medicinal product

3.2.1. Definitions

A set of certificates: a maximum of six identical original certificates for a medicinal product with a distinct marketing authorisation number, addressed to the same importing country, issued in the same official language of the European Union and having identical annexes.

Standard procedure: procedure for issuing certificates of medicinal product within 10 working days.

Urgent procedure: procedure for issuing certificates of medicinal product within 2 working days.

3.2.2. Standard procedure

Basic fee (Level I)	260 EURO For each request for certificates, including one set of certificates.
Additional fee	130 EURO For each additional set of certificates included in the same request.

3.2.3. Urgent procedure

Basic fee (Level II)	780 EURO For each request for certificates, including one set of certificates.
Additional fee	390 EURO For each additional set of certificates included in the same request.

3.2.4. Withdrawal of request for certificates

Basic fee	260 EURO When a request for certificates is withdrawn by the requester following confirmation by the Agency of the start of the procedure.

Note: Refer to section A.3.2. in the annex for examples of the determination of fees for certificates of medicinal product

3.3. Notification of parallel distribution for each initial parallel distribution notification

Basic fee	3 870 EURO For all pack-sizes of a particular strength and pharmaceutical form for a given medicinal product.

3.4. Worksharing procedures for variations to marketing authorisations

Refer to section 1.1.5 and 2.1.5 for details of administrative charges applicable to worksharing procedures under the terms of Article 20 of Commission Regulation (EC) No 1234/2008.

4. Fee exemptions

Where an applicant could, in respect of the same fee, benefit from more than one category of fee reduction or incentive (e.g. advanced therapy medicinal product, orphan medicinal product, small and medium sized enterprises) the provisions which are the most favourable to the applicant would apply. The applicant can contact the Agency prior to submission of the application to confirm the fee that could be applied.

4.1. Micro, small or medium-sized enterprise (SMEs)

4.1.1. Definitions

Pursuant to Article 70.2 of Regulation (EC) No 726/2004 of 31 March 2004, applicants that meet the definition of a micro, small or medium-sized enterprise are eligible for fee incentives from the Agency. Companies developing medicinal products for human and/or veterinary use can benefit from fee reductions, exemptions and/or deferrals, as applicable. Applicants must be established in the EEA and fulfil the definition of an SME as set out in Commission Recommendation 2003/361/EC of 6 May 2003.

4.1.2. Fee incentives

Scientific advice	90% fee reduction for non-orphan medicinal products
	100% fee reduction for designated orphan medicinal products (see section 4.2.4)
Inspection (pre-authorisation)	90% fee reduction
	Deferral
Application for a marketing authorisation	Deferral
	Conditional fee exemption
Scientific services	90% fee reduction for non-orphan medicinal products
	100% fee reduction for designated orphan medicinal products (see section 4.2.4)
Establishment of maximum residue limit for a veterinary medicinal product	90% fee reduction
Administrative services (excluding parallel distribution)	100% fee reduction
Inspection (post-authorisation)	90% fee reduction

4.2. Orphan medicinal products

4.2.1. Definitions

Total or partial exemptions from the payment of fees for applications for designated orphan medicinal products for human use shall be granted as laid down in a decision of the Executive Director on the use of the special contribution from the European Union, provided for by Article 7(2) of Regulation (EC) No 141/2000, that reflects the advice of the Committee for Orphan Medicinal Products.[4]

4.2.2. Fee incentives for all applicants

Inspection (pre-authorisation)	100% fee reduction to the total applicable fee

4.2.3. Fee incentives for applicants other than micro, small and medium sized enterprises

Protocol assistance (non-paediatric-related*)	75% fee reduction to the total applicable fee
Protocol assistance (paediatric-related*)	100% fee reduction to the total applicable fee
Application for a marketing authorisation	10% fee reduction to the total applicable fee

* Paediatric-related protocol assistance is restricted to development of an orphan medicinal product for the paediatric population, where the advice requested does not include the adult population.

4.2.4. Fee incentives for micro, small and medium sized enterprises

Protocol assistance	100% fee reduction to the total applicable fee
Scientific services	100% fee reduction to the total applicable fee
Application for a marketing authorisation	100% fee reduction to the total applicable fee
Post-authorisation activities, including annual fees, during the first year after marketing authorisation	100% fee reduction to the total applicable fee

4.3. Multiple applications on usage patent grounds

4.3.1. Definitions

The full or partial exemptions from payment of fees described below are applicable for as long as the concerned marketing authorisation is affected **by usage patent(s)** pertaining to indication(s) and/or dosage form(s).

The following ranges and classification shall apply for fees for:

- generic medicinal product applications submitted under Article 10(1) of Directive 2001/83/EC;

[4] Executive Decision of 15 February 2011 applicable from 1 April 2011 (EMA/60514/2011)

- hybrid applications submitted under Article 10(3) of Directive 2001/83/EC;
- similar biological medicinal product applications submitted under Article 10(4) of Directive 2001/83/EC.

4.3.2. Fee incentives for an application for a marketing authorisation

4.3.2.1. Reduced fee

Second and each subsequent multiple application submitted under Articles 10(1) and 10(3) of Directive 2001/83/EC	19 300 EURO
Second and each subsequent multiple application submitted under Articles 10(4) of Directive 2001/83/EC	32 100 EURO
Additional strengths, pharmaceutical forms and presentations submitted at the same time as the aforementioned applications	100% fee reduction to the total applicable fee

4.3.3. Fee incentives for post-authorisation activities for a second and for each subsequent multiple application

4.3.3.1. Reduced fee

Extension of a marketing authorisation	18 600 EURO
Additional strengths and presentations of the same pharmaceutical form submitted at the same time as the aforementioned application	100% fee reduction to the total applicable fee

Type-IA variation to a marketing authorisation. This fee shall only apply in the case of grouping of the same type-IA variations to the terms of multiple marketing authorisations on usage patent grounds owned by the same holder (as defined in Article 7(2)(a) of Commission Regulation (EC) No 1234/2008). The applicable fee shall be payable for each individual type-IA variation relating to the second and each of the subsequent multiple marketing authorisations in the grouping	540 EURO

Worksharing procedure under the terms of Article 20 of Commission Regulation (EC) No 1234/2008. Administrative fees for variations to multiple centralised marketing authorisations on usage patent grounds	Refer to section 1.1.5.2

Renewal of a marketing authorisation	2 470 EURO
Additional strengths associated with a pharmaceutical form submitted at the same time as the aforementioned application	100% fee reduction to the total applicable fee

Annual fee for a marketing authorisation granted under Articles 10(1) and	4 400 EURO

10 (3) of Directive 2001/83/EC	
Annual fee for a marketing authorisation granted under Article 10(4) of Directive 2001/83/EC	8 900 EURO

4.4. Medicinal products for paediatric use

4.4.1. Definitions

A partial exemption from the payment of the fees laid down in the fee regulation is granted for paediatric use marketing authorisation applications (PUMAs) submitted under Article 30 of Regulation (EC) No 1901/2006 on medicinal products for paediatric use.

A total exemption from the payment of the fees laid down in the fee regulation is granted for scientific advice provided by the Agency to sponsors developing medicinal products for the paediatric population as laid down in Regulation (EC) No 1901/2006 on medicinal products for paediatric use.

4.4.2. Fee incentives for PUMAs

Application for a paediatric use marketing authorisation	50% reduction to the total applicable fee
Inspection (pre-authorisation)	
During the first year after marketing authorisation for: • extension of a marketing authorisation; • type-IA, type-IB and type-II variations; • annual fee; • inspection (post-authorisation).	

4.4.3. Fee incentives for scientific advice

Scientific advice on development of a medicinal product for the paediatric population (when the advice requested does not include the adult population)	100% reduction to the total applicable fee

4.5. Advanced therapy medicinal products

4.5.1. Definitions

Total or partial exemptions from the payment of fees for applications for advanced therapy medicinal products for human use are granted as laid down in Articles 16(2), 19 and 29 of Regulation (EC) No 1394/2007.

Fee reductions for applications for marketing authorisation and for post-authorisation activities during the first year from granting of a marketing authorisation apply to tissue-engineered products only until 30 December 2012. The corresponding incentives for advanced therapy medicinal products other than tissue-engineered products ceased to apply after 30 December 2011.

4.5.2. Fee incentives for applicants other than micro, small and medium-sized enterprises or hospitals

Scientific advice	65% fee reduction to the total applicable fee

4.5.3. Fee incentives for micro, small and medium-sized enterprises

Scientific advice	90% fee reduction to the total applicable fee
Application for a marketing authorisation (subject to proof of a particular public health interest in the European Union in the product concerned)	50% fee reduction to the total applicable fee
Post-authorisation activities including annual fee during the first year after marketing authorisation	50% fee reduction to the total applicable fee

4.5.4. Fee incentives for hospitals other than micro, small and medium-sized enterprises

Scientific advice	65% fee reduction to the total applicable fee
Application for a marketing authorisation (subject to proof of a particular public health interest in the European Union in the product concerned)	50% fee reduction to the total applicable fee
Post-authorisation activities including annual fee during the first year after marketing authorisation	50% fee reduction to the total applicable fee

4.5.5. Fee incentives for advanced therapy medicinal products which were legally on the European Union market in accordance with national or European Union legislation on 30 December 2008

Application for a marketing authorisation	100% fee reduction to the total applicable fee
Post-authorisation activities including annual fee during the first year after marketing authorisation	50% fee reduction to the total applicable fee (applicable only to micro, small and medium sized enterprises or hospitals)

4.6. Core dossier medicinal products to be used in a human pandemic situation

4.6.1. Definitions

A total exemption from the payment of the fees laid down in the fee regulation is granted for the regulatory activities specified below within the framework of the submission of a core dossier for a pandemic influenza vaccine and the follow-up submission of a pandemic variation, as described in the 'Guideline on Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application' (EMEA/VEG/4717/03 of 5 April 2004).

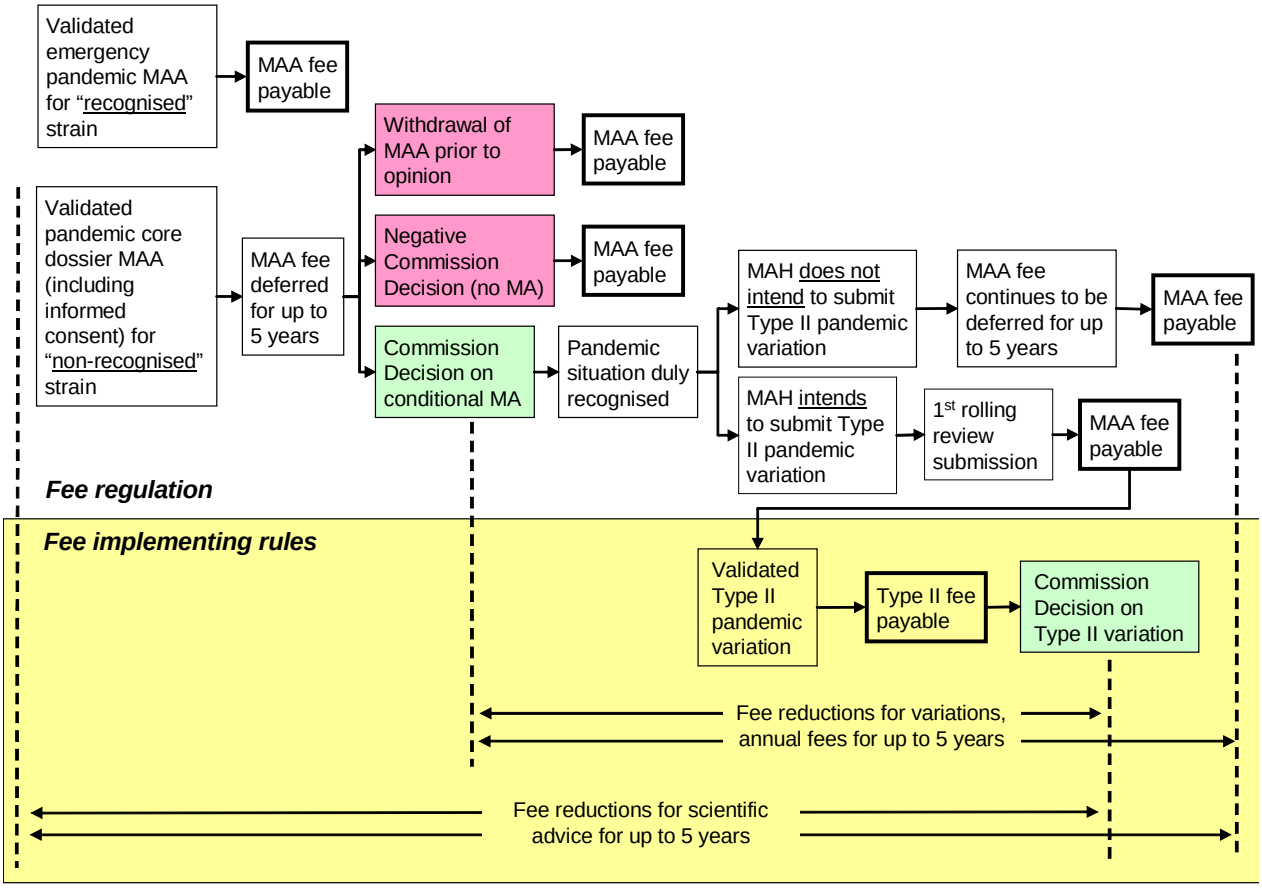
The following total exemptions apply until the type II pandemic variation, that is submitted once the human pandemic situation is duly recognised, has been authorised by the European Union but, in any case, do not apply after the five-year period from the date of administrative validation of the marketing authorisation application for the core dossier has elapsed.

4.6.2. Fee incentives related to pandemic core dossier (including informed consent) for 'non-recognised' strain

Scientific advice	100% fee reduction to the total applicable fee
Post-authorisation activities including type-IA, type-IB, type-II variations (but excluding the type-II pandemic variation) and annual fee	100% fee reduction to the total applicable fee
Negative validation of a type-IB or type-II variation (but excluding the type-II pandemic variation)	100% fee reduction to the total applicable fee

- The fee for a validated pandemic core dossier marketing authorisation application (MAA), including informed consent application, for a pandemic strain that has not yet been "duly recognised, either by the World Health Organisation or by the Community" is deferred.
- If the core dossier MAA is withdrawn prior to opinion or receives a negative Commission Decision, the fee becomes payable and the deferral comes to an end.
- If the core dossier receives a positive Commission Decision, the fee shall continue to be deferred. The MAH also receives fee reductions on variations and annual fees.
- When the pandemic situation becomes duly recognised, the marketing authorisation holder (MAH) may choose not to submit a Type II pandemic variation. In this case the MAA fee continues to be deferred for up to 5 years from the MAA validation date. The MAH continues to receive fee reductions on variations and annual fees for up to 5 years from the MAA validation date.
- If the MAH chooses to submit a Type II pandemic variation, the initial MAA fee becomes payable on the first submission made as part of the rolling review. When the Type II pandemic variation is validated the applicable Type II fee becomes payable. The MAH continues to receive fee reductions on variations and annual fees until the date of the Type II Commission Decision.
- Fee reductions for scientific advice are applicable to requests in the context of a pandemic core dossier and at any time up to 5 years from the MAA validation date or the date of the Type II Commission Decision, whichever comes first.
- The fee for an emergency pandemic MAA submitted when the pandemic situation has been duly recognised becomes payable on validation.

SCHEMATIC OVERVIEW OF PANDEMIC VACCINE FEE REDUCTIONS, DEFERRALS AND PAYMENTS



4.7. Medicinal products for minor uses and minor species (MUMS) / limited markets

4.7.1. Definitions

Exemptions and reductions are granted on fees relating to applications for products classified by the Committee for Medicinal Products for Veterinary Use (CVMP) as indicated for minor use and/or minor species or for which the market is confirmed by the Committee as 'limited' and for which no alternative products are authorised in the EU.

4.7.2. Fee incentives

Scientific advice	100% fee exemption
Administrative charges for negative validations	100% fee exemption

Establishment or extension of an MRL for a substance with respect to an relevant indication	50% fee reduction
Application for a marketing authorisation	50% fee reduction
Extension of a marketing authorisation for a product indicated for a food-producing species to add a minor species	50% fee reduction
Type II variation to a marketing authorisation for a non-food-producing species to add a minor species.	50% fee reduction
Extrapolations of existing MRLs to relevant minor species for which no data are required and therefore no assessment is performed	100% fee reduction
Annual fee for a product authorised exclusively for indications classified by the CVMP	75% fee reduction

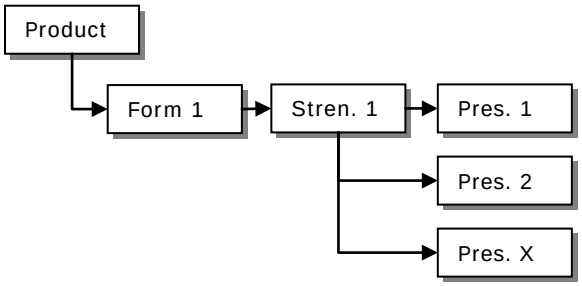
Annex

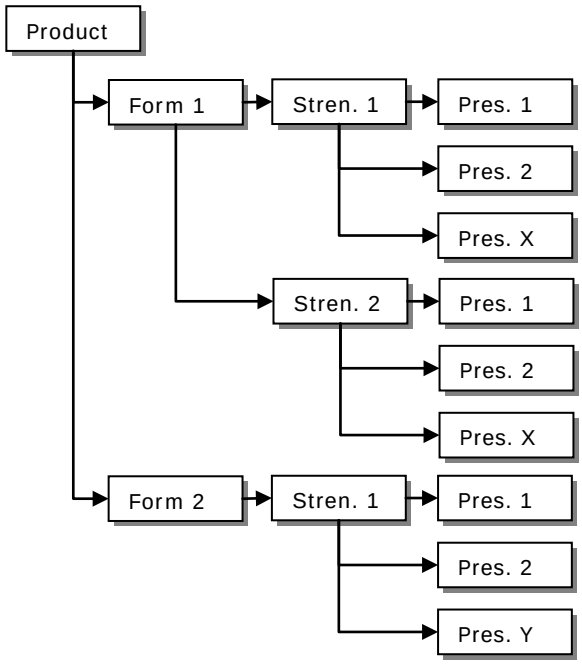
The additional information in this annex is listed using the same numbering as the corresponding sections in chapters 1 to 4. For example, section A.1.1.2. in this annex relates to section 1.1.2. in Chapter 1.

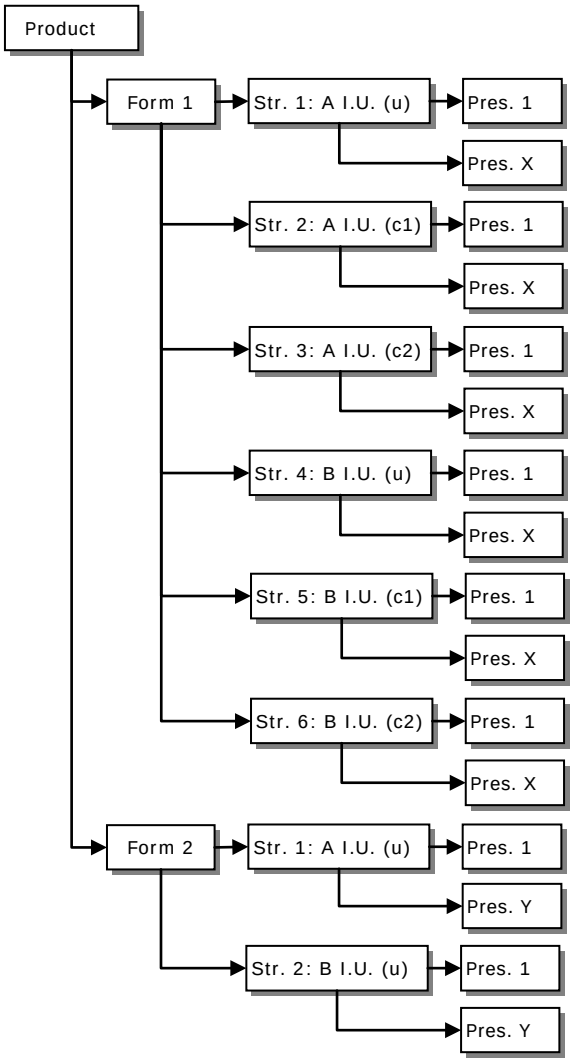
A.1. Medicinal products for human use

A.1.1.2. Examples of the determination of fees for applications for marketing authorisation

It should be noted that the calculation of the total fee for a marketing authorisation application is driven by the pharmaceutical forms, the associated strengths and the associated presentations. The examples shown below do not represent an exhaustive list.

Scenario		**Fee payable**
1. Full dossier application for a medicinal product having one pharmaceutical form with one strength and X presentations		259 400 EURO (basic fee including one pharmaceutical form and one associated strength and one presentation) + (X-1)*6 500 EURO (additional presentations associated with the single strength)

Scenario		Fee payable
2. Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X presentations/ strength associated with the first form and one strength and Y presentations associated with the second form		259 400 EURO (basic fee including one pharmaceutical form and one associated strength and one presentation) + (X-1)*6 500 EURO (additional presentations associated with the first form and strength) + 26 000 EURO (second strength associated with the first form including one presentation) + (X-1)*6 500 EURO (additional presentations associated with the first form and second strength) + 26 000 EURO (second form including its associated strength and one presentation) + (Y-1)*6 500 EURO (additional presentations associated with the second form and its strength)

Scenario		Fee payable
3. Full dossier application for an insulin product having two pharmaceutical forms with six strengths (consisting of two sets of one uncombined preparation and two combination preparations (having different proportions of insulin) with insulin amounts corresponding to A I.U. and B I.U.) and X presentations/strength associated with the first form; and two strengths (of un-combined preparations with insulin amounts corresponding to A I.U. and B I.U.) and Y presentations/strength associated with the second form	 (u) = un-combined insulin preparation (c) = combination insulin preparation (refer to section 1.1.1 for definition of strength of insulin products)	259 400 EURO (basic fee including one pharmaceutical form and one associated strength and one presentation) + (X-1)*6 500 EURO (additional presentations associated with the first form and strength) + 5*26 000 EURO (for second to sixth strengths associated with the first form including one presentation for each strength) + 5*(X-1)*6 500 EURO (additional presentations associated with the second to sixth strengths of the first form) + 26 000 EURO (second form including one associated strength and one presentation) + (Y-1)*6 500 EURO (additional presentations associated with the second form and first strength) + 26 000 EURO (second strength associated with the second form including one presentation) + (X-1)*6 500 EURO (additional presentations associated with the second form and second strength)

A.1.1.3. Examples of the determination of fees for extensions of marketing authorisation

It should be noted that the basic fee for an extension of a marketing authorisation is driven by the pharmaceutical form. The examples shown below do not represent an exhaustive list.

Scenario	Extension application	Fee payable
1. New pharmaceutical form with two strengths and X presentations/strength, for authorised or new route of administration (with submitted/cross-referenced clinical data)	One pharmaceutical form, first strength and X presentations Second strength (of same new pharmaceutical form) and X presentations	77 900 EURO (basic fee for extension) + (X-1)*6 500 EURO (additional presentation fees) + 19 500 EURO (additional strength fee) + (X-1)*6 500 EURO (additional presentation fees)
2. New route of administration for authorised pharmaceutical form with two authorised strengths and X presentations/strength (with submitted/cross-referenced clinical data)	Route of administration for authorised pharmaceutical form, first strength and X presentations Second strength (same new route of administration for same authorised pharmaceutical form) and X presentations	77 900 EURO (basic fee for extension) + (X-1)*6 500 EURO (additional presentation fees) + 19 500 EURO (additional strength fee) + (X-1)*6 500 EURO (additional presentation fees)
3. Two new strengths of same authorised pharmaceutical form and X presentations/strength (without submitted/cross-referenced clinical data)	First new strength and X presentations Second new strength (of same authorised pharmaceutical form) and X presentations	58 400 EURO (basic fee for extension) + (X-1)*6 500 EURO (additional presentation fees) + 19 500 EURO (additional strength fee) + (X-1)*6 500 EURO (additional presentation fees)
4. One new strength of each of two authorised pharmaceutical forms and X presentations/strength (without submitted/cross-referenced clinical data) *THESE SHOULD BE SUBMITTED AS TWO EXTENSION APPLICATIONS*	New strength (of first authorised pharmaceutical form) and X presentations	58 400 EURO (basic fee for extension) + (X-1)*6 500 EURO (additional presentation fees)
	New strength (of second authorised pharmaceutical form) and X presentations	58 400 EURO (basic fee for extension) + (X-1)*6 500 EURO (additional presentation fees)

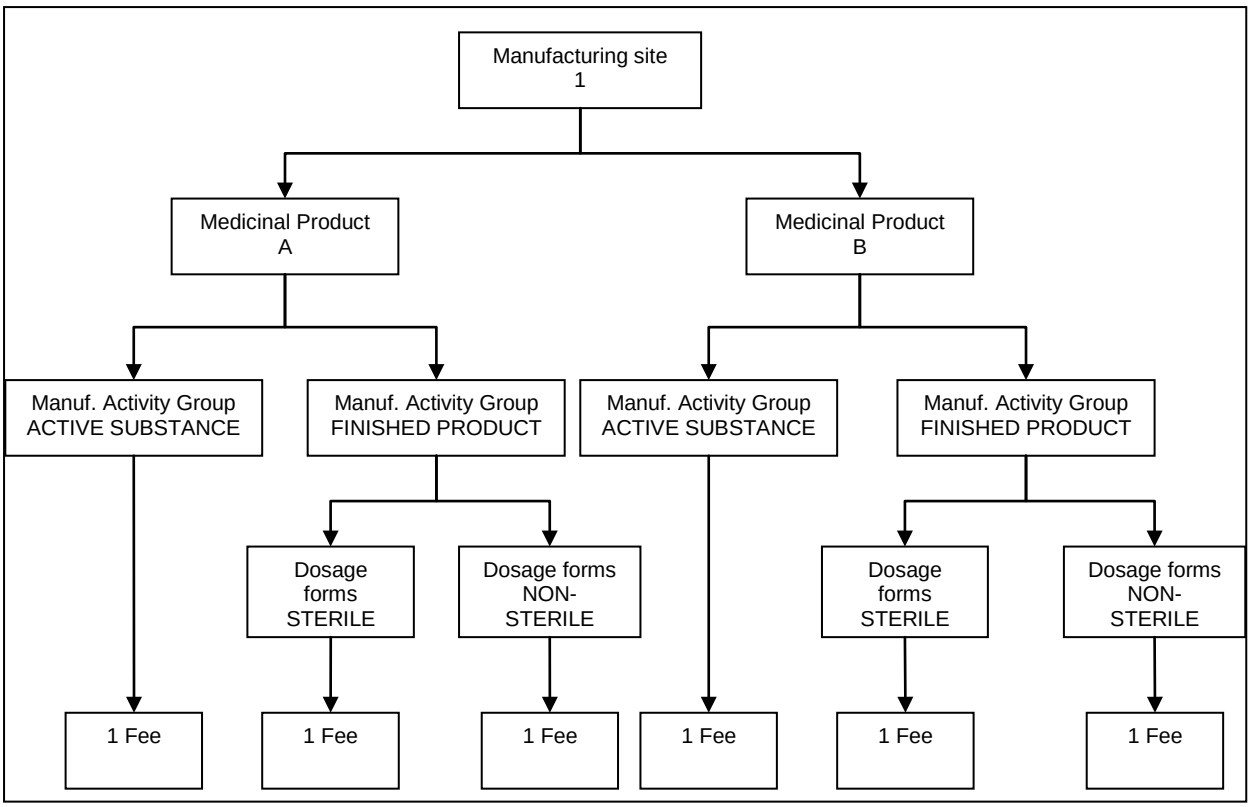
A.1.1.6. Examples of the determination of fees for renewals of marketing authorisation

It should be noted that the number of renewal fees charged for a medicinal product depends on the number of strengths associated with each pharmaceutical form determined as shown in section A.1.1.2. The number of presentations is not taken into consideration for the calculation of the renewal fee. The examples shown below do not represent an exhaustive list.

Scenario	**Strengths associated with a pharmaceutical form**	**Fee payable**
1. Full dossier application for a medicinal product having one pharmaceutical form with one strength and X presentations	One strength associated with one pharmaceutical form	12 900 EURO (basic fee for renewal)
2. Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X presentations/ strength associated with the first form and one strength and Y presentations associated with the second form	Two strengths associated with first pharmaceutical form One strength associated with second pharmaceutical form	2*12 900 EURO (basic fee for renewal) + 12 900 EURO (basic fee for renewal)
3. Full dossier application for an insulin product having two pharmaceutical forms with six strengths (consisting of two sets of one un-combined preparation and two combination preparations (having different proportions of insulin) with insulin amounts corresponding to A I.U. and B I.U.) and X presentations/ strength associated with the first form; and two strengths (of un-combined preparations with insulin amounts corresponding to A I.U. and B I.U.) and Y presentations/strength associated with the second form	Six strengths associated with first pharmaceutical form Two strengths associated with second pharmaceutical form	6*12 900 EURO (basic fee for renewal) + 2*12 900 EURO (basic fee for renewal)

A.1.1.7. Examples of the determination of fees for GMP inspections

In accordance with Annex IV of the "Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures", applicants are liable for more than one inspection fee on the basis of the following flowchart.



The examples shown below do not represent an exhaustive list. They apply to good manufacturing practice (GMP) inspections in relation to medicines for human use and to medicines for veterinary use.

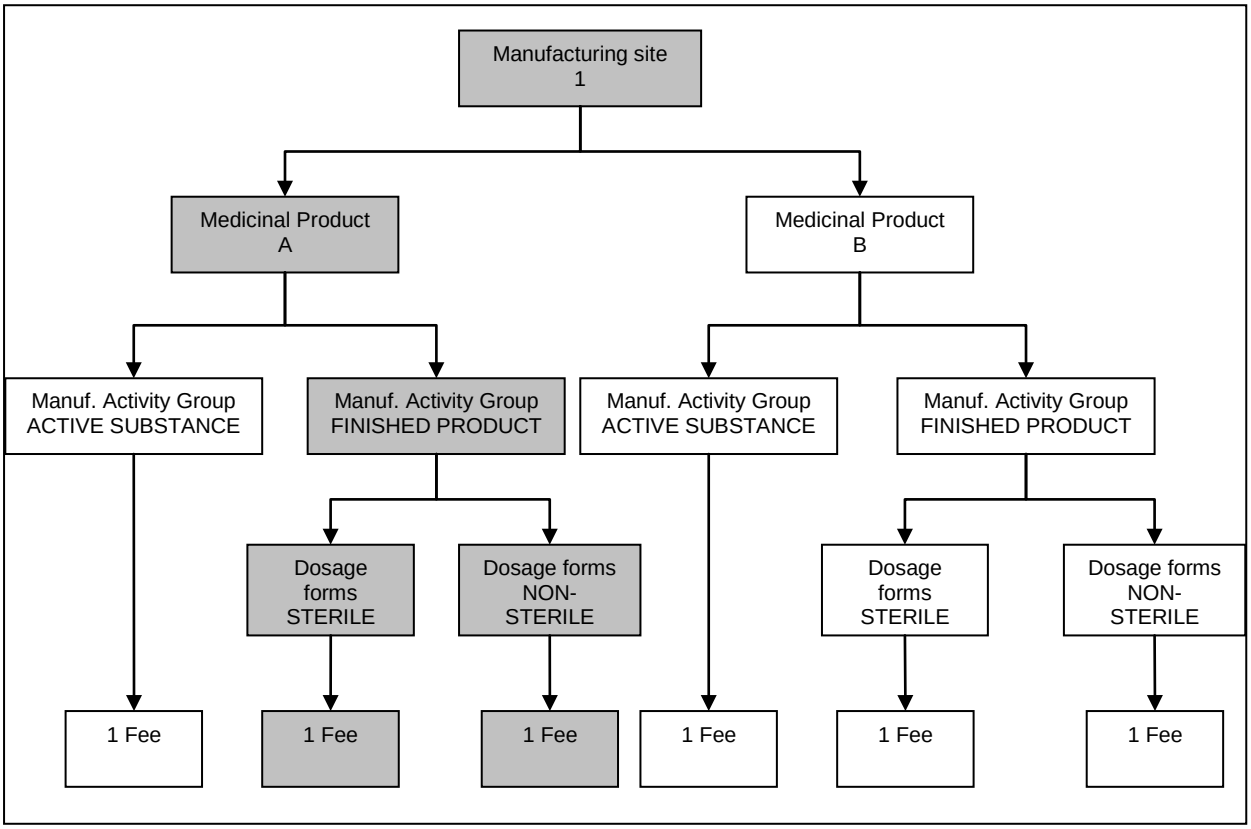
Scenario 1:

GMP inspection of manufacturing site 1 for one medicinal product A and involving two pharmaceutical forms: capsules (non-sterile) and solution for injection (sterile). The manufacturing activity for the two pharmaceutical forms is the same, i.e. manufacture of the finished product.

Fee payable: 2 basic fees (level I), i.e. 19 500 EURO + 19 500 EURO = 39 000 EURO

Rationale: there are two types of dosages forms (sterile and non-sterile) and each one attracts a basic fee (Level I).

The applicable fees to be paid are represented by the grey boxes in the flowchart below.



Scenario 2:

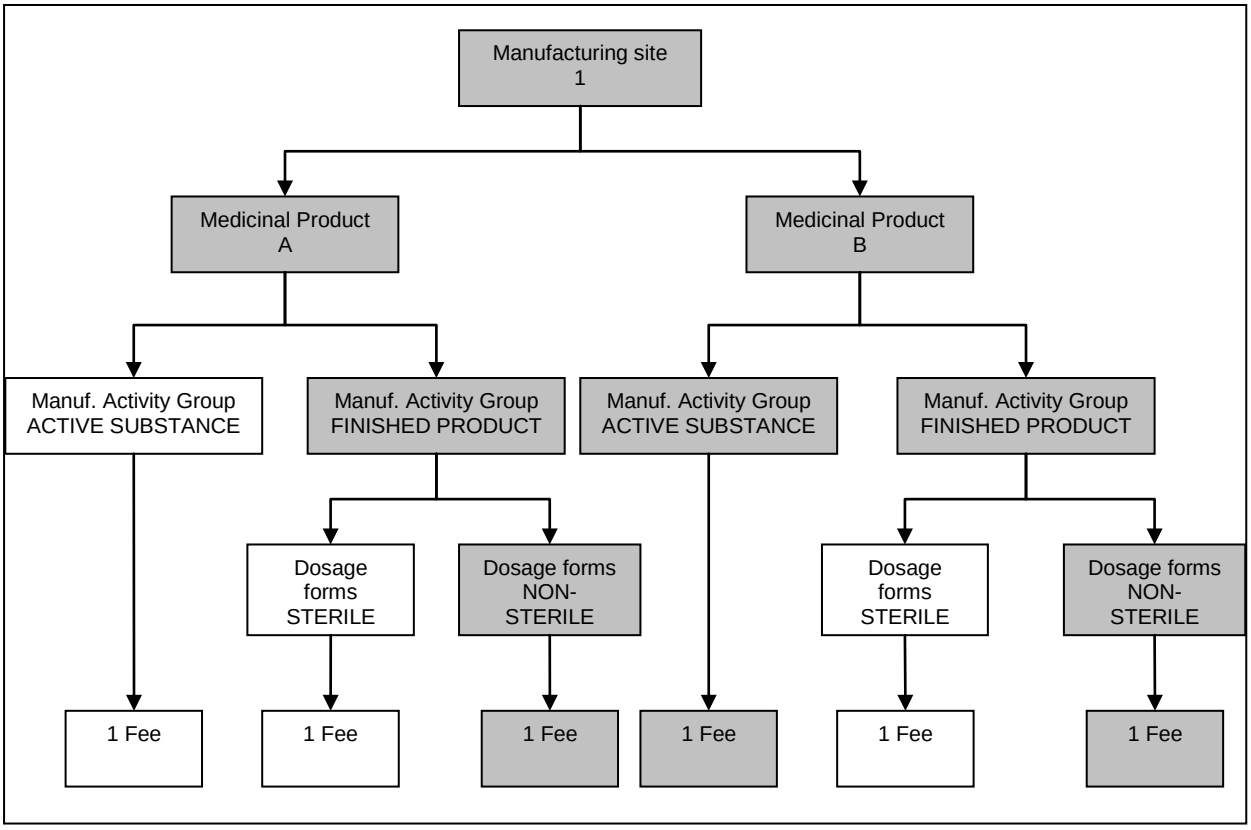
GMP inspection of manufacturing site 1 for two medicinal products (A and B). Product A involves only one pharmaceutical form (capsules) and one pharmaceutical activity (primary packaging). Product B also involves one pharmaceutical form (tablets) and four manufacturing activities (manufacture of the active substance, quality control of the active substance, manufacture of the finished product and primary packaging).

Fee payable: 3 basic fees (Level I), i.e. 19 500 EURO + 19 500 EURO + 19 500 EURO = 58 500 EURO

Rationale: Product A attracts only one fee because there is only one group of manufacturing activities (i.e. finished product) and one dosage form (non-sterile). Product B attracts two fees because there are manufacturing activities related to each group as follows:

- Group Active Substance: manufacture of the active substance and quality control of the active substance
- Group Finished Product: manufacture of the finished product and Primary Packaging

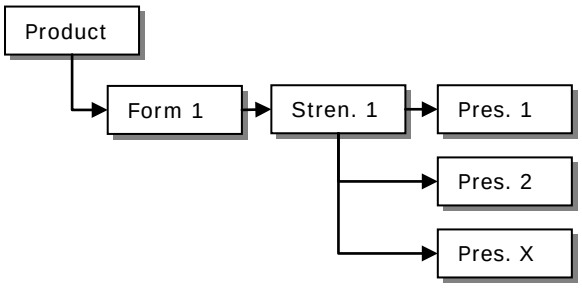
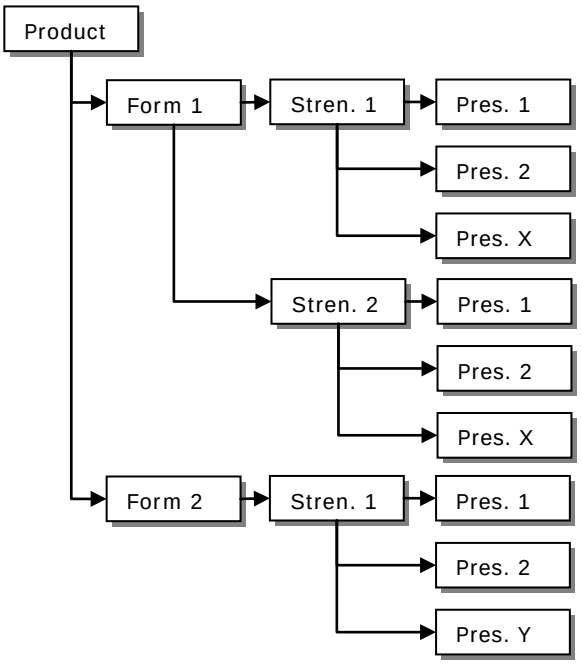
The applicable fees to be paid are represented by the grey boxes in the flowchart below.



A.2. Medicinal products for veterinary use

A.2.1.2. Examples of the determination of fees for applications for marketing authorisation

It should be noted that the calculation of the total fee for a marketing authorisation application is driven by the pharmaceutical forms, the associated strengths and the associated presentations. The number of target species is irrelevant. The examples shown below do not represent an exhaustive list.

Scenario		**Fee payable**
1. Full dossier application for a medicinal product having one pharmaceutical form with one strength and X presentations		129 800 EURO (basic fee including one pharmaceutical form and one associated strength and one presentation) + (X-1)*6 500 EURO (additional presentations associated with the single strength)
2. Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X presentations/ strength associated with the first form and one strength and Y presentations associated with the second form		129 800 EURO (basic fee including one pharmaceutical form and one associated strength and one presentation) + (X-1)*6 500 EURO (additional presentations associated with the first form and strength) + 12 900 EURO (second strength associated with the first form including one presentation) + (X-1)*6 500 EURO (additional presentations associated with the first form and second strength) + 12 900 EURO (second form including its associated strength and one presentation) + (Y-1)*6 500 EURO (additional presentations associated with the second form and its strength)

A.2.1.3. Examples of the determination of fees for extensions of marketing authorisation

It should be noted that the basic fee for an extension of a marketing authorisation is driven by the pharmaceutical form. The examples shown below do not represent an exhaustive list.

Scenario	Extension application	Fee payable
1. New pharmaceutical form with two strengths and X presentations/strength, for authorised/new route of administration (with submitted/cross-referenced clinical data)	One pharmaceutical form, first strength and X presentations Second strength (of same new pharmaceutical form) and X presentations	EUR 32 400 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees) + EUR 8 100 (additional strength fee) + (X-1)*EUR 6 500 (additional presentation fees)
2. New route of administration for authorised pharmaceutical form with two authorised strengths and X presentations/strength (with submitted/cross-referenced clinical data)	Route of administration for authorised pharmaceutical form, first strength and X presentations Second strength (same new route of administration for same authorised pharmaceutical form) and X presentations	EUR 32 400 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees) + EUR 8 100 (additional strength fee) + (X-1)*EUR 6 500 (additional presentation fees)
3. Two new strengths of same authorised pharmaceutical form and X presentations/strength (without submitted/cross-referenced clinical data)	First new strength and X presentations Second new strength (of same authorised pharmaceutical form) and X presentations	EUR 29 200 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees) + EUR 8 100 (additional strength fee) + (X-1)*EUR 6 500 (additional presentation fees)
4. One new strength of each of two authorised pharmaceutical forms and X presentations/strength (without submitted/cross-referenced clinical data)	New strength (of first authorised pharmaceutical form) and X presentations	EUR 29 200 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees)

Scenario	Extension application	Fee payable
THESE SHOULD BE SUBMITTED AS TWO EXTENSION APPLICATIONS	New strength (of second authorised pharmaceutical form) and X presentations	EUR 29 200 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees)
	New pharmaceutical form for new target species, first strength and X presentations Second strength (of same new pharmaceutical form for same new target species) and X presentations	EUR 32 400 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees) + EUR 8 100 (additional strength fee) + (X-1)*EUR 6 500 (additional presentation fees)
	New pharmaceutical form for a new target species, one strength and X presentations	EUR 32 400 (basic fee for extension) + (X-1)*EUR 6 500 (additional presentation fees)
	Second new target species of authorised pharmaceutical form, new strength and X presentations Second strength (for same new target species of authorised pharmaceutical form) and X presentations	EUR 32 400 + (X-1)*EUR 6 500 (additional presentation fees) +EUR 8 100 (additional strength fee) + (X-1)*EUR 6 500 (additional presentation fees)

A.2.1.6. Examples of the determination of fees for renewals of marketing authorisation

It should be noted that the number of renewal fees charged for a medicinal product depends on the number of strengths associated with each pharmaceutical form determined as shown in section A.2.1.2. The number of presentations is not taken into consideration for the calculation of the renewal fee. The examples shown below do not represent an exhaustive list.

Scenario	Strengths associated with a pharmaceutical form	Fee payable
1. Full dossier application for a medicinal product having one pharmaceutical form with one strength and X number of presentations	One strength associated with one pharmaceutical form	6 500 EURO (basic fee for renewal)
2. Full dossier application for a medicinal product having two pharmaceutical forms with two strengths and X number of presentations/strength associated with the first form and one strength and Y number of presentations associated with the second form	Two strengths associated with first pharmaceutical form One strength associated with second pharmaceutical form	2*6 500 EURO (basic fee for renewal) + 6 500 EURO (basic fee for renewal)

A.3. Administrative fees

A.3.2. Examples of the determination of fees for certificates of medicinal product

In accordance with Annex III of the "Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures", requesters are liable for more than one fee depending on the number of medicinal products, importing countries, languages and annexes.

The examples shown below do not represent an exhaustive list.

Scenario 1:

One request for certificates for one medicinal product, as follows:

- Addressed to country 1: 5 certificates with annex 1
- Addressed to country 2: 10 certificates with annex 1

Fee payable using the standard procedure:

1 basic fee for the first set of 5 certificates for country 1 = 260 EURO

1 additional fee for the second set of maximum 6 out of 10 certificates for country 2 = 130 EURO

1 additional fee for the third set of 4 out of 10 certificates for country 2 = 130 EURO

Total fee: 260 EURO + 130 EURO + 130 EURO = 540 EURO

Fee payable using the urgent procedure:

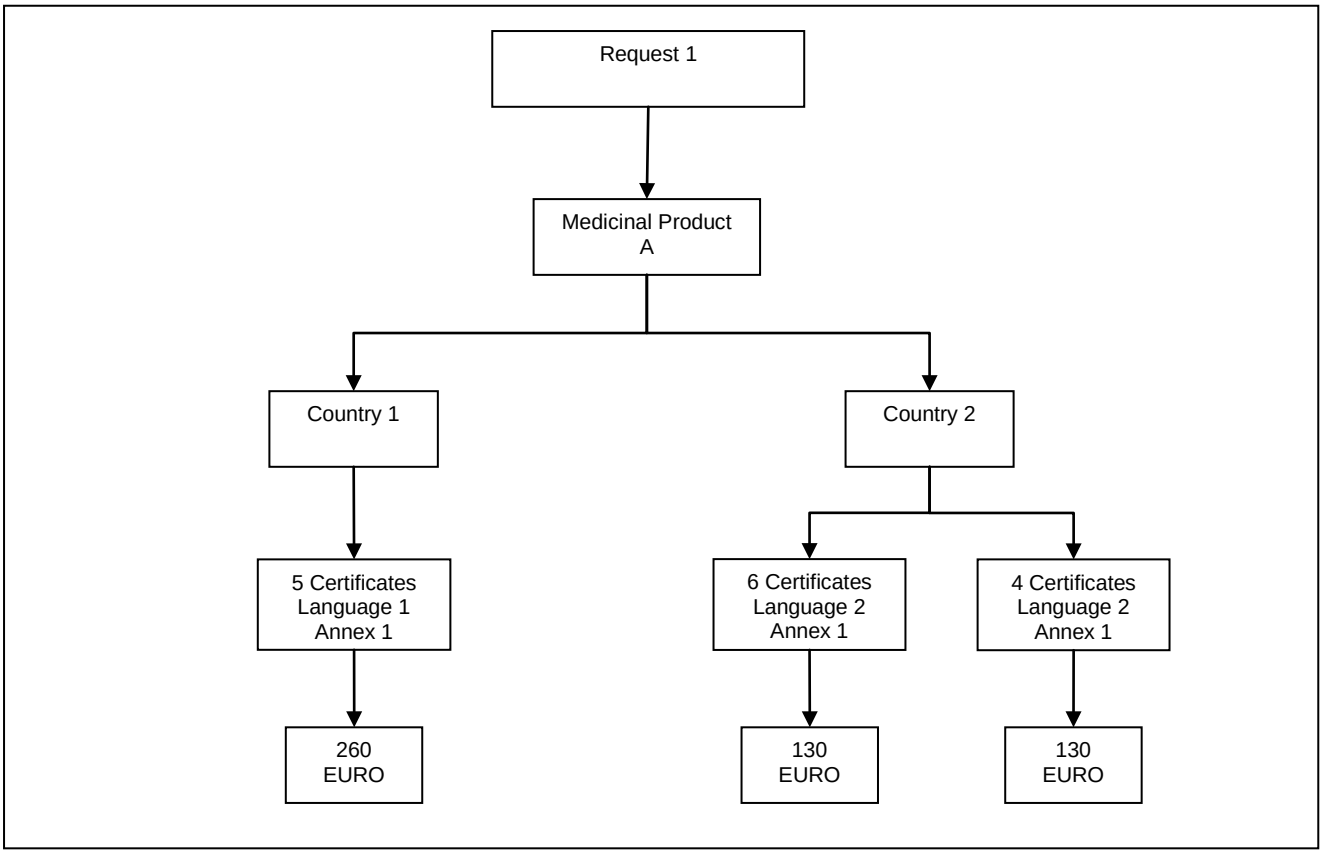
1 basic fee for the first set of 5 certificates for country 1 = 780 EURO

1 additional fee for the second set of maximum 6 out of 10 certificates for country 2 = 390 EURO

1 additional fee for the third set of 4 out of 10 certificates for country 2 = 390 EURO

Total fee: 780 EURO + 390 EURO + 390 EURO = 1 560 EURO

The applicable fees to be paid using the standard procedure are represented in the flowchart below.



Scenario 2:

One request for certificates for two medicinal products, as follows:

- Medicinal product A:
  - Addressed to country 1: 5 certificates with annex 1
  - Addressed to country 2: 6 certificates with Annex 1, 9 certificates with annexes 1 and 2
- Medicinal product B:
  - Addressed to country 1: 15 certificates with annex 1
  - Addressed to country 2: 6 certificates with annex 1

Fee payable using the standard procedure:

1 basic fee for the first set of 5 certificates for medicinal product A for country 1 = 260 EURO

1 additional fee for the second set of 6 certificates for medicinal product A for country 2 = 130 EURO

1 additional fee for the third set of maximum 6 out of 9 certificates for medicinal product A for country 2 = 130 EURO

1 additional fee for the fourth set of 3 out of 9 certificates for medicinal product A for country 2 = 130 EURO

1 additional fee for the fifth set of maximum 6 out of 15 certificates for medicinal product B for country 1 = 130 EURO

1 additional fee for the sixth set of maximum 6 out of 15 certificates for medicinal product B for country 1 = 130 EURO

1 additional fee for the seventh set of 3 out of 15 certificates for medicinal product B for country 1 = 130 EURO

1 additional fee for the eighth set of 6 certificates for medicinal product B for country 2 = 130 EURO

Total fee: 260 EURO + (130 EURO * 7) = 1 170 EURO

Fee payable using the urgent procedure: applying the same rationale as for the standard procedure, one basic fee and seven additional fees are payable.

Total fee = 780 EURO (390 EURO* 7) = 3 510 EURO

The applicable fees to be paid using the standard procedure are represented in the flowchart below.