European Medicines Agency

EMA/MB/170391/2009/Rev.4
10 December 2009

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 Agency[1], 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[2], 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[3],

HAVING REGARD to European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use[4], and in particular Annex I,

HAVING REGARD to Regulation (EC) No 141/2000 of the European Parliament and the Council on orphan medicinal products[5]

HAVING REGARD to Regulation (EC) No 1901/2006 of the European Parliament and the Council on medicinal products for paediatric use[6],

HAVING REGARD to Regulation (EC) No 1394/2007 of the European Parliament and the Council on advanced therapy products[7],

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[8],

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[9],

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[10],

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[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
[9] OJ L 329, 16.12.2005, p. 4
[10] OJ L 334, 12.12.2008, p. 7

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

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 (ATMP) developed by micro, small and medium-sized enterprises[11],

HAS DECIDED:

Article 1

Scientific advice and protocol assistance

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 Community 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 125 800. 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 75 500 for medicinal products for human use and of EUR 31 400 for medicinal products for veterinary use:

   - The fee payable for an extension of a marketing authorisation for a medicinal products for human use shall be EUR 37 700 for all quality extensions for which no new clinical data are submitted by the marketing authorisation holder.

   - The fee payable for an extension of a marketing authorisation for a medicinal products for veterinary use shall be EUR 18 900 for all quality extensions for which no new clinical data are submitted by the marketing authorisation holder.

   - In the case of immunological veterinary medicinal products, the fee payable for an extension shall be EUR 7 800 for all quality extensions for which no new clinical data are submitted by the marketing authorisation holder.

2. The fee of EUR 75 500 shall be payable for an extension of a marketing authorisation made under Article 29 of Regulation (EC) No 1901/2006.

3. The fee of EUR 6 300 shall be payable for each additional presentation of the same extension submitted at the time of the extension application.

[11] OJ L 194, 25.7.2009, pg. 7

Article 4

Type II variations

By derogation from the applicable full fee of EUR 75 500 for medicinal products for human use and of EUR 37 700 for medicinal products for veterinary use (except for immunological medicinal products for which the fee shall be EUR 6 300 for all categories of variations):

1. The category of variations for which the fee shall be EUR 56 600 for medicinal products for human use and EUR 28 300 for medicinal products for veterinary use is as follows:

   - All quality changes, i.e. all amendments to the chemical, pharmaceutical and biological documentation, for which no new clinical data are submitted by the marketing authorisation holder.

2. The applicable full fee of EUR 75 500 shall be payable for each new indication applied for under Article 29 of Regulation (EC) No 1901/2006.

3. 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:

   i) 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.

   ii) 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 sub-paragraph 2(i), if applicable.

   iii) 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

By derogation from the applicable full fee of EUR 90 200 for medicinal products for human use and of EUR 30 100 for medicinal products for veterinary use:

- The annual fee shall be EUR 45 100 for medicinal products for human use authorised pursuant to Article 10(3) and for similar biological medicinal products for human use authorised pursuant to Article 10(4) of Directive 2001/83/EC and EUR 15 000 for medicinal prodcuts for veterinary use

authorised pursuant to Article 13(3) and for similar biological medicinal products for veterinary use authorised pursuant to Articles 13(4) of Directive 2001/82/EC.

- The annual fee shall be EUR 22 500 for generic medicinal products for human use authorised pursuant to Articles 10(1) of Directive 2001/83/EC and EUR 7 500 for generic medicinal products for veterinary use authorised pursuant to Article 13(1) of Directive 2001/82/EC.

Article 6

Administrative services

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

Article 7

Inspections

By derogation from the applicable full fee of EUR 18 900 for medicinal products for human use and for medicinal products for veterinary use:

The fee for inspections shall be EUR 9 400 in the case of consecutive distinct inspection(s) performed in conjunction with an inspection requiring a full fee, provided that such a consecutive inspection(s) require(s) in the opinion of the lead inspector no more than one day duration on site, concerns the same original application, the same inspection team and the location of the site allows it to be conducted on successive working days.

The policy concerning financial transactions and payments for inspections requested by the CHMP or CVMP is set out in Annex IV.

Article 8

Scale of fees payable to national competent authorities

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.

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

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

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.

Bank transfer charges relating to payments to national competent authorities under this decision shall be borne by the Agency.

Article 11

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.

This decision shall enter into force on 1 January 2010 and shall be published on the Agency's web site.

London, 10 December 2009

Pat O'Mahony
Chairman of the Management Board

Annex I

Scientific advice and protocol assistance

1. Definitions

For the purposes of this decision, the following definitions shall apply:

i) Quality development: chemical, pharmaceutical and biological testing.
ii) Safety development: toxicological and pharmacological tests.
iii) 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.
iv) 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.
v) 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).
vi) 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.

i) Initial request

EUR 75 500 for multidisciplinary requests on:
- Quality, safety and clinical development, or
- Quality and clinical development, or
- Safety and clinical development, or
- Qualification advice

EUR 56 600 for requests on:
- Clinical development, or
- Quality and safety development, or
- Quality and bioequivalence studies for generic medicinal products

EUR 37 700 for requests on:
- Quality development, or
- Safety development, or
- Bioequivalence studies for generic medicinal products

ii) Follow-up to the initial request

EUR 37 700 for follow-up on:
- Quality, safety and clinical development, or
- Quality and clinical development, or
- Safety and clinical development, or
- Qualification advice

EUR 28 300 for follow-up on:
- Clinical development, or
- Quality and safety development, or
- Quality and bioequivalence studies for generic medicinal products

EUR 18 900 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.

i) Initial request

EUR 37 700 for multidisciplinary requests request on:
- Quality, safety and clinical development, or
- Quality and clinical development, or
- Safety and clinical development

EUR 18 900 for requests on:
- Quality and safety development, or
- Clinical development, or
- Quality and bioequivalence studies for generic medicinal products

EUR 12 500 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

ii) Follow-up to the initial request

EUR 18 900 for follow-up on:
- Quality, safety and clinical development, or
- Quality and clinical development, or
- Safety and clinical development

EUR 12 500 for follow-up on:
- Quality and safety development, or
- Clinical development, or
- Quality and bioequivalence studies for generic medicinal products

EUR 9 400 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

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

EUR 9 400 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 18 900 for request for scientific support and advice by the HMPC on multiple areas related to traditional herbal medicinal products.

EUR 12 500 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 derivates, incorporated in medical devices*

Paragraphs iv) and v) of the definitions in Annex I shall apply by analogy to this section.

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

i) Initial request

EUR 75 500 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 EMEA in connection with a previous marketing authorisation and/or a previous successful notified body consultation.

EUR 56 600 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 EMEA in connection with a previous marketing authorisation and/or a previous successful notified body consultation.

EUR 37 700 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 EMEA 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.

ii) Follow-up to the initial request

EUR 18 900 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 EMEA in connection with a previous marketing authorisation and/or a previous successful notified body

consultation. In this case a further consultation is requested by a notified body after a first consultation, i.e. when additional data are submitted to the EMEA for evaluation in response to a list of deficiencies notified in an initial EMEA report.

EUR 37 700 for consultation on an amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the EMEA (amendments will be classified by analogy to Annex I of Commission Regulation (EC) No 1234/2008).

EUR 37 700 for consultation on a major amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the EMEA (amendments equivalent to a Type II variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

EUR 6 300 for consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the EMEA (amendments equivalent to a Type IB variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

EUR 2 700 for consultation on a minor amendment to the documentation on an ancillary medicinal substance or blood derivative already evaluated by the EMEA. (Amendments equivalent to a Type IA variation will be classified by analogy to Commission Regulation (EC) No 1234/2008).

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

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

i) Initial certification

a) Not submitted simultaneously with a new application under the centralised procedure

- EUR 62 800 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 56 600 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 18 900 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.

b) Submitted simultaneously with a new application under the centralised procedure

- EUR 6 300 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 EMEA simultaneously with a centralised marketing authorisation application.

ii) Variations to a certified PMF

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

- EUR 56 600 for review and certification of a variation on a major amendment to the PMF (Amendment classified in accordance with Commission Regulation (EC) No 1234/2008).

- EUR 6 300 for review and certification of a variation on a minor amendment to the PMF (Type IB variation classified in accordance with Commission Regulation (EC) No 1234/2008).

- EUR 2 700 for review and certification of a variation on a minor amendment to the PMF (Type IA variation classified in accordance with Commission Regulation (EC) No 1234/2008).

iii) Annual re-certification of PMF

- EUR 12 500 for review and annual re-certification of the PMF under this scheme where no variations are included in the submitted documentation.

- EUR 56 600 for review and annual re certification of the PMF under this scheme where one or more variations are included in the submitted documentation.

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

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

i) Initial certification

a) Not submitted simultaneously with a new application under the centralised procedure

- EUR 62 800 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 62 800. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 75 500.

- EUR 56 600 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 56 600. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 75 500.

- EUR 18 900 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 18 900. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 75 500.

b) Submitted simultaneously with a new application under the centralised procedure

- EUR 6 300 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 6 300. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 75 500.

ii) Variations to a certified VAMF

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

- EUR 56 600 for review and certification of a variation on a major amendment to the VAMF (Amendment classified 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 56 600. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 75 500.

- EUR 6 300 for review and certification of a variation on a minor amendment to the VAMF (Type IB variation classified 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 6 300. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 6 300 per VAMF up to a maximum of EUR 37 700.

- EUR 2 700 for review and certification of a variation on a minor amendment to the VAMF (Type IA variation classified 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 2 700. VAMF applications submitted simultaneously for antigens from the same group will be charged at EUR 2 700 per VAMF up to a maximum of EUR 18 900.

5. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMP) 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 ATMP developed by SMEs.

- EUR 56 600 for the evaluation of an application relating to quality and non-clinical data.

- EUR 37 700 for the evaluation of an application relating to quality data.

The fees in sub-paragraph 1 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.

1. *Fees for issuing certificates for medicinal products*

   EUR 130 for a set of certificates, which includes six identical original duplicates.
   EUR 130 for a request for certificates which includes one or more sets.

2. *Fees for notifications of parallel distribution*

   A fee of EUR 3 750 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 EMEA notice.

3. *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 2 700 shall be payable where an application has been rejected following the conclusion of the administrative validation.

   The fee specified in sub-paragraph 1 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.

4. *Fees for worksharing procedures*

   The following fees shall be payable for each variation as specified in Article 4bis(2)(ii) of these Rules, included in the same worksharing application.

   EUR 6 300 for medicinal products for human use and EUR 3 100 for medicinal products for veterinary use for Type II variations to which the respective full fees would otherwise be applicable.

   EUR 3 600 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 1050 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 520 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

Policy on financial transactions and payments for inspections requested by the CHMP or CVMP

1. Background

The legal basis for charging fees for inspections carried out in the context of the assessment of marketing authorisation applications, marketing authorisations and/or the assessment of matters referred to the CHMP and CVMP in accordance with this Community legislation is provided by Council Regulation (EC) No 297/95 Articles 3(4) and 5(4) (human and veterinary sectors respectively). This Regulation specifies a maximum fee for each inspection, and also provides that, for inspections outside the Community, travel expenses incurred by the inspectors are charged in addition.

Article 3(4) and 5(4) also state that the inspection fee shall differ according to the extent and nature of the inspection and on the basis of the conditions laid down in accordance with Article 11(2). The circumstances where reduced fees may be applied are described in this Annex.

2. Definition of distinct inspection

In the context of assessing a single dossier, manufacturer, clinical trial, non-clinical study or pharmacovigilance inspection, it is possible that more than one "inspection" (see below) is requested, and thus the applicant/MAH will be liable for more than one inspection fee, since the fee Regulation provides that a fee is charged for each inspection arising. This note aims to clarify the basis upon which it is determined what constitutes a single, distinct inspection, and thus how the number of inspection fees for which an applicant/MAH is liable is calculated. It also sets out various administrative arrangements concerning such fees and related payments.

2.1 Good Manufacturing Practices

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

A GMP compliance or product and process-related inspection concerning:

- *a particular manufacturing activity*
- *relating to a medicinal product the subject of a particular application*
- *carried out at a specific manufacturing site*
- *involving the same inspection team and conducted on successive working days.*

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

In the above definition:

- *A single processing step or series of uninterrupted processing steps involved in the manufacture of either a specific active substance or a specific finished medicinal product (or, in special cases, both) constitute a single manufacturing activity;*
- *A group of up to five blood establishments, operating in accordance with the same procedures and belonging to the same organisation may also be considered to operate a single manufacturing activity.*

and:

- *A physical location which contains one or more manufacturing facilities at the same address constitutes a single manufacturing site;*

whereby:

- *A manufacturing facility comprises a separate building or complex of buildings in which a manufacturing activity or activities are carried out.*

2.2 Good Clinical Practices

For the purposes of determining liability for GCP inspection fees, separate inspections are distinguished one from another as follows:

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

For the purposes of determining liability for GLP inspection fees, separate 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 Inspection

For the purposes of determining liability for Pharmacovigilance inspection fees, separate inspections are distinguished one from another as follows:

- *Each inspection is the subject of a separate inspection report.*
- *A single inspection is one with a Pharmacovigilance obligation compliance and/ or product and/or process-related scope concerning:*
  - *a particular pharmacovigilance activity*
    and
  - *relating to a medicinal product the subject of a particular authorisation*
    and
  - *carried out at a specific pharmacovigilance site of pharmacovigilance activity*
    and
  - *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.

3. Liability for Inspection Fees

3.1 An applicant/MAH is liable to pay a separate fee for each distinct inspection requested by the CHMP or CVMP in connection with the assessment of marketing authorisation applications and/or the assessment of matters referred to these committees in accordance with Community legislation and for each inspection specifically requested by CHMP / CVMP post-authorisation.[12]

3.2 A separate, full inspection fee will be charged for each distinct inspection (as defined above).

3.3 In the case of *concurrent multiple applications for exactly the same medicinal product*, the applicants may agree between themselves that one of them will be regarded as the "lead" applicant for the purpose of inspections. The identity of the "lead" applicant must be notified in writing to the EMEA at the pre-submission stage. In such a case, the multiple applications will be treated as a *single* application for the purpose of calculating the inspection fee(s) due, and the total fee(s) (calculated in accordance with the above criteria) will be charged to the "lead" applicant. However, if no "lead" applicant is notified as above, or if the "lead" applicant's application is withdrawn before any inspection has been formally notified, then the applications will be treated as being completely separate and, according to the general rule that inspections are defined per application, all applicants will be charged separate full inspection fee(s). If the "lead" applicant withdraws his application after an inspection has been formally notified then the provisions of section 8 below apply.

[12] Note however that routine GMP inspections of manufacturing sites initiated by the Supervisory Authorities of the EU / EEA Member States do not give rise to fees levied by the EMEA. Supervisory Authorities will make their own arrangements for reimbursement.

4. Invoices

4.1 Invoices are issued within 20 days of the confirmation of the inspection dates by the relevant inspectors and are sent by registered post to the applicant.

5 Payment Arrangements for Inspection Fees

5.1 Applicants for marketing authorisations/MAHs are required to pay the total fee charged within 45 days from the date on which the inspection is carried out.

6. Payments to Competent Authorities

6.1. In accordance with the conditions of the Contract between the EMEA and the Competent Authorities of the European Union Member States, the Competent Authorities are remunerated once a *final* report of satisfactory quality is received. This must be prepared following the agreed Community Guidelines[13]. It must also be written following the agreed Community format[14] and it must meet the quality criteria agreed between the inspectors, the Scientific Committees and the EMEA.

6.2. The remuneration of Competent Authorities is made in accordance with the current scale of fees to be paid by the EMEA to National Competent Authorities, as adopted by the EMEA Management Board.

6.3. This payment is divided equally between all inspectorates comprising the inspection team, unless otherwise agreed by all parties involved and notified before the inspection takes place. This equal division will include one part of each fee to be paid to the 'reporting Inspectorate' for the reporting inspector role, in addition to the part of the fee that inspectorate may receive if it is participating in the site inspections.
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 EMEA and, where applicable (e.g. GCP inspections), writing and co-signing the integrated report (a report that summaries the critical and major findings of the inspection of several sites).

7. Travel Expenses

7.1. The travel expenses of the inspectors involved in inspections requested by the CHMP / CVMP are reimbursed in accordance with Article 3(4) or Article 5(4) respectively of Council Regulation (EC) No 297/95. These expenses are to be paid directly by the applicant to the inspectors' Authorities.

8. Cancellation of Inspections and Changes to Inspection Arrangements – Refunds etc.

8.1. Where an inspection request is cancelled by CHMP / CVMP, any inspection fee(s) already collected are repaid in full to the applicant/MAH.

8.2. Where an inspection that has been formally notified to the applicant/MAH is cancelled due to the withdrawal of or change to the application/MA at any stage in the processing of the

[13] Procedure for reporting of inspections requested by the EMEA
[14] Procedure for reporting of inspections requested by the EMEA

application/MA, the applicant/MAH will be liable for 50% payment of inspection fee(s) due as follows:

8.2.1. Applicant/MAH decides to withdraw the application/MA

8.2.2. Change to manufacturing arrangements by the manufacturer necessitating cancellation of the inspection, agreed at any time before the inspection is carried out.

8.2.3. Change to the scope of the application or submitted data, or access to, ownership of, or location of facilities or data necessitating cancellation of the inspection, agreed at any time before the inspection is carried out.

8.3. Where the fee(s) have already been paid in full by the applicant, half of this payment will be refunded.

8.4. Payments made to or retained by the EMEA in accordance with 8.2 above will be divided as follows: half the payment to be retained by the EMEA; half to be paid to the inspectors in accordance with 6.3 above.

8.5. Where an inspection that has been carried out is cancelled due to the withdrawal of or change to the application/MA at any stage in the processing of the application/MA, the applicant/MAH will be liable for 100% payment of inspection fee(s).

8.6. Where the cancelled inspection was to take place outside the Community, the applicant/MAH will be liable for any travel expenses already incurred by the inspectors at the date of cancellation for which they are not able to obtain reimbursement.

8.7. The applicant/MAH will not be liable for any financial consequences arising from changes made to notified inspection arrangements by parties other than the applicant/MAH e.g. change in travel arrangements by the inspectors.

8.8. The EMEA / inspectors will not be liable for any financial consequences suffered by the applicant/MAH 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 EMEA 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 EMEA 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 EMEA 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 EMEA 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 EMEA (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 Community obligations.

30 percent to be attributed to special activities to be determined by the Management Board, in consultation with the EMEA scientific committees. The decision on special activities portion on annual fee is set in Annex VI.

(up to) 10 percent under the EDQM-EMEA 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 EMEA 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 EMEA 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 EMEA 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 a specific safety 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 251 600 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 125 800

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 97 600 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 48 800
Fees paid to the Agency: for applications under Article 10(4) of Directive 2001/83/EC from
EUR 162 600 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 81 300

Extension:
Fees paid to the Agency: up to EUR 75 500 (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 37 700 (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 75 500
Resources allocated to the evaluation team(s): half of the fee - up to EUR 37 700

Renewal:
Fees paid to the Agency: EUR 12 500
Resources allocated to the evaluation team(s): half of the fee - EUR 6 250

Inspection:
Fees paid to the Agency: up to EUR 18 900
Resources allocated to the inspection team(s): half of the fee – up to EUR 9 400
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 Community.

Scientific advice and protocol assistance
Fees paid to the Agency: up to EUR 75 500
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 37 700.

Evaluation of traditional medicinal products
Fees paid to the Agency: up to EUR 18 900
Resources allocated to the evaluation team(s): half of the fee - up to EUR 9 400.

EMEA consultation by notified bodies for certain types of substances incorporated in medical devices:
Fees paid to the Agency: up to EUR 75 500
Resources allocated to the evaluation team(s): half of the fee - up to EUR 37 700.

Certification of compliance for plasma master files and vaccine antigen master files
Fees paid to the Agency:
- Up to EUR 75 500 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 37 700
- Up to EUR 37 700 for annual re-certification of plasma master files
  Resources allocated to the evaluation team: half of the fee - up to EUR 18 900

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 56 600
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 28 300

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 62 800
Resources allocated to the evaluation team(s): half of the fee EUR 31 400

Annual fee:
Fees paid to the Agency: up to EUR 90 200
30 percent to be divided between rapporteurs and co-rapporteurs as necessary for scientific evaluation services provided at the request of the EMEA (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 125 800 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 62 900

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 62 800 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 31 400
Fees paid to the Agency: for applications under Article 13(4) of Directive 2001/82/EC from EUR 106 300 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 53 150

Extension:
Fees paid to the Agency: up to EUR 31 400 (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 15 700 (subject to additional presentations)

Type II variation:
Fees paid to the Agency: up to EUR 37 700
Resources allocated to the evaluation team(s): half of the fee - up to EUR 18 900

- **Immunological veterinary medicinal products**

Full application:
Total fees paid to the Agency: from EUR 62 800 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 31 400

Abridged application:
Fees paid to the Agency: from EUR 31 400 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 15 700

Extension:
Total fees paid to the Agency: EUR 7 800
Resources allocated to the evaluation team(s): half of the fee - EUR 3 900

Type II variation:
Fees paid to the Agency: EUR 6 300
Resources allocated to the evaluation team(s): half of the fee - EUR 3 150

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

Renewal:
Fees paid to the Agency: EUR 6 300
Resources allocated to the evaluation team(s): half of the fee - EUR 3 150

Inspection:
Fees paid to the Agency: EUR 18 900
Resources allocated to the inspection team(s): half of the fee - EUR 9 400
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 Community.

Scientific advice:
Fees paid to the Agency: up to EUR 37 700
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 18 900.

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 37 700
Resources allocated to the evaluation team(s): half of the fee - EUR 18 900

Annual fees:
Fees paid to the Agency: EUR 30 100
30 percent to be divided between rapporteurs and co-rapporteurs as necessary for scientific evaluation services provided at the request of the EMEA (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 62 800
Resources allocated to the evaluation team(s): half of the fee - EUR 31 400

Modification and extension of an MRL:
Fees paid to the Agency: EUR 18 900
Resources allocated to the evaluation team(s): half of the fee - EUR 9 400

Annex VI

Allocation of 'special activities' portion of the annual fee

Activity	Activities planned	Budget line
Meetings	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/MRLs) 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 € 30 000) 8. Mission expenses for the Management Board Chairman or members at the request of the Board (up to € 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	Following activities undertaken by CHMP or CVMP members or European experts, at the request of CHMP or CVMP 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	1. Fee exemptions for human and veterinary medicines and maximum residue limits (MRLs) 2. Funds to cover fee exemptions or reductions for medicinal products 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 3. Fee exemptions for pilot project for scientific advice for veterinary medicines for minor uses and minor species	
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 Community, 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:*

   i) 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 18 700 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 31 100 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.

   ii) Post authorisation activities

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

   EUR 18 000 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 520 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 2 400 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.

iii) Annual fee

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

EUR 4 250 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.

EUR 8 600 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.

iv) 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.

i) Pre-authorisation activities

The following partial exemption 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.

ii) 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*

   i) A total exemption from fees is granted from the following types of applicable fees for MUMS/Limited market applications submitted for:

      - Scientific Advice
      - 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

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

      a) 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 of the total applicable fee
      - In the case of initial marketing authorisation a 50% reduction of the total applicable fee

      b) Post-authorisation activities

      - In the case of an extension of an existing marketing authorisation to include an indication classified by CVMP as MUMS/limited markets a 50% reduction of the total applicable fee
      - In the case of the annual fee for a product authorised exclusively for indications classified by CVMP as MUMS/limited markets a 75% reduction of 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" (EMEA/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 Community 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:

   i) 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.

   ii) 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 annual fees a 100% reduction to the total applicable fee.