



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2011
EMA/MB/239263/2011

Amendments to the Management Board implementing rules on the Agency's fees

Management Board meeting 15 December 2011

Background note

Clarification of text for inspection fees

In the context of evaluation of a single application or medicinal product, it is possible that more than one distinct inspection is requested and, therefore, the applicant or marketing authorisation holder (MAH) is liable for more than one inspection fee.

It is proposed that Annex IV of the Fee Implementing Rules be revised in order to clarify the following:

- The basis for determining what constitutes a distinct inspection.
- The basis for determining the applicable fees for each plasma master file inspection.

This proposal does not increase the current fees charged for inspections but aligns the rules with the actual practice for charging fees. Additional amendments to Annex IV are proposed to delete information that is already covered elsewhere in the rules or in Council Regulation (EC) No 297/95.

It is also proposed that Article 7 of the Fee Implementing Rules be amended to delete the fee for consecutive distinct inspections as, in practice, this fee has not been charged by the Agency.

Amendments to plasma master file fees

Variations to plasma master files (PMF) may be included in the documentation submitted for the purpose of review and annual re-certification of a PMF. The Fee Implementing Rules currently refer to two fee levels for review and annual re-certification (i) without variations and (ii) with variations. No distinction is made between minor and major variations submitted in the same documentation.

It is proposed that the rules be clarified to allow charging of the applicable fees for each type IA and/or type IB (minor) variation submitted in the same documentation in addition to the basic fee of EUR 12 900 for review and annual re-certification, to a maximum of EUR 58 400 (equivalent to a type II variation fee). Consequently, a second clarification is proposed for the current fee of EUR 58 400, applicable to variations submitted in the same documentation, to apply when at least one of the variations is a type II (major) variation.



Administrative fees for certificates of medicinal product

The basic fee for certificates of medicinal product is charged per request that includes one set of up to six identical original certificates. If the request comprises more than one set, an additional fee is charged for each of the second and subsequent set in that same request. It is proposed that the Fee Implementing Rules be revised to clarify how these fees are being charged, i.e. EUR 260 for a request including the first set and EUR 130 for each additional set in that request.

Under the current standard procedure for processing requests, certificates are issued within 10 working days. As the pharmaceutical industry has requested, in addition, a voluntary fast-track procedure for processing of urgent requests within 2 working days, it is proposed that the Fee Implementing Rules be revised to introduce new administrative fees for this service, i.e. EUR 780 for a request including the first set and EUR 390 for each additional set in that request.

An additional revision of the rules is proposed for the charging of an administrative fee of EUR 260 when a request for certificates is withdrawn by the requester following confirmation by the Agency of the start of processing of the request.

Fee reductions for Type II variations to MUMS marketing authorisation for a non-food-producing species

The Agency implemented the Policy on Classification and Incentives for Veterinary medicinal products indicated for Minor Use Minor Species/Limited markets (MUMS/Limited markets) on 1 September 2009 (EMA/429080/2009).

The Fee Implementing Rules currently refer to fee reductions for MUMS products applicable only to extensions of marketing authorisations. The intention of the policy agreed by the Committee for Veterinary Medicinal Products (CVMP) is to provide financial assistance for any application that seeks to amend a centralised marketing authorisation to approve the use of the product in an additional minor species.

Such an application can be an extension of a marketing authorisation for a product indicated for a food-producing species, or a Type II variation to a marketing authorisation for a non-food-producing species.

The Fee Implementing Rules should be amended to allow fee reductions also in the latter case.

Fee reductions for core dossier medicinal products to be used in a human pandemic situation

Since 2005 the Agency has been granting a total exemption from the payment of fees for certain procedures relating to core dossiers submitted for human pandemic influenza vaccines in the period leading up to the type II variation for the implementation of the influenza pandemic strains in a duly recognised pandemic situation. The exemptions are specified in point 5 of Annex VII of the Fee Implementing Rules.

A 100% reduction in fees applies to scientific advice and to post authorisation activities, namely variations and annual fees. As the administrative validation of some variations can lead to a negative outcome and rejection of a notification or application, a fee of EUR 2 800 would be payable. In order to ensure consistency in the fees due to the Agency, a 100% reduction should also be applicable to the fee for rejection following conclusion of administrative validation laid down in point 1 (as renumbered) of Annex III of the Fee Implementing Rules.

Matters for consideration

The following modifications to the Fee Implementing Rules are proposed:

- To amend the text of Article 7 and Annex IV to bring the text for inspection fees in line with the text for other types of applications and with the existing procedures as well as clarifying what is a distinct inspection.
- To amend the text in paragraph 3.3 of Annex II on PMF fees to introduce a capping on fees charged for minor variations submitted in the documentation for review and annual re-certification, and to clarify that the fee of EUR 58 400 for review and annual re-certification is due when at least a major variation is included in the documentation.
- To renumber section 3 in Annex III on fee for rejection following conclusion of administrative validation as section 1 for more clarity, and consequently renumbering sections 1 and 2 as sections 2 and 3, respectively.
- To amend the text in section 2 (as renumbered) in Annex III in order to clarify the fees charged for certificates of medicinal product and to introduce fees for urgent requests for certificates and withdrawal of confirmed requests.
- To amend the text in sub-paragraph 4.2.2 in Annex VII in order to clarify that fee incentives for MUMS/limited markets are also applicable to a type II variation that seeks to add a minor species to a marketing authorisation for a non-food-producing species.
- To amend the text in paragraph 5.2 of Annex VII in order to add as an additional exemption a 100% reduction to the fees for rejection following conclusion of administrative validation.

In accordance with Article 11(1) of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency, the European Commission was consulted to give its opinion on the attached proposal and a favourable opinion is expected prior to the Management Board meeting.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/MB/239263/2011

Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures

THE MANAGEMENT BOARD,

Having regard to Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency¹, and in particular Article 11(1) and (2) thereof,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency², and in particular Article 62(3) thereof,

Having regard to European Parliament and Council Directive 2001/82/EC on the Community code relating to medicinal products for veterinary use³,

Having regard to European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use⁴, and in particular Annex I,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and the Council on orphan medicinal products⁵,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and the Council on medicinal products for paediatric use⁶,

Having regard to Regulation (EC) No 1394/2007 of the European Parliament and the Council on advanced therapy products⁷,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuff of animal origin⁸,

¹ OJ L 35, 15.2.1995, p.1.

² OJ L 136, 30.4.2004, p.1.

³ OJ L 311, 28.11.2001, p.1.

⁴ OJ L 311, 28.11.2001, p.67.

⁵ OJ L 18, 22.1.2000, p.1.

⁶ OJ L 378, 27.12.2006, p.1.

⁷ OJ L 324, 10.12.2007, p.121.

⁸ OJ L 152, 16.6.2009, p.11.



Having regard to Commission Regulation (EC) No 2049/2005 laying down rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises⁹,

Having regard to Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of the marketing authorisation for medicinal products for human and veterinary products¹⁰,

Having regard to Commission Regulation (EC) No 668/2009 on evaluation and certification of evaluation and certification of quality and non-clinical data related to advanced therapy medicinal products (ATMPs) developed by micro, small and medium-sized enterprises¹¹,

HAS DECIDED:

Article 1 – Scientific advice and protocol assistance

1. The definitions and fees payable for requests for scientific advice, protocol assistance and follow-up requests are laid down in Annex I.

Article 2 – Scientific services

1. Scientific opinions for the evaluation of medicinal products for human use intended exclusively for markets outside the European Union pursuant to Article 58 of Regulation (EC) No 726/2004 shall be subject to the fees stated in Articles 3, 4 and 7 and Annex IV of these Rules.
2. The fee payable for an opinion on medicinal products for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004 shall be EUR 129 800. In accordance with Article 9 of Council Regulation (EC) No 297/95, this amount shall be deducted from the respective fee payable for a marketing authorisation application for the same product.
3. The fees payable for other scientific services are laid down in Annex II.

Article 3 – Extension of marketing authorisations

1. By derogation from the applicable full fee of EUR 77 900 for medicinal products for human use and of EUR 32 400 for medicinal products for veterinary use:
 - 1.1. the fee payable for an extension of a marketing authorisation for a medicinal product for human use shall be EUR 58 400 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 marketing authorisation holder;
 - 1.2. the fee payable for an extension of a marketing authorisation for a medicinal product for veterinary use shall be EUR 29 200 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 marketing authorisation holder;
 - 1.3. in the case of immunological veterinary medicinal products, the fee payable for an extension shall be EUR 8 100 for all quality extensions, i.e. requiring chemical, pharmaceutical and

⁹ OJ L 329, 16.12.2005, p.4.

¹⁰ OJ L 334, 12.12.2008, p.7.

¹¹ OJ L 194, 25.7.2009, p.7.

biological documentation, for which no clinical data are submitted or no cross-references to previously submitted clinical data are made by the marketing authorisation holder.

- 1.4. the applicable full fees and the fees specified in subparagraphs 1.1, 1.2 and 1.3 shall cover a single pharmaceutical form and one associated strength/potency and one presentation. In the case of medicinal products for veterinary use these fees shall cover one or more target species associated with that pharmaceutical form.
2. The fee of EUR 77 900 shall be payable for an extension of a marketing authorisation made under Article 29 of Regulation (EC) No 1901/2006.

The fee specified in subparagraph 1 shall cover a single pharmaceutical form and one associated strength/potency and one presentation.

3. The fee payable for each additional strength/potency of the same pharmaceutical form of the same extension submitted at the time of the extension application shall be:
 - 3.1. EUR 19 500 for a medicinal product for human use;
 - 3.2. EUR 8 100 for a medicinal product for veterinary use.

That increase shall cover one additional strength/potency and one presentation. In the case of medicinal products for veterinary use these fees shall cover one or more target species.

4. The fee of EUR 6 500 shall be payable for each additional presentation of the same extension submitted at the time of the extension application.

Article 4 – Type II variations

1. By derogation from the applicable full fee of EUR 77 900 for medicinal products for human use and of EUR 38 900 for medicinal products for veterinary use (except for immunological medicinal products for which the fee shall be EUR 6 500 for all categories of variations):
 - 1.1. the fee of EUR 58 400 for medicinal products for human use and EUR 29 200 for medicinal products for veterinary use is applicable for all quality variations, i.e. all 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 marketing authorisation holder;
 - 1.2. by derogation from subparagraph 1.1 the fee of EUR 19 500 for medicinal products for human use and EUR 9 700 for medicinal products for veterinary use is applicable to each of the third and subsequent type II variation that is grouped in a single application made under the terms of Article 7 of Commission Regulation (EC) No 1234/2008 or, in the case of a worksharing application, to each of the third and subsequent type II variation to the centralised marketing authorisation referred to in subparagraph 2.1 of Article 4bis. The applicable full fee and reduced fee specified in subparagraph 1.1 shall be payable for the first and second Type II variation respectively when both full and reduced fees are applicable to variations in the same grouping or worksharing application.
 - 1.3. the applicable full fee of EUR 77 900 shall be payable for each new indication applied for under Article 29 of Regulation (EC) No 1901/2006;
 - 1.4. fees for applications for variations to certified plasma master files and vaccine antigen master files are given in Annex II.

Article 4bis – Grouping of variations and worksharing procedures

1. The applicable fee as specified in Council Regulation (EC) No 297/95 or in these Rules shall be payable for each individual variation to a marketing authorisation that is grouped in a single notification or a single application made under the terms of Article 7 of Commission Regulation (EC) No 1234/2008.
2. The fees payable for an application for a worksharing procedure made under the terms of Article 20 of Commission Regulation (EC) No 1234/2008 are as follows:
 - 2.1. the applicable fee as specified in Council Regulation (EC) No 297/95 or in these Rules for each individual variation to one of the centralised marketing authorisations, 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;
 - 2.2. the administrative fee laid down in Annex III for each individual variation to the other centralised marketing authorisation(s) included in the same worksharing application as in subparagraph 2.1, above, if applicable;
 - 2.3. the provisions for fee reductions or waivers that are the most favourable to the applicant shall apply to an application for a worksharing procedure.

Article 5 – Annual fee

1. By derogation from the applicable full fee of EUR 93 000 for medicinal products for human use and of EUR 31 000 for medicinal products for veterinary use:
 - 1.1. the annual fee shall be EUR 46 600 for medicinal products for human use authorised pursuant to Article 10(4) of Directive 2001/83/EC, and EUR 15 400 for medicinal products for veterinary use authorised pursuant to Article 13(4) of Directive 2001/82/EC;
 - 1.2. the annual fee shall be EUR 23 200 for medicinal products for human use authorised pursuant to Articles 10(1), 10(3) and 10c of Directive 2001/83/EC and EUR 7 800 for medicinal products for veterinary use authorised pursuant to Articles 13(1), 13(3) and 13c of Directive 2001/82/EC.

Article 6 – Administrative services

1. The classification and fees for administrative services are laid down in Annex III.

Article 7 – Inspections

1. The definition for a distinct inspection laid down in Annex IV shall apply to any inspection within or outside the Union in relation to a medicinal product for human use or a medicinal product for veterinary use.
2. By derogation from the applicable full fee of EUR 19 500 for medicinal products for human use and for medicinal products for veterinary use:
 - 2.1. The fee for a plasma master file (PMF) inspection shall be EUR 9 700 in the case of each consecutive distinct inspection(s) carried out in conjunction with a PMF inspection for which a full fee is payable, provided that such consecutive inspection(s) concern(s) the same PMF application and is conducted by the same inspection team in the same PMF inspection tour;

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New

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- 2.2. The fee of EUR 9 700 shall be payable when a distinct inspection, that has been formally notified, is cancelled due to:
- withdrawal of the application by the applicant;
 - changes to manufacturing arrangements made by the manufacturer necessitating a cancellation of the inspection, at any time before the inspection is carried out;
 - changes made by the applicant or marketing authorisation holder to the scope of the application or submitted data, or access to, changes to the ownership of, or location of manufacturing facilities or data necessitating a cancellation of the inspection, at any time before the inspection is carried out.
3. The conditions for costs incurred in relation to inspections are laid down in Annex IV.

Article 8 – Scale of fees payable to national competent authorities

1. In accordance with Article 62(2) of Regulation (EC) No 726/2004 and Article 11(1) of Council Regulation (EC) No 297/95, a scale of fees to be paid by the Agency to national competent authorities is given in Annex V.
2. The allocation of part of the resources deriving from annual fees for special activities referred to in Annex V is given in Annex VI.

Article 9 – Total or partial exemption from payment of fees

1. Conditions for the implementation of the second paragraph of Article 9 of Council Regulation (EC) No 297/95 for the total or partial exemption from the payment of fees are given in Annex VII.

Article 10 – Implementing provisions

1. Bank transfer charges relating to payments by applicants under Council Regulation (EC) No 297/95 or relating to this decision shall be borne by the applicant.
2. Bank transfer charges relating to payments to national competent authorities under this decision shall be borne by the Agency.

Article 11

1. These rules replace and annul all previous decisions of the Management Board relating to the implementation of Council Regulation (EC) No 297/95, and on scales of fees under Article 62(3) of Regulation (EC) No 726/2004.
2. This decision shall enter into force on 1 January 2012 and shall be published on the Agency's website.

London, 15 December 2011

Kent Woods
Chair of the Management Board

Annex I

Scientific advice and protocol assistance

1. Definitions

For the purposes of these rules, the following definitions shall apply.

1. Quality development: chemical, pharmaceutical and biological testing.
2. Safety development: toxicological and pharmacological tests.
3. 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.
4. Initial request: first request for scientific advice or protocol assistance introduced in relation to the submission of an application in the pre- or post-authorisation phase.
5. 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, safety and/or clinical development including pharmacovigilance/risk management aspects).
6. 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.

Scientific advice on comparability of similar biological medicinal products is considered as part of clinical development and the relevant fees apply.

2. Medicinal products for human use

The following ranges and classification shall apply for fees for scientific advice and protocol assistance relating to medicinal products for human use.

2.1. Initial request

EUR 77 900 for multidisciplinary requests on:

- quality, safety and clinical development, or
- quality and clinical development, or
- safety and clinical development, or
- qualification advice.

EUR 58 400 for requests on:

- clinical development, or
- quality and safety development, or
- quality and bioequivalence studies for generic medicinal products.

EUR 38 900 for requests on:

- quality development, or
- safety development, or
- bioequivalence studies for generic medicinal products.

2.2. Follow-up to the initial request

EUR 38 900 for follow-up on:

- quality, safety and clinical development, or
- quality and clinical development, or
- safety and clinical development, or
- qualification advice.

EUR 29 200 for follow-up on:

- clinical development, or
- quality and safety development, or
- quality and bioequivalence studies for generic medicinal products.

EUR 19 500 for follow-up on:

- quality development, or
- safety development, or
- bioequivalence studies for generic medicinal products.

3. Medicinal products for veterinary use

The following ranges and classification shall apply for fees for scientific advice related to medicinal products for veterinary use.

3.1. Initial request

EUR 38 900 for multidisciplinary requests request on:

- quality, safety and clinical development, or
- quality and clinical development, or
- safety and clinical development.

EUR 19 500 for requests on:

- quality and safety development, or
- clinical development, or
- quality and bioequivalence studies for generic medicinal products.

EUR 12 900 for requests:

- related to an application to set a new maximum residue limit, or
- quality development, or
- safety development, or
- bioequivalence studies for generic medicinal products.

3.2. Follow-up to the initial request

EUR 19 500 for follow-up on:

- quality, safety and clinical development, or
- quality and clinical development, or
- safety and clinical development.

EUR 12 900 for follow-up on:

- quality and safety development, or
- clinical development, or
- quality and bioequivalence studies for generic medicinal products.

EUR 9 700 for follow-up:

- related to an application to set a new maximum residue limit, or
- quality development, or
- safety development, or
- bioequivalence studies for generic medicinal products.

4. Scientific advice in relation to products classified by the Committee for Medicinal Products for Veterinary Use (CVMP)

EUR 9 700 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.

Annex II

Scientific services

1. Evaluation of traditional herbal medicinal products

The following ranges and classification shall apply for fees for evaluation of traditional herbal medicinal products:

- EUR 19 500 for request for scientific support and advice by the HMPC on multiple areas related to traditional herbal medicinal products.
- EUR 12 900 for requests for scientific support and advice by the HMPC on single areas, e.g. quality or safety or long-standing use, related to traditional herbal medicinal products.

2. Consultation on ancillary substances, including blood derivatives, incorporated in medical devices

Definitions 4 and 5 of the definitions in Annex I shall apply by analogy to this section.

The following ranges and classification shall apply for consultation on ancillary medicinal substances, including blood derivatives, incorporated in medical devices.

2.1. Initial request

EUR 77 900 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.

EUR 58 400 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.

EUR 38 900 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.

The determination of the fee shall be guided by the following principles:

- Where a device incorporates two or more ancillary substances/derivatives, the fee relates to one of the substances/derivatives only – the one that commands the highest fee.
- One application may include a range of strengths or concentrations of the ancillary substance/derivative and/or a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same substance/derivative from the same manufacturer.

2.2. Follow-up to the initial request

EUR 19 500 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 for evaluation in response to a list of deficiencies notified in an initial report.

EUR 38 900 for consultation on an amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency (amendments will be classified by analogy to Annex I of Commission Regulation (EC) No 1234/2008).

EUR 38 900 for consultation on a major amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency (amendments equivalent to a type-II variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

EUR 6 500 for consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency (amendments equivalent to a type-IB variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

EUR 2 800 for consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency. (Amendments equivalent to a type-IA variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

3. Certification of compliance with European Union legislation for plasma master files (PMF)

The following ranges and classification shall apply for certification of compliance with European Union legislation for PMF.

3.1. Initial certification

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

EUR 64 700 for review of the PMF and its initial certification where the data contained in the PMF have not been previously evaluated within the centralised procedure.

EUR 58 400 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.

EUR 19 500 for 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, but which requires a full evaluation report according to current standards for the grant of a certificate.

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

EUR 6 500 for 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.

3.2. Variations to a certified PMF

Article 4bis of these rules shall apply by analogy to variations to a certified PMF.

EUR 58 400 for review and certification of a major variation to the PMF in accordance with Commission Regulation (EC) No 1234/2008.

EUR 6 500 for review and certification of a minor variation of type IB to the PMF in accordance with Commission Regulation (EC) No 1234/2008.

EUR 2 800 for review and certification of a minor variation of type IA to the PMF in accordance with Commission Regulation (EC) No 1234/2008.

By derogation from subparagraphs 1 and 2 of this paragraph, a single fee of EUR 58 400 shall be payable 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.

3.3. Annual re-certification of PMF

EUR 12 900 for review and annual re-certification of the PMF under this scheme where no major variations are included in the submitted documentation. The fee shall be increased by the applicable fees specified in paragraph 3.2 for each minor variation of type IA or type IB included in the submitted documentation, up to a maximum of EUR 58 400.

EUR 58 400 for 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.

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4. Certification of compliance with European Union legislation for vaccine antigen master files (VAMF)

The following ranges and classification shall apply for certification of compliance with European Union legislation for VAMF.

4.1. Initial certification

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

EUR 64 700 for 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 EUR 64 700. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

EUR 58 400 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 EUR 58 400. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

EUR 19 500 for review of the VAMF and its initial certification where the data contained in the vaccine antigen master file has been previously evaluated under the centralised procedure and where no changes or harmonisation have been included, but which requires a full evaluation report according to current standards for the grant of a certificate.

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 EUR 19 500. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

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

EUR 6 500 for 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 EUR 6 500. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

4.2. Variations to a certified VAMF

Article 4bis of these rules shall apply by analogy to variations to a certified VAMF.

EUR 58 400 for 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 EUR 58 400. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

EUR 6 500 for 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 EUR 6 500. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 38 900.

EUR 2 800 for 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 EUR 2 800. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 2 800 per VAMF up to a maximum of EUR 19 500.

By derogation from subparagraphs 1, 2 and 3 of this paragraph, a single fee of EUR 58 400 shall be payable 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 EUR 58 400. Variations submitted simultaneously in the same grouped application for antigens from the same group will be charged at EUR 6 500 per VAMF up to a maximum of EUR 77 900.

5. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs)

The following ranges and classification shall apply for certification of quality and non-clinical data relating to ATMPs developed by SMEs:

- EUR 58 400 for the evaluation of an application relating to quality and non-clinical data;
- EUR 38 900 for the evaluation of an application relating to quality data.

The fees in the first bullet-point, above, shall be subject to the fee reduction for scientific services applicable to SMEs under Commission Regulation (EC) No 2049/2005.

Annex III Administrative services

The following classification and amounts shall apply to fees for administrative services provided by the Agency.

Previously point 3 **1. Fee for rejection following conclusion of administrative validation**

In accordance with Article 8(3) of Council Regulation (EC) No 297/95, a fee of EUR 2 800 shall be payable where an application has been rejected following the conclusion of the administrative validation.

The fee specified in paragraph 1, above, shall be payable in the case of rejection following the conclusion of the administrative validation of a notification or an application for grouping of variations and worksharing procedures referred to in Article 4bis of these Rules.

2. Fees for issuing certificates of medicinal product

2.1. Definitions

For the purposes of these rules, the following definitions shall apply,

1. A set of certificates of medicinal product is composed of 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.
2. The standard procedure for issuing certificates of medicinal product applies to certificates issued within 10 working days.
3. The urgent procedure for issuing certificates of medicinal product applies to certificates issued within 2 working days.

2.2. Standard procedure

EUR 260 for each request for certificates for medicinal products, including one set of certificates, made using the standard procedure.

The fee payable for each additional set of certificates for medicinal products included in the same request made using the standard procedure shall be EUR 130.

2.3. Urgent procedure

EUR 780 for each request for certificates for medicinal products, including one set of certificates, made using the urgent procedure.

The fee payable for each additional set of certificates for medicinal products included in the same request made using the urgent procedure shall be EUR 390.

Where a request made using the urgent procedure cannot be processed within 2 working days, the fees applicable to the standard procedure shall be payable.

2.4. Withdrawal of request for certificates

A fee of EUR 260 shall be payable when a request for certificates is withdrawn by the requester following confirmation of the start of the procedure.

3. Fees for notifications of parallel distribution

A fee of EUR 3 870 for the administrative service of the regulatory check in the case of parallel distribution applies for each initial parallel distribution notification. This fee covers the regulatory check of all pack sizes of a particular strength and pharmaceutical form for a given medicinal product. However, in case a given medicinal product is available in a particular strength and pharmaceutical form but has several presentations for administration (e.g. a solution for injection in a vial, a cartridge and a pre-filled pen presentation or a solution for injection in a pre-filled syringe and in an injection device presentation), a separate fee is applicable to the different presentations as the information on the labelling and the package leaflet is different.

The fee covers the regulatory check of the parallel distribution notification for a given Member State of destination. In case of a parallel distribution notification for different Member States of destination with different official language(s) (e.g. Germany and Denmark), a separate fee for each Member State of destination will be charged. However, in case of the same official language(s) in the different Member States of destination (e.g. United Kingdom, Ireland and Malta), only one fee is applicable. This fee covers all notifications of a change made during a one-year period after obtaining the Agency notice.

4. Fees for worksharing procedures

The following fees shall be payable for each variation as specified in Article 4bis, subparagraph 2.2 of these Rules, included in the same worksharing application.

- EUR 6 500 for medicinal products for human use and EUR 3 210 for medicinal products for veterinary use for Type II variations to which the respective full fees would otherwise be applicable.
- EUR 3 720 for multiple medicinal products for human use submitted solely on usage patent grounds for type-II variations to marketing authorisations granted under Articles 10(1), 10(3) and 10(4) of Directive 2001/83/EC to which the respective full fees would otherwise be applicable.
- EUR 1 080 for medicinal products for human use and for veterinary use for type-IB variations to which the fee specified in Council Regulation (EC) No 297/95 would otherwise be applicable.
- EUR 540 for medicinal products for human use and for veterinary use for type-IA variations to which the fee specified in Council Regulation (EC) No 297/95 would otherwise be applicable.

Annex IV Inspections

Revision of
Annex IV

1. Background

In the context of assessing a single dossier, manufacturer, blood establishment, clinical trial, non-clinical study or pharmacovigilance inspection, it is possible that more than one 'inspection' is requested, and thus the applicant, marketing authorisation holder, plasma master file holder or vaccine antigen master file holder (hereinafter the "applicant") will be liable for more than one inspection fee, since Council Regulation (EC) No 297/95 provides for a fee for each inspection. This Annex defines the basis for determining what constitutes a single, distinct inspection, and how the number of inspection fees for which an applicant is liable is calculated.

2. Definition of distinct inspection

2.1. Good manufacturing practices (GMP)

For the purposes of determining liability for GMP inspection fees, distinct inspections are distinguished one from another as follows.

- A distinct inspection is one concerning:
 - a specific manufacturing site, and
 - relates to a medicinal product which is the subject of a particular application/authorisation, and
 - relates to a particular group of manufacturing activities (manufacture of active substance or medicinal product), and
 - relates to a particular group of manufacturing operations (manufacture of sterile or non-sterile medicinal products), and
- involves the same inspection team and is conducted on successive working days.

Irrespective of it being in the context of the same application, any other inspection concerning any additional group of manufacturing activities or operations and/or site is considered to be a further, distinct inspection.

In the above definition:

- a manufacturing site is a physical location identifiable by a distinct address which contains one or more manufacturing facilities at the same address; whereby a manufacturing facility comprises a separate building or complex of buildings in which a manufacturing activity or activities are carried out;
- a medicinal product is distinguished by its unique EMA number.
- two separate groups of manufacturing activities are distinguished one from another as follows:
 - all activities related to the manufacture of the active substance
 - activities related to the manufacture of the medicinal product
- two separate groups of manufacturing operations are distinguished one from another as follows:
 - manufacture of sterile products

- manufacture of non-sterile products

Fee calculations for inspections of VAMF manufacturers shall be done by analogy to the calculation of inspections for active substances.

2.2. Good clinical practices (GCP)

For the purposes of determining liability for GCP inspection fees, **distinct** inspections are distinguished one from another as follows.

- Each distinct inspection is the subject of a separate inspection report.
- A **distinct** inspection is one with a GCP compliance and/or product and/or process-related scope concerning:
 - a particular clinical trial activity, and
 - relates to a medicinal product which is the subject of a particular application, and
 - is carried out at a specific clinical trial related site, and
 - is conducted on a specific occasion.

Irrespective of it being in the context of the same application, any other inspection concerning any additional clinical trial related activity and/or site is considered to be a further, distinct inspection.

In the above definition:

- a single responsibility or set of directly related responsibilities involved in the conduct of clinical trials constitutes a single clinical trial activity, and
- a physical location which contains one or more clinical trial facilities at the same address constitutes a single clinical trial site, where
- a clinical trial facility comprises a separate building or complex of buildings in which a clinical trial activity or activities are carried out.

2.3. Good laboratory practices (GLP)

For the purposes of determining liability for GLP inspection fees, **distinct** inspections are distinguished one from another as follows.

- A general GLP compliance inspection covering general GLP compliance of a single test facility which has carried out non-clinical safety, toxicological and pharmacological studies proposed in an application for marketing authorisation for either human or veterinary medicinal products.
- A specific GLP study related inspection covering studies performed at a single test facility to assess issues related to the assessment of the non-clinical part of the dossier.

2.4. Pharmacovigilance inspections

For the purposes of determining liability for pharmacovigilance inspection fees, **distinct** inspections are distinguished one from another as follows.

- Each inspection is the subject of a separate inspection report.
- A **distinct** inspection is one with a pharmacovigilance obligation compliance and/or product and/or process-related scope concerning:

- a particular pharmacovigilance activity, and
- relates to a medicinal product the subject of a particular authorisation, and
- is carried out at a specific pharmacovigilance site of pharmacovigilance activity, and
- is conducted on a specific occasion.

Irrespective of it being in the context of the same authorisation, any other inspection concerning any additional pharmacovigilance related activity and/or site is considered to be a further, distinct inspection.

In the above definition:

- a single responsibility or set of directly related responsibilities involved in the conduct of pharmacovigilance constitutes a single pharmacovigilance activity, and
- a physical location which contains one or more pharmacovigilance facilities at the same address constitutes a single pharmacovigilance site, where
- a pharmacovigilance facility comprises a separate building or complex of buildings in which a pharmacovigilance activity or activities are carried out.

2.5. Plasma master file (PMF)

For the purposes of determining liability for PMF inspection fees, distinct inspections are distinguished one from another as follows.

- A distinct inspection is one which
 - relates to a specific PMF dossier, the subject of a particular PMF certificate, and
 - is carried out at a specific blood establishment site, and
 - is conducted on a specific occasion.

Irrespective of it being in the context of the same PMF application, any other inspection concerning any additional blood/plasma related activity and/or blood establishment is considered to be a further, distinct inspection.

In the above definition:

- a blood establishment may comprise a separate building or complex of buildings in which a blood/plasma activity or activities related to the production of a plasma pool defined by the PMF dossier are carried out.

3. Cost of inspections

Where an inspection has been carried out the applicable inspection fee(s) shall be payable by the applicant.

Where an inspection, cancelled by the applicant at any stage in the processing of the application, was to take place outside the European Union, the applicant shall be charged the costs of any travel expenses already incurred by the inspecting authority on the date of cancellation for which the authority is not able to obtain reimbursement.

No costs shall be payable by the applicant for any financial consequences arising from changes made to notified inspection arrangements by parties other than the applicant e.g. change in travel arrangements for the inspectors.

No costs shall be payable by the European Medicines Agency and the inspecting authority for any financial consequences suffered by the applicant arising out of a failure to conduct a notified inspection or a consequential need to rearrange that inspection.

Annex V

Scale of fees to be paid by the European Medicines Agency to national competent authorities

1. General considerations

Article 62(3) of Regulation (EC) No 726/2004 states the Agency's Management Board is required to establish a fixed scale of fees in remuneration of the services of rapporteurs, co-rapporteurs and experts.

2. Repayment of certain costs to national competent authorities

As laid out in Regulation (EC) No 726/2004, the Agency is responsible for the implementation of uniform regulatory procedures concerning the authorisation and supervision of centrally approved medicinal products and those presented for arbitration through the CHMP and CVMP.

Member State competent authorities undertake to make available to the Agency the necessary human scientific resources needed for the preparation of the opinions of the Agency's scientific committees.

The Agency is expected to cover all administrative costs as well as all expenses related to the organisation of meetings and to the travel and accommodation of committee members and experts. Member States competent authorities must be fairly compensated for putting resources at the disposal of the Agency.

2.1. The amount of financial resources redistributed to national competent authorities will be half of the fees received by the Agency for the following activities

- In the human medicines sector: full applications, abridged applications, extensions, type-II variations, renewals, inspections, scientific advice, scientific services and referrals under Article 30 or 31 of Directive 2001/83/EC, where the procedure has been initiated at the instigation of the applicant or the marketing authorisation holder, as laid down in Part A of this Annex.
- In the veterinary medicines sector: full applications, abridged applications, extensions, type-II variations, renewals, full applications immunological veterinary medicinal products, abridged applications immunological veterinary medicinal products, extensions immunological veterinary medicinal products, establishment of maximum residue limits (MRLs), extensions or modifications of MRLs for substances intended to be used in veterinary medicinal products and in biocidal products used in animal husbandry, inspections, scientific advice, scientific services and referrals under Article 34 or 35 of Directive 2001/82/EC where the procedure has been initiated at the instigation of the applicant or the marketing authorisation holder, as laid down in Part B of this Annex.

2.2. Distribution of annual fees

The distribution of annual fees is as follows:

30 percent	For Agency pharmacovigilance and inspection staff costs.
30 percent	To be divided between rapporteurs and co-rapporteurs where applicable for scientific evaluation services provided at the request of the Agency (e.g. annual product reports and specific reporting for pharmacovigilance and safety reports). This is also intended to contribute to other activities carried out by Member States under their European Union obligations.
30 percent	To be attributed to special activities to be determined by the Management Board, in consultation with the Agency's scientific committees. The decision on special activities portion on annual fee is set in Annex VI.
(up to) 10 percent	Under the EDQM-EMA scientific agreement and programme for sampling and testing of centralised products.

3. Activities of the Agency

The Agency's secretariat is responsible for:

- ensuring the cooperation and the coordination of European scientific resources undergoing evaluation work foreseen in Regulation (EC) No 726/2004;
- making available an optimal administrative and logistical support and the highest possible quality of working organisation and conditions.

The transfer of marketing authorisations and type-I variations are handled essentially by the Agency's Secretariat, and the total corresponding fees will be fully retained by the Agency.

4. Travel and accommodation expenses

All travel and accommodation allowances paid to Management Board, committee members and other experts will be financed separately on the Agency's budget in accordance with the applicable decision of the Management Board.

5. Arbitration and referrals

No fees are payable to the Agency for arbitrations and referrals under Articles 29, 30, 31 and 35 of Directive 2001/83/EC (human medicines) and Articles 33, 34, 35 and 39 of Directive 2001/82/EC (veterinary medicines), triggered at the instigation of the Commission or a Member State.

6. Mechanism of financial compensation

A simple mechanism of financial compensation between the Agency and national competent authorities has been established.

The Management Board and the CHMP/CVMP have agreed on the principle of excluding direct payments to individuals. Instead, periodical compensation mechanisms will be ensured through the

channel of national competent authorities, whereby credits and debits of each of the institutions are to be settled.

Each national competent authority notifies to the Agency the name and banking references of the national institution(s) entitled to receive payments.

Payments made by the Agency in accordance with this decision shall be divided equally between the national competent authorities of the rapporteur and co-rapporteur, who are responsible for the allocation of resources within their evaluation team(s).

Where no co-rapporteur has been appointed, the rapporteur shall receive the whole payment due to national competent authorities.

Where the rapporteur and co-rapporteur have agreed on a different allocation of resources between the two teams, notification should be made to the Secretariat.

Payments to relevant national competent authorities shall be made in EUR within 30 days following the performance of the services in accordance with the timetable of operations annexed to the contract between the Agency and the national competent authority concerned.

Payments to national authorities for the provision of scientific advice by coordinator(s) and experts will be similar to current provisions for rapporteurs.

Payment to national authorities of rapporteurs and co-rapporteurs of the agreed share of the annual fee will be made within 30 days from the receipt of an annual product report.

Part A – Medicinal products for human use

According to Council Regulation (EC) No 297/95, the Agency will receive the following fees, which will accompany each corresponding application. The allocation of resources is to be made as indicated below.

Full application

Fees paid to the Agency: from EUR 259 400 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 129 700.

Abridged application

Fees paid to the Agency: for applications under Article 10(1) and (3), and Article 10c of Directive 2001/83/EC from EUR 100 700 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 50 350.

Fees paid to the Agency: for applications under Article 10(4) of Directive 2001/83/EC from EUR 167 600 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 83 800.

Extension

Fees paid to the Agency: up to EUR 77 900 (subject to additional presentations) for extension to new strength, new pharmaceutical form or new route of administration.

Resources allocated to the evaluation team(s): up to EUR 38 950 (subject to additional presentations).

Type-II variation (including by analogy for plasma master files and vaccine antigen master files)

Fees paid to the Agency: up to EUR 77 900.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 38 950.

Renewal

Fees paid to the Agency: EUR 12 900.

Resources allocated to the evaluation team(s): half of the fee - EUR 6 450.

Inspection

Fees paid to the Agency: up to EUR 19 500.

Resources allocated to the inspection team(s): half of the fee - up to EUR 9 750.

As stated in Article 3(7) of Council Regulation (EC) No 297/95, travel expenses are to be paid by the company for inspections outside the European Union.

Scientific advice and protocol assistance

Fees paid to the Agency: up to EUR 77 900.

Resources allocated to compensate the work of the co-ordinator(s) and the costs of external experts where appropriate: half of the fee - up to EUR 38 950.

Evaluation of traditional medicinal products

Fees paid to the Agency: up to EUR 19 500.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 9 750.

Consultation by notified bodies for certain types of substances incorporated in medical devices

Fees paid to the Agency: up to EUR 77 900.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 38 950.

Certification of compliance for plasma master files and vaccine antigen master files

Fees paid to the Agency:

- Up to EUR 77 900 for initial certification for plasma master files and vaccine antigen master files not submitted simultaneously with a new application within the centralised procedure.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 38 950.

- Up to EUR 38 900 for annual re-certification of plasma master files.

Resources allocated to the evaluation team: half of the fee - up to EUR 19 450.

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

Fees paid to the Agency: up to EUR 58 400.

Resources allocated to compensate the work of the co-ordinator(s) and the costs of external experts where appropriate: half of the fee: up to EUR 29 200.

Arbitration and referrals

For referrals under Article 30 or 31 of Directive 2001/83/EC where the procedure has been initiated at the instigation of the applicant or the marketing authorisation holder.

Fee paid to the Agency: EUR 64 700.

Resources allocated to the evaluation team(s): half of the fee EUR 32 350.

Annual fee

Fees paid to the Agency: up to EUR 93 000.

30 percent to be divided between rapporteurs and co-rapporteurs as necessary for scientific evaluation services provided at the request of the Agency (e.g. specific services and specific reporting, for pharmacovigilance and safety reports).

Part B – Medicinal products for veterinary use

According to Council Regulation (EC) No 297/95, the Agency will receive the following fees, which will accompany each corresponding application. The allocation of resources is to be made as indicated below.

Medicinal products for veterinary use other than immunological veterinary medicinal products

Full application

Fees paid to the Agency: from EUR 129 800 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 64 900.

Abridged application

Fees paid to the Agency: for applications under Article 13(1) and (3), and Article 13c of Directive 2001/82/EC from EUR 64 700 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 32 350.

Fees paid to the Agency: for applications under Article 13(4) of Directive 2001/82/EC from EUR 109 700 upwards, subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 54 850.

Extension

Fees paid to the Agency: up to EUR 32 400 (subject to additional presentations) for extension to new strength, new pharmaceutical form, new target species or new route of administration.

Resources allocated to the evaluation team(s): half of the fee - up EUR 16 200 (subject to additional presentations).

Type-II variation

Fees paid to the Agency: up to EUR 38 900.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 19 450.

Immunological veterinary medicinal products

Full application

Total fees paid to the Agency: from EUR 64 700 upwards subject to the number of additional strengths, pharmaceutical forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 32 350.

Abridged application

Fees paid to the Agency: from EUR 32 400 upwards subject to the number of additional strengths, forms and presentations requested by the applicant.

Resources allocated to the evaluation team(s): half of the fee - from EUR 16 200.

Extension

Total fees paid to the Agency: EUR 8 100.

Resources allocated to the evaluation team(s): half of the fee - EUR 4 050.

Type-II variation

Fees paid to the Agency: EUR 6 500.

Resources allocated to the evaluation team(s): half of the fee - EUR 3 250.

Operations for all categories of veterinary medicinal products

Renewal

Fees paid to the Agency: EUR 6 500.

Resources allocated to the evaluation team(s): half of the fee - EUR 3 250.

Inspection

Fees paid to the Agency: EUR 19 500.

Resources allocated to the inspection team(s): half of the fee - EUR 9 750.

As stated in Article 3(7) of Council Regulation (EC) No 297/95, travel expenses are to be paid by the company for inspections outside the European Union.

Scientific advice

Fees paid to the Agency: up to EUR 38 900.

Resources allocated to compensate the work of the co-ordinator(s) and the costs of external experts where appropriate: half of the fee – up to EUR 19 450.

Arbitration and referrals

For referrals under Article 34 or 35 of Directive 2001/82/EC where the procedure has been initiated at the instigation of the applicant or the marketing authorisation holder.

Fees paid to the Agency: EUR 38 900.

Resources allocated to the evaluation team(s): half of the fee - EUR 19 450.

Annual fees

Fees paid to the Agency: EUR 31 000.

30 percent to be divided between rapporteurs and co-rapporteurs as necessary for scientific evaluation services provided at the request of the Agency (e.g. specific services and specific reporting, for pharmacovigilance and safety reports).

Maximum residue limits (for substances intended to be used in veterinary medicinal products and in biocidal products used in animal husbandry in accordance with Article 10 of Regulation (EC) 470/2009)

Establishment of a maximum residue limit (MRL)

Fees paid to the Agency: EUR 64 700.

Resources allocated to the evaluation team(s): half of the fee - EUR 32 350.

Modification and extension of an MRL

Fees paid to the Agency: EUR 19 500.

Resources allocated to the evaluation team(s): half of the fee - EUR 9 750.

Annex VI

Allocation of 'special activities' portion of the annual fee

Activity	Activities planned	Budget line
Meetings	<ol style="list-style-type: none"> 1. Pharmacovigilance working parties meetings followed by video-conferences with the US FDA. 2. Pharmacovigilance database development and implementation meetings. 3. Extraordinary CHMP or CVMP meetings on product-related safety issues. 4. Ad hoc group of experts to salvage old substances for which MRLs could not previously be set under the Availability of Medicines initiative. 5. Meetings of European Task Force on Availability of Medicines. 6. Non-product related aspects of therapeutic advisory groups, ad hoc experts groups or workshops with interest groups on new or special scientific issues (e.g. paediatric medicines, emerging therapies, new assessment methodologies, risk management plan to reduce resistance development as a result of veterinary medicine use and its potential transfer to man, analytical/MRL related issues). 7. Mission expenses for CHMP or CVMP members and European experts attending international conferences or symposia, at the request of CHMP or CVMP (up to EUR 30 000). 8. Mission expenses for the Management Board Chairman or members at the request of the Board (up to EUR 3 000). 	3000
Additional expertise	Costs for bringing additional expertise at the request of CHMP or CVMP, particularly in the development of points to consider or guidelines and special assessment (e.g. class-related issues).	3000
Special evaluation activities	<p>Following activities undertaken by CHMP or CVMP members or European experts, at the request of CHMP or CVMP.</p> <ol style="list-style-type: none"> 1. Management of complex procedures (urgent safety restrictions, suspensions, withdrawals), to include implementation at national level and communication issues. 2. Special assessment activities by committee members other than (co)-rapporteurs. 3. Assessment of safety issues arising from non-compliance with approved summary of product characteristics or patient/package leaflets during promotional campaigns, with a view to facilitate enforcement at national level. 	3010
Fee exemptions	<ol style="list-style-type: none"> 1. Fee exemptions for human and veterinary medicines and maximum residue limits (MRLs). 2. Funds to cover fee exemptions or reductions for medicinal products 	

Activity	Activities planned	Budget line
	<p>used for the treatment of rare diseases that were authorised prior to the entry into force of the Regulation on orphan medicines and qualify for fee reduction, or under similar mechanisms under the Fee Regulation for veterinary medicines and MRLs.</p> <p>3. Fee exemptions for pilot project for scientific advice for veterinary medicines for minor uses and minor species.</p>	
Training	Training on particular topics of interest to assessors throughout the EU, at the request of CHMP or CVMP.	3010
Information access or safety data access	Access to adequate information (e.g. databases) in order to perform pharmacovigilance to increase the Agency's ability to investigate, confirm or refute possible safety signals.	2252

Annex VII

Implementation of the second paragraph of Article 9 of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures

1. Exemptions from payment of fees for applications for orphan medicinal products for human use designated in accordance with Regulation (EC) No 141/2000

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.

2. Exemptions from payment of fees for multiple applications submitted under Article 10(1), 10(3) and 10(4) of Directive 2001/83/EC on usage patent grounds:

2.1. Initial applications

The following ranges and classification shall apply for fees for applications for generics submitted under Article 10(1), for hybrid applications submitted under Article 10(3) and for similar biological medicinal products applications submitted under Article 10(4) when the reference medicinal product is subject to a usage patent:

- EUR 19 300 for a second and for each subsequent multiple application submitted under Articles 10(1) and 10(3) of Directive 2001/83/EC solely on usage patent grounds. A fee exemption is granted from all applicable fees for additional strengths, pharmaceutical forms and presentations submitted at the same time as the aforementioned applications;
- EUR 32 100 for a second and for each subsequent multiple application submitted under Article 10(4) of Directive 2001/83/EC solely on usage patent grounds. A fee exemption is granted from all applicable fees for additional strengths, pharmaceutical forms and presentations submitted at the same time as the aforementioned applications.

2.2. Post-authorisation activities

The following ranges and classification shall apply for fees for generic, hybrid and similar biological medicinal products:

- EUR 18 600 for a second and for each subsequent multiple application submitted solely on usage patent grounds for extension of marketing authorisations granted under Articles 10(1), 10(3) and 10(4) of Directive 2001/83/EC. A fee exemption is granted from all applicable fees for additional presentations submitted at the same time as the aforementioned applications;
- EUR 540 for a second and for each subsequent multiple application submitted solely on usage patent grounds for a Type IA variation to marketing authorisations granted under Articles 10(1), 10(3) and 10(4) of Directive 2001/83/EC. This fee shall only apply to each grouped Type IA variation to the aforementioned marketing authorisation(s) as specified in Article 4bis(1) of these Rules;

- EUR 2 470 for a second and for each subsequent multiple application submitted solely on usage patent grounds for renewal of marketing authorisations granted under Articles 10(1), 10(3) and 10(4) of Directive 2001/83/EC. A fee exemption is granted from all applicable fees for additional strengths associated with a pharmaceutical form submitted at the same time as the aforementioned applications.

2.3. Annual fee

The following ranges and classification shall apply for fees for generic, hybrid and similar biological medicinal products:

- EUR 4 400 for a second and for each subsequent multiple application submitted solely on usage patent grounds for an annual fee for marketing authorisations granted under Articles 10(1) and 10(3)
- 8 900 for a second and for each subsequent multiple application submitted solely on usage patent grounds for an annual fee for marketing authorisations granted under Article 10(4) of Directive 2001/83/EC.

2.4. Applicability of exemptions on usage patent grounds

The full or partial exemptions from payment of fees described in this Annex 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).

3. Exemptions from payment of fees for applications submitted under Article 30 of Regulation (EC) No 1901/2006 on medicinal products for paediatric use

A partial exemption from the payment of the fees laid down in the fee regulation is granted for paediatric use marketing authorisation applications submitted under Article 30.

3.1. Pre-authorisation activities

The following partial exemptions shall apply:

- in the case of initial marketing authorisation applications, a 50% reduction to the total applicable fee;
- in the case of inspections, a 50% reduction to the total applicable fee.

3.2. Post-authorisation activities

The following partial exemptions shall apply only in the first year from granting of a marketing authorisation:

- in the case of an extension of the marketing authorisation, a 50% reduction to the total applicable fee;
- in the case of Type IA, Type IB and Type II variations, a 50% reduction to the total applicable fees;
- in the case of annual fees, a 50% reduction to the total applicable fee;
- in the case of inspections, a 50% reduction to the total applicable fee.

4. Exemptions and reductions 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 and for which the market is confirmed by the Committee as 'limited', henceforth termed MUMS/limited markets

4.1. A total exemption from fees is granted from the following types of applicable fees for MUMS/limited market applications submitted for:

- scientific advice;
- extrapolation of maximum residue limits involving no assessment of data
- where an application has been rejected following the conclusion of the administrative validation.

The total exemption from payment of fees is applicable for as long as the indication concerned remains classified by CVMP as MUMS/limited markets.

4.2. The following partial exemptions shall apply for as long as the product concerned remains classified by CVMP as indicated for MUMS/limited markets

4.2.1. Pre-authorisation activities

In the case of an application to establish, or to extend, an MRL for a substance with respect to an indication classified by CVMP MUMS/limited markets, a 50% reduction to the total applicable fee.

In the case of initial marketing authorisation, a 50% reduction to the total applicable fee.

4.2.2. Post-authorisation activities

In the case of an application classified by CVMP as MUMS/limited markets, a 50% reduction to the total applicable fee for:

- an extension of a marketing authorisation for a product indicated for a food-producing species to add a minor species;
- a Type II variation to a marketing authorisation for a product indicated for a non-food-producing species to add a minor species.

In the case of the annual fee for a product authorised exclusively for indications classified by CVMP as MUMS/limited markets, a 75% reduction to the total applicable fee.

5. Exemptions from payment of fees relating to core dossier medicinal products to be used in a human pandemic situation

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' (EMA/VEG/4717/03 of 5 April 2004).

**Revised
text**

The following total exemptions shall 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, shall not apply after the five-year period from the date of administrative validation of the marketing authorisation application for the core dossier has elapsed.

5.1. Scientific advice

In the case of initial requests, a 100% reduction to the total applicable fee.

In the case of follow-up to the initial request, a 100% reduction to the total applicable fee.

5.2. Post-authorisation activities

In the case of type-IA, type-IB and type-II variations (but excluding the type-II pandemic variation), a 100% reduction to the total applicable fees.

In the case of fees for rejection following conclusion of administrative validation, a 100% reduction to the total applicable fee.

In the case of annual fees, a 100% reduction to the total applicable fee.

6. Fee for multi-strain veterinary immunological product

In line with the **fourth paragraph** of Article 5(1)(a) of Council Regulation No 297/95, the fee that shall apply for a multi-strain application for veterinary medicinal products as described in the guideline on data requirements for multi-strain applications for inactivated vaccines against avian influenza, Bluetongue and Foot-and-Mouth Disease is EUR 64 700 for the first presentation in the application and EUR 6 500 for each of the second and subsequent presentations, up to a maximum of EUR 129 800.

In this context, each combination of strain identified in the application represents a presentation.

**New
text**

Correction