



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/MB/316533/2020  
Management Board meeting on 11 March 2021

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

Revised implementing rules to the Fee Regulation as of 1 April 2021

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THE MANAGEMENT BOARD,

Having regard to Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency<sup>1</sup>, 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 Agency<sup>2</sup>, 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 use<sup>3</sup>,

Having regard to European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use<sup>4</sup>, and in particular Annex I,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and the Council on orphan medicinal products<sup>5</sup>,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and the Council on medicinal products for paediatric use<sup>6</sup>,

Having regard to Regulation (EC) No 1394/2007 of the European Parliament and the Council on advanced therapy products<sup>7</sup>,

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 origin<sup>8</sup>,

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 enterprises<sup>9</sup>,

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 products<sup>10</sup>,

Having regard to Commission Regulation (EC) No 668/2009 on evaluation and certification of quality and non-clinical data related to advanced therapy medicinal products (ATMPs) developed by micro, small and medium-sized enterprises<sup>11</sup>,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC<sup>12</sup>,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU<sup>13</sup>,

HAS DECIDED:

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<sup>1</sup> OJ L 35, 15.2.1995, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p.1.

<sup>3</sup> OJ L 311, 28.11.2001, p.1.

<sup>4</sup> OJ L 311, 28.11.2001, p.67.

<sup>5</sup> OJ L 18, 22.1.2000, p.1.

<sup>6</sup> OJ L 378, 27.12.2006, p.1.

<sup>7</sup> OJ L 324, 10.12.2007, p.121.

<sup>8</sup> OJ L 152, 16.6.2009, p.11.

<sup>9</sup> OJ L 329, 16.12.2005, p.4.

<sup>10</sup> OJ L 334, 12.12.2008, p.7.

<sup>11</sup> OJ L 194, 25.7.2009, p.7.

<sup>12</sup> OJ L 117, 5.5.2017, p. 1

<sup>13</sup> OJ L 117, 5.5.2017, p. 176

## **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 by analogy to the fees stated in Articles 3(1), 3(2), 3(4) and 3(6) of Regulation (EC) No 297/95 as well as Articles 3, 4, 4bis, 5 and 7 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 148 400. 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 89 000 for medicinal products for human use and of EUR 37 100 for medicinal products for veterinary use:
  - 1.1. the fee of EUR 66 800 for medicinal products for human use, EUR 33 500 for medicinal products for veterinary use, and EUR 9 200 for immunological veterinary medicinal products is applicable for all quality extensions of marketing authorisations, i.e. requiring chemical, pharmaceutical and biological documentation, for which no clinical or non-clinical data are submitted or no cross-references to previously submitted clinical or non-clinical data are made by the marketing authorisation holder.
  - 1.2. the applicable full fees and the fees specified in subparagraph 1.1 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 89 000 shall be payable for an extension of a marketing authorisation made under Article 29 of Regulation (EC) No 1901/2006.

The fee specified in the first subparagraph 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 22 400 for a medicinal product for human use;
  - 3.2. EUR 9 200 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 7 400 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 89 000 for medicinal products for human use and of EUR 44 400 for medicinal products for veterinary use (except for immunological medicinal products for which the fee shall be EUR 7 400 for all categories of variations):
  - 1.1. the fee of EUR 66 800 for medicinal products for human use and EUR 33 500 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 or non-clinical data are submitted or no cross-references to previously submitted clinical or non-clinical data are made by the marketing authorisation holder;
  - 1.2. by derogation from subparagraph 1.1 the fee of EUR 22 400 for medicinal products for human use and EUR 11 200 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 89 000 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 for variations

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 106 300 for medicinal products for human use and of EUR 35 600 for medicinal products for veterinary use:
  - 1.1. the annual fee shall be EUR 53 200 for medicinal products for human use authorised pursuant to Article 10(4) of Directive 2001/83/EC, and EUR 17 700 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 26 600 for medicinal products for human use authorised pursuant to Articles 10(1), 10(3) and 10c of Directive 2001/83/EC and EUR 8 700 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 22 400 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 11 200 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;
  - 2.2. The fee of EUR 11 200 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 (or medical device manufacturers, in the case of consultations on medical devices) under Council Regulation (EC) No 297/95 or relating to this decision shall be borne by the applicant (or the medical device manufacturer).
2. Bank transfer charges relating to payments to national competent authorities under this decision shall be borne by the Agency.

## **Article 11 – Repeal and entry into force**

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 April 2021 and shall be published on the Agency's website.

Amsterdam, 11 March 2021

Signature on file

Christa Wirthumer-Hoche  
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, whether patients or non-patient volunteers, including clinical pharmacological trials designed to determine the efficacy and safety of the product; may also include guidance to demonstrate significant benefit over authorised medicines in the context of a designated orphan medicinal 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 89 000 for multidisciplinary requests on:

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

EUR 66 800 for requests on:

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



EUR 44 400 for requests on:

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

## **2.2. Follow-up to the initial request**

EUR 44 400 for follow-up on:

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

EUR 33 500 for follow-up on:

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

EUR 22 400 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 44 400 for multidisciplinary requests request on:

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

EUR 22 400 for requests on:

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

EUR 14 600 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 22 400 for follow-up on:

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

EUR 14 600 for follow-up on:

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

EUR 11 200 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 11 200 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 22 400 for request for scientific support and advice by the HMPC on multiple areas related to traditional herbal medicinal products.
- EUR 14 600 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 medical devices**

The fees payable for consultations on medical devices shall be charged to the medical device manufacturer that, according to the application form submitted to the Agency, requested the assessment of conformity of the medical device by a notified body on the basis of which the consultation is applied for.

When the medical device manufacturer has been assigned SME status by the Agency, the 90% fee reduction to the scientific service fees foreseen in Article 7(1)(c) Commission Regulation (EC) No 2049/2005 shall apply by analogy.

##### ***2.1. 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.

##### **2.1.1. Initial request**

EUR 89 000 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 66 800 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 44 400 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.

### **2.1.2. Follow-up to the initial request**

Article 4bis of these rules shall apply by analogy to amendments to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency.

EUR 44 400 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 44 400 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 7 400 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 3 300 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).

By derogation from subparagraphs 3 and 4 of this paragraph, a single fee of EUR 44 400 shall be payable for consultation on two or more amendments to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the Agency that are grouped in a single application by analogy to the terms of Articles 7(2)(b) or 7(2)(c) of Commission Regulation (EC) No 1234/2008 where at least one of the amendments is classified by analogy to Annex I of Commission Regulation (EC) No 1234/2008 or is a major amendment.

## ***2.2. Consultation on a medical device composed of substances or combinations of substances that are systemically absorbed to achieve their intended purpose***

Definition 4 in Annex I shall apply by analogy to this section.

The following classification and amounts shall apply for consultation on medical devices composed of substances or combinations of substances that are systemically absorbed to achieve their intended purpose.

### **2.2.1. Initial request**

EUR 66 800 for consultation on the compliance of medical devices composed of substance(s) or combination of substances that are systemically absorbed to achieve their intended purpose with the relevant requirements of Annex I to Directive 2001/83/EC.

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

- Where a device is composed of two or more substances the consultation commands one fee only.
- One application may include a range of presentations of the substance(s) from the same manufacturer.

### **2.3. Consultation on companion diagnostic medical devices**

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

The following classification and amount shall apply for consultation on companion diagnostic medical devices.

#### **2.3.1. Initial request**

The fee of EUR 44 400 applies for a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product. This fee applies in case a consultation is requested by a notified body to support a new conformity assessment.

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

- The consultation will be charged at EUR 44 400 for suitability of the device to medicinal product(s) containing the same active substance(s) or the same combination of active substances<sup>14</sup>.
- Applications for consultation submitted simultaneously for suitability of the device in relation to more than one active substance(s) or combination of substances will be charged at EUR 7 400 per additional active substance or combination of substances up to a maximum of EUR 89 000.

#### **2.3.2. Follow-up to the initial request**

EUR 22 400 for consultation on an amendment to the documentation of a companion diagnostic already evaluated by the Agency in connection with a previous successful notified body consultation. In this case a further consultation is requested by a notified body after a first consultation, in response to changes to a companion diagnostic that affect the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product(s) concerned, which results in a supplement to the EU technical documentation assessment certificate or EU type-examination certificate.

## **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.

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<sup>14</sup> In the context of the consultation for companion diagnostics, the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.

### **3.1. Initial certification**

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

EUR 73 800 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 66 800 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 22 400 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 7 400 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 66 800 for review and certification of a major variation to the PMF in accordance with Commission Regulation (EC) No 1234/2008.

EUR 7 400 for review and certification of a minor variation of type IB to the PMF in accordance with Commission Regulation (EC) No 1234/2008.

EUR 3 300 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 66 800 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 Articles 7(2)(b) or 7(2)(c) 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 14 600 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 66 800.

EUR 66 800 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.

## **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 73 800 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 73 800. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

EUR 66 800 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 66 800. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

EUR 22 400 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 22 400. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

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

EUR 7 400 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 7 400. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

### **4.2. Variations to a certified VAMF**

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

EUR 66 800 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 66 800. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

EUR 7 400 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 7 400. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 44 400.

EUR 3 300 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 3 300. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 3 300 per VAMF up to a maximum of EUR 22 400.

By derogation from subparagraphs 1, 2 and 3 of this paragraph, a single fee of EUR 66 800 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 Articles 7(2)(b) or 7(2)(c) 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 66 800. Variations submitted simultaneously in the same grouped application for antigens from the same group will be charged at EUR 7 400 per VAMF up to a maximum of EUR 89 000.

## **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 66 800 for the evaluation of an application relating to quality and non-clinical data;
- EUR 44 400 for the evaluation of an application relating to quality data.

## **6. Assessment on whether a full MRL evaluation is required or not for a chemical-unlike biological substance**

A fee of EUR 22 400 shall be payable for the assessment to determine whether a chemical-unlike biological substance requires a full MRL evaluation or not.



## **7. 'Rolling Review' Assessment for potential marketing authorisations in a human pandemic situation**

The fee payable for a 'Rolling Review' assessment for potential marketing authorisations in a human pandemic situation shall be EUR 148 400. This amount shall be deducted from the respective fee payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.

In case of multiple Rolling Review cycles, the fee would only be charged once.

## **Annex III**

### **Administrative services**

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

#### **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 3 220 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 300 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 150.

##### **2.3. Urgent procedure**

EUR 900 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 450.

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 300 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**

### **3.1. Definitions**

For the purpose of these rules, the following definitions shall apply:

1. Notification: submission made by the parallel distributor in the appropriate format, which enables the Agency to check that the conditions laid down in Union legislation on medicinal products and in the marketing authorisations are observed.
2. Initial notification: first notification of parallel distribution of a medicinal product for human or veterinary use. Each initial notification shall apply to a single EU presentation for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.
3. Notification of changes: submission of a notification of a one or more changes at any point in time after the approval of an initial notification, at the parallel distributor's discretion, and not included in an annual update notification. Each notification of changes shall apply to a single EU presentation of a medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.
4. Annual update notification: submission of a notification due on the first and each subsequent anniversary after the initial notification, if applicable. Each annual update covers all changes made in one year from the anniversary of the initial notification to all the EU presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.
5. Safety update notification: submission of a notification of a change triggered by a safety update adopted by the Committee for Medicinal Products for Human Use or the Committee for Medicinal Products for Veterinary Use, which is identified and communicated by the Agency to the parallel distributor.
6. Notification of bulk changes: submission of a notification of one or more changes that affect all of a parallel distributor's initial notifications, at any point in time after the approval of the initial notification. The scope(s) of the changes in a bulk change shall be limited to: a change in the name and/or address of a parallel distributor, addition or deletion of a re-packager, and/or a change in the name and/or address of a re-packager.
7. Dormant product: a product that is subject to a parallel distribution notice but has not been parallel distributed in the past twelve months and/or it will not be distributed in the next twelve months.

### **3.2. Initial notification**

EUR 3 220 for each initial notification for each EU presentation of a medicinal product, for one Member State of destination having one or more official languages or for several Member States of destination having the same official language.

This fee shall cover any subsequent safety update notification relating to the initial notification.

### **3.3. Annual update notification**

#### **3.3.1. Manual checks not using text comparison software**

EUR 620 for each annual update notification for which a report generated by text comparison software has not been provided or has not met the specific conditions laid down by the Agency for the acceptance of the report. The report should ensure a comprehensive audit trail that documents all steps taken during the text comparison exercise.

This fee shall cover all the EU presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.

No fee shall be charged if there were no regulatory updates in the past twelve months or if the product was dormant.

#### **3.3.2. Automated checks using text comparison software**

EUR 300 for each annual update notification for which a report generated by text comparison software has been provided and has met the specific conditions laid down by the Agency for the acceptance of the report.

This fee shall cover all the EU presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.

No fee shall be charged if there were no regulatory updates in the past twelve months or if the product was dormant.

### **3.4. Notification of changes**

#### **3.4.1. Manual check not using text comparison software**

EUR 620 for each notification of a changes for which a report generated by text comparison software has not been provided or has not met the specific conditions laid down by the Agency for the acceptance of the report. The report should ensure a comprehensive audit trail that documents all steps taken during the text comparison exercise.

This fee shall cover one EU presentation of a medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.

#### **3.4.2. Automated check using text comparison software**

EUR 300 for each notification of a changes for which a report generated by text comparison software has been provided and has met the specific conditions laid down by the Agency for the acceptance of the report.

This fee shall cover one EU presentation of a medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language.

### **3.4.3. Notification of bulk changes**

EUR 3 220 for each notification of bulk changes. This fee shall cover all of a parallel distributor's initial notifications approved by the date of submission of the notification of bulk changes.

## **4. Fees for worksharing procedures for variations**

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 7 430 for medicinal products for human use and EUR 3 680 for medicinal products for veterinary use for Type II variations to which the respective full fees would otherwise be applicable.
- EUR 4 270 for multiple medicinal products for human use and EUR 2 130 for medicinal products for veterinary 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 or Articles 13(1), 13(3) and 13(4) of Directive 2001/82/EC to which the respective full fees would otherwise be applicable.
- EUR 1 240 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 620 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

## 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:

- A distinct inspection is one concerning:
  - A medicinal product which is subject of a particular application/authorisation, and
  - relates to a particular clinical trial protocol, and
  - a specific clinical trial related site, and
  - relates to a particular activity group (Activity group I or Activity group II or Activity group III or Activity Group IV), 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 site and/or clinical trial protocol and/or clinical trial related activity group is considered to be a further, distinct inspection.

In the above definition:

- a medicinal product is distinguished by its unique EMA number;
- a specific clinical trial is distinguished by its unique protocol number;
- a specific clinical trial related site is a physical location identifiable by a distinct address which contains one or more clinical trial facilities in which one or more clinical trial activity group(s) are carried out, for one or more clinical trial protocol(s);
- four separate groups of clinical trial activities are distinguished one from another as follows:
  - Activity Group I: Investigator site activities (e.g. verification of the existence of the patients, availability of informed consent, adherence to inclusion and exclusion criteria, source data verification etc.);
  - Activity Group II: Laboratory/Technical facility activities (e.g. analytical laboratory activities, central laboratory activities);
  - Activity Group III: Data management, statistical analysis and clinical study reporting activities;
  - Activity Group IV: Study set up, monitoring and/or audit activities

## **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 for the following activities***

1. 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.
2. 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**

For referral procedures initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004 fees are payable according to Regulation (EU) No 658/2014.

For any other arbitration or referral procedure, triggered at the instigation of the Commission or a Member State under Articles 29, 30, 31 and 35 of Directive 2001/83/EC (human medicines) and Articles 33, 34, 35, 39 and 78 of Directive 2001/82/EC (veterinary medicines), no fee is payable to the Agency.

## 6. Mechanism for financial compensation

A simple mechanism for financial compensation between the Agency and national competent authorities has been established. The details governing the financial compensation are laid down in the cooperation agreement between the Agency and the National Competent Authorities.

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.

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.

Where multinational assessment teams have been established, direct payment by the Agency to the participating NCAs could be made upon notification by the leading NCA to the Secretariat before the validation of the application of the allocation of resources as agreed between the leading and the participating NCAs.

For inspections the payment to National Authorities is divided by  $n+1$ , where  $n$  = number of inspectorates participating in a site inspection, unless otherwise agreed by all parties involved and notified before the inspection takes place. The additional (+1) fee portion is allocated to the reporting inspectorate, for the reporting inspector role, in addition to the part of the fee that the inspectorate receives for participating in the site inspection.

The reporting inspectorate is the leading inspectorate, which takes the responsibility for organising, planning and reporting the inspection(s), acting as the main communication point between the inspection team and the Agency and, where applicable (e.g. GCP inspections), writing and co-signing the integrated inspection report (a report that summarises the critical and major findings of the inspection of several sites).

The travel expenses of the inspectors involved in inspections requested by the CXMP are reimbursed in accordance with Article 3(4) of Council Regulation (EC) No 297/95. These expenses are to be paid directly by the applicant/MAH to the inspectors' authorities.

## **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 296 500 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 148 250.

### **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 115 100 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 57 550.

Fees paid to the Agency: for applications under Article 10(4) of Directive 2001/83/EC from EUR 191 700 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 95 850.

### **Extension**

Fees paid to the Agency: up to EUR 89 000 (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 44 500 (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 89 000.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 44 500.

### **Renewal**

Fees paid to the Agency: EUR 14 600.

Resources allocated to the evaluation team(s): half of the fee - EUR 7 300.

### **Inspection**

Fees paid to the Agency: up to EUR 22 400 (per distinct inspection, as defined in Annex IV).

Resources allocated to the inspection team(s): half of the fee – up to EUR 11 200.

## **Scientific advice and protocol assistance**

Fees paid to the Agency: up to EUR 89 000.

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 44 500.

## **Evaluation of herbal traditional medicinal products**

Fees paid to the Agency: up to EUR 22 400.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 11 200.

## **Consultation by notified bodies for certain types of medical devices**

Fees paid to the Agency: up to EUR 89 000.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 44 500.

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

Fees paid to the Agency:

- Up to EUR 89 000 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 44 500.

- Up to EUR 44 400 for annual re-certification of plasma master files.

Resources allocated to the evaluation team: half of the fee - up to EUR 22 200.

## **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 66 800.

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 33 400.

## **Arbitration and referrals**

For referrals under Article 30 or 31<sup>15</sup> 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 73 800.

Resources allocated to the evaluation team(s): half of the fee EUR 36 900.

## **Annual fee**

Fees paid to the Agency: up to EUR 106 300.

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<sup>15</sup> For procedures initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004 fee levels and remuneration to the evaluation teams are specified in Regulation (EU) No 658/2014

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).

### **Scientific opinions on medicinal products for human use intended exclusively for markets outside the European Union pursuant to Article 58 of Regulation (EC) No 726/2004**

Fees paid to the Agency: Full, abridged, extension and type II variation applications, and inspection and annual fees (as stated above) by analogy.

Resources allocated to the evaluation/inspection team(s): half of the fee – for full, abridged, extension and type II variation applications, and inspection fee (as stated above) by analogy; annual fee - 30 per cent to be divided between rapporteurs and co-rapporteurs as necessary (as stated above) by analogy.

### **Rolling review**

Fees paid to the Agency: up to EUR 148 400; this amount shall be deducted from the respective fee payable for the evaluation of one marketing authorisation application for the same product, where such application is submitted by the same applicant.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 74 200; this amount shall be deducted from the respective remuneration payable to the national competent authority for a marketing authorisation application for the same product, where such application is submitted by the same applicant.

## **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 148 400 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 74 200.

#### **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 73 800 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 36 900.

Fees paid to the Agency: for applications under Article 13(4) of Directive 2001/82/EC from EUR 125 300 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 62 650.

#### **Extension**

Fees paid to the Agency: up to EUR 37 100 (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 18 550 (subject to additional presentations).

#### **Type-II variation**

Fees paid to the Agency: up to EUR 44 400.

Resources allocated to the evaluation team(s): half of the fee - up to EUR 22 200.

### ***Immunological veterinary medicinal products***

#### **Full application**

Total fees paid to the Agency: from EUR 73 800 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 36 900.



## **Abridged application**

Fees paid to the Agency: from EUR 37 100 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 18 550.

## **Extension**

Total fees paid to the Agency: EUR 9 200.

Resources allocated to the evaluation team(s): half of the fee - EUR 4 600.

## **Type-II variation**

Fees paid to the Agency: EUR 7 400.

Resources allocated to the evaluation team(s): half of the fee - EUR 3 700.

## ***Operations for all categories of veterinary medicinal products***

### **Renewal**

Fees paid to the Agency: EUR 7 400.

Resources allocated to the evaluation team(s): half of the fee - EUR 3 700.

### **Inspection**

Fees paid to the Agency: EUR 22 400 (per distinct inspection, as defined in Annex IV).

Resources allocated to the inspection team(s): half of the fee - EUR 11 200.

### **Scientific advice**

Fees paid to the Agency: up to EUR 44 400.

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 22 200.

### **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 44 400.

Resources allocated to the evaluation team(s): half of the fee - EUR 22 200.

## **Annual fees**

Fees paid to the Agency: EUR 35 600.

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 73 800.

Resources allocated to the evaluation team(s): half of the fee - EUR 36 900.

#### **Modification and extension of an MRL and assessment on whether a full MRL evaluation is required or not for a chemical-unlike biological substance**

Fees paid to the Agency: EUR 22 400.

Resources allocated to the evaluation team(s): half of the fee - EUR 11 200.

## Annex VI

### Allocation of 'special activities' portion of the annual fee

Activity	Activities planned	Budget line
Meetings	<ol style="list-style-type: none"> <li>1. PRAC and CVMP Pharmacovigilance Working Party meetings followed by video-conferences with the US FDA.</li> <li>2. Pharmacovigilance database development and implementation meetings.</li> <li>3. Extraordinary CHMP or CVMP meetings on product-related safety issues.</li> <li>4. Ad hoc group of experts to salvage old substances for which MRLs could not previously be set under the Availability of Medicines initiative.</li> <li>5. Meetings of European Task Force on Availability of Medicines.</li> <li>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).</li> <li>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).</li> <li>8. Mission expenses for the Management Board Chairman or members at the request of the Board (up to EUR 3 000).</li> </ol>	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"> <li>1. Management of complex procedures (urgent safety restrictions, suspensions, withdrawals), to include implementation at national level and communication issues.</li> <li>2. Special assessment activities by committee members other than (co)-rapporteurs.</li> <li>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.</li> </ol>	3010
Fee exemptions	<ol style="list-style-type: none"> <li>1. Fee exemptions for human and veterinary medicines and maximum residue limits (MRLs).</li> <li>2. Funds to cover fee exemptions or reductions for medicinal products</li> </ol>	

<b>Activity</b>	<b>Activities planned</b>	<b>Budget line</b>
	<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.	2700

## **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 on usage patent grounds**

### ***2.1. Initial applications***

The following ranges and classification shall apply for fees for applications for generics, for hybrid applications and for similar biological medicinal products applications when the reference medicinal product is subject to a usage patent:

- EUR 22 000 for a second and for each subsequent multiple application submitted under Articles 10(1) and 10(3) of Directive 2001/83/EC or 14 600 for a second and for each subsequent multiple application submitted under Articles 13(1) and 13(3) of Directive 2001/82/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 36 800 for a second and for each subsequent multiple application submitted under Article 10(4) of Directive 2001/83/EC or EUR 26 600 for a second and for each subsequent multiple application submitted under Articles 13(4) of Directive 2001/82/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 14 600 for a second and for each subsequent multiple application for veterinary immunological products solely on usage patent grounds.

### ***2.2. Post-authorisation activities***

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

- EUR 21 200 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 or EUR 7 430 for a second and for each subsequent multiple application submitted solely on usage patent grounds for extension of marketing authorisations

granted under Articles 13(1), 13(3) and 13(4) of Directive 2001/82/EC. A fee exemption is granted from all applicable fees for additional presentations submitted at the same time as the aforementioned applications;

- EUR 620 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 2 840 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 or EUR 1 240 for a second and for each subsequent multiple application submitted solely on usage patent for renewal of marketing authorisations granted under Articles 13(1), 13(3) and 13(4) of Directive 2001/82/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 5 100 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) of Directive 2001/83/EC or EUR 1 770 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 13(1), 13(3) and 13c of Directive 2001/82/EC.
- EUR 10 200 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 or EUR 3 680 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 12(3), 13(4), 13a and 13b of Directive 2001/82/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 from payment of fees for applications indicated for minor use minor species/limited market**

A full or partial exemption from payment of fees relating to applications for products classified by the Committee for Medicinal Products for Veterinary Use (CVMP) as indicated for minor use minor species/limited market and for which eligibility for fee incentives under Article 9 paragraph 2 of Council Regulation (EC) No 297/95 is confirmed in accordance with the *EMA Policy for classification and incentives for veterinary medicinal products indicated for minor use and minor species (MUMS)/limited market* (EMA/308411/2014). The exemption from payment of fees is applicable for as long as the product concerned remains classified by CVMP as (a) MUMS and (b) eligible for fee incentives.

### **4.1. Pre-authorisation activities**

The following full or partial exemptions shall apply to applications classified by CVMP as (a) MUMS/limited market and (b) eligible for fee incentives:

- in the case of the rejection of an application following the conclusion of the administrative validation, a 100% reduction to the total applicable fee;
- in the case of scientific advice, a 100% reduction to the total applicable fee;
- in the case of extension of maximum residue limits involving no assessment of data, a 100% reduction to the total applicable fee;
- in the case of an application to establish, or to extend, an MRL requiring an assessment of data, a 50% reduction to the total applicable fee;
- in the case of an initial marketing authorisation, a 50% reduction to the total applicable fee.

### **4.2. Post-authorisation activities**

The following partial exemptions shall apply:

- 50% reduction to the total applicable fee in the case of an application for extension of a marketing authorisation, to add to an existing veterinary medicinal product:

- another species of food producing animal; or
- another indication classified as MUMS;
- in the case of the annual fee for a product authorised exclusively for indications classified by CVMP as MUMS, 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).

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.

### **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 dossiers**

In line with the fourth paragraph of Article 5(1)(a) of Council Regulation No 297/95, the fee that shall apply for an application based on a multi-strain dossier for veterinary vaccines as described in the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, Bluetongue and Foot-and-Mouth Disease is EUR 73 800 for the first presentation in the application and EUR 7 400 for each of the second and subsequent presentations, up to a maximum of EUR 148 400.

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

## **7. Exemptions from payment of fees for certain pharmacovigilance-related variations to marketing authorisations for veterinary medicinal products**

A total exemption from the payment of the fees laid down in the fee regulation or in these rules is granted for the following variations to marketing authorisations for medicinal products for veterinary



use listed in the *'Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures'* (2013/C 223/01) or that were the subject of recommendations on the classification of unforeseen variations delivered under Article 5 of Commission Regulation (EC) No 1234/2008.

The total exemption shall apply to the following variations for medicinal products for veterinary use:

- Type IA (immediate and non-immediate notification) variation relating to scope C.I.9, i.e. change(s) to an existing pharmacovigilance system as described in the detailed description of the pharmacovigilance system (DDPS);
- Type IA (immediate notification) variation relating to scope C.II.8, i.e. change in the frequency and/or date of submission of periodic safety update reports (PSUR).

They shall apply whether the above variations were:

- notified individually; or
- grouped in a single notification made under the terms of Article 7 of Commission Regulation (EC) No 1234/2008; or
- notified as part of an application for a worksharing procedure made under the terms of Article 20 of Commission Regulation (EC) No 1234/2008.

## **8. Exemptions from payment of fees by micro, small and medium-sized enterprises for certain post-authorisation activities for medicinal products for human or veterinary use**

A total or partial exemption from the payment of the fees laid down in the fee regulation is granted to micro, small and medium-sized enterprises, except for SMEs that are regulatory consultancies acting as marketing authorisation holders on behalf of non-SMEs legal entities, for the following post-authorisation activities:

- extension of a marketing authorisation;
- type-IA, type-IB and type-II variations;
- renewal of a marketing authorisation;
- transfer of a marketing authorisation to a second micro, small or medium-sized enterprise;
- annual fee;
- referral procedure laid down in Article 30(1) or the first sub-paragraph of Article 31(1) of Directive 2001/83/EC initiated by the marketing authorisation holder.

The following exemptions shall apply:

- in the case of a micro enterprise, a 100% reduction to the total applicable fee;
- in the case of a small or medium-sized enterprise, a 40% reduction to the total applicable fee.

## **9. Exemptions from payment of certain fees for vaccines against certain major epizootic diseases**

A total exemption from the payment of the fees laid down in the fee regulation is granted for the following post-authorisation activities in relation to vaccines against bluetongue, pandemic avian influenza, foot and mouth disease and classical swine fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the EU/EEA at any time during the totality of the period covered by the fee:

- 100% fee reduction for annual fee;
- 100% fee reduction for renewal of marketing authorisation.

## **10. Exemptions from payment of post-authorisation fees for certain human vaccines authorised under exceptional circumstances for preparedness against biological agents that might be used as weapons of bio-terrorism**

A partial exemption from the payment of the fees laid down in the fee regulation is granted for the following post-authorising activities in relation to vaccines authorised under exceptional circumstances for preparedness against biological agents that might be used as weapons of bio-terrorism as detailed in the [EMA/CHMP Guidance document on use of medicinal products for the treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism](#)<sup>1617</sup>:

- 50% fee reduction for annual fee;
- 50% fee reduction for type-IA, type-IB and type-II variations;
- 50% fee reduction for renewal of marketing authorisation;
- 50% fee reduction for extension of a marketing authorisation;
- 50% fee reduction for transfer of a marketing authorisation.

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<sup>16</sup> i. e. anthrax, plague, tularaemia, smallpox, viral haemorrhaging fever, botulism, brucellosis, Q-fever, glanders and melioidosis and other infectious diseases

<sup>17</sup> CPMP/4048/01 16.01.2002 as last amended