



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 June 2024  
EMA/MB/183645/2024  
Management Board meeting of 12-13 June 2024

## Fee Regulation working arrangements on fees and charges payable to the European Medicines Agency applicable from 1 January 2025

THE MANAGEMENT BOARD OF THE EUROPEAN MEDICINES AGENCY (hereafter *Agency* or *EMA*)

Having regard to Article 8 of Regulation (EU) 2024/568 (hereafter *Fee Regulation*)

Having regard to the reasoned proposal from the Executive Director,

Having regard to the favourable opinion from the Commission,

Whereas:

- (1) According to Article 8 of Regulation (EU) 2024/568, the Management Board of the Agency shall, on a reasoned proposal from the Executive Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of said Regulation.
- (2) The remuneration referred to in Article 37(2) of Regulation (EU) 2022/123 for the assessment activities of the rapporteurs in relation to the Emergency Task Force (EFT) under said Regulation is established by the Management Board by means of ad hoc Decisions. Therefore, there is no need to establish any provisions on that matter in these working arrangements.
- (3) Pursuant to Article 7(2) of Regulation (EC) No 141/2000 on the use of the special contribution from the European Union, fee reductions shall apply for orphan medicinal products. Designated orphan medicinal products are an important source of innovation and enhance the development product pipelines. Applicants often lack experience with the Agency and require enhanced regulatory support. The level of said fee reductions shall be set out in these working arrangements.
- (4) Certain medicinal products for human use are authorised for preparedness against biological agents that might be used as weapons of bioterrorism, for stockpiling in preparation of a bioterrorism health threat. Fee reductions should be granted for these medicines, as they are not on the market and no- or limited post-authorisation activities apply. However, such fee reduction shall not be granted should the terms of such marketing authorisation be varied to include a therapeutic indication unrelated to preparedness against biological agents that might be used as weapons of bioterrorism.
- (5) As part of the transitional rules for Regulation (EU) 2019/6 (hereafter *VMP Regulation*) laid down in Regulation (EU) 2022/839, the labelling and package leaflet of all existing veterinary medicinal

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products (VMPs) which were authorised in accordance with repealed Directive 2001/82/EC or with the deleted provisions on VMPs of Regulation (EC) No 726/2004 must be brought into compliance with Articles 10 to 16 of the VMP Regulation by 29 January 2027. Therefore, marketing authorisation holders (MAHs) must transfer the product information from the previous QRD template v.8.2 to the new QRD template v.9 and submit it for regulatory approval by means of a variation requiring assessment (VRA) with a stand-alone application for each product. Fee reductions shall be granted for non-immunological products considering that such transfer to the new QRD template v.9 (VRA scope G.I.18) doesn't require assessment of new scientific data and thus the associated fee would be considered disproportionate.

- (6) Fee reductions shall be granted for pharmacovigilance inspection activities related to veterinary medicinal products in order to take account of the specific economic reality and market conditions for veterinary medicinal products, as well as the reduced workload of pharmacovigilance inspections activities related to said medicines.

HAVE ADOPTED THESE WORKING ARRANGEMENTS

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# 1. Clarifications on terminology and requirements

## 1.1. Scientific advice (Annexes I.1 and II.1)

The terms used in Annex I, point 1, to the Fee Regulation, in relation to scientific advice for medicinal products for human use, are to be understood as follows:

1. **Quality development:** related to Module 3 of the Common Technical Document (CTD), includes all chemical, pharmaceutical and biological testing of active substance and finished product intended to demonstrate the quality of the medicinal product.
2. **Non-clinical development:** related to Module 4 of the Common Technical Document (CTD), includes all in vitro and animal toxicological and pharmacological tests intended to provide preliminary animal pharmacokinetic and pharmacodynamic information and primarily to demonstrate adequate safety in animals prior to various stages of clinical use.
3. **Clinical development:** related to Module 5 of the Common Technical Document (CTD), includes all studies in human subjects, whether patients or healthy volunteers, including clinical pharmacological trials and confirmatory trials designed to determine the efficacy and safety of the product; scientific advice on clinical development may also include advice on pharmacovigilance and risk management plans (including post-authorisation studies) and on clinical evidence generation plans intended to support specific types of marketing authorisation and regulatory entitlements or to demonstrate significant benefit over authorised medicines in the context of a designated orphan medicinal product.
4. **Qualification of novel methodologies:** regulatory acceptability of a specific use of the proposed method (e.g. use of a biomarker) in a research and development (R&D) context based on the assessment of submitted data.

Scientific advice on comparability of similar biological medicinal products may encompass any area of advice (Quality, Non-clinical, Clinical) and the relevant fees apply.

For the purpose of Annex I, point 1, to the Fee Regulation, **protocol assistance** shall be understood as scientific advice for orphan medicinal products.

The terms used in Annex II, point 1, to the Fee Regulation, in relation to scientific advice for veterinary medicinal products, are to be understood as follows:

1. **Quality development:** related to Part 2 of the dossier. Includes, for example, physicochemical, biological and microbiological tests/assays of active substance and finished product, intended to demonstrate the quality of the veterinary medicinal product.
2. **Safety development:** related to Part 3 of the dossier, other than residue tests, including e.g., in vitro tests and studies, and toxicological and pharmacological studies intended to provide pharmacokinetic and pharmacodynamic information and to demonstrate adequate safety of the veterinary medicinal product for users, consumers and environment.
3. **Clinical development:** related to Part 4 of the dossier, including, for example, studies in target animals to determine safety and efficacy of the veterinary medicinal product.
4. **Maximum residue limit (MRL):** related to residue tests in the Part 3 of the dossier, tests and assays to determine levels of residues of a veterinary medicinal product in the tissues of a food-producing target animal in order to establish the MRLs.

5. **Preliminary risk profile assessment:** specific type of scientific advice given to developers of new antimicrobial substances and antimicrobial veterinary medicinal products, which assesses the antimicrobial resistance risk to public health from the new substance or veterinary medicinal product, and the potential need for risk management measures, in order to provide increased regulatory predictability at an early stage of product development.
6. **Bioequivalence studies:** scientific advice on bioequivalence studies for generic veterinary medicinal products.

## **1.2. Rolling review (Annex I.3.1(b))**

Annex I, point 3.1(b), to the Fee Regulation establishes fees for “*an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.*”

Said assessment is to be understood as referring to the ‘**Rolling Review**’, that is, an *ad hoc* procedure used in a public health emergency context to allow the Agency to continuously assess the data for an upcoming promising application for marketing authorisation as they become available, i.e. preceding the formal submission of a complete application for a new marketing authorisation. Through this process, the Agency is able to complete the review of marketing authorisation application dossier earlier while ensuring robust scientific opinions. Such rolling reviews are conducted under the EMA emerging health threats plan and starting them requires specific agreement by the Emergency Task Force (ETF).

## **1.3. Annual fee (Annex III)**

### **1.3.1. Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004 and veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6**

The annual fee for medicinal products authorised under the centralised procedure covers a period of one year. The total payable amount for each marketing authorisation holder shall be calculated by the Agency on the basis of the information recorded in the Agency’s systems on 1 January of each year.

The annual fee shall be due on the first and each subsequent anniversary date of the Commission Implementing Decision granting the marketing authorisation, and shall relate to the preceding year.

If the marketing authorisation concerned ceases to be valid during the reference year<sup>1</sup>, the total payable amount shall be calculated by the Agency in proportion to the period elapsing from the latest anniversary date up to the date of the relevant Commission decision withdrawing or revoking the marketing authorisation at issue.

### **1.3.2. Annual pharmacovigilance fee**

The annual pharmacovigilance fee covers the period from 1 January to 31 December of the year in which said fee is charged.

The total amount payable for each marketing authorisation holder for a given year shall be calculated by the Agency on the basis of the information available in the ‘Article 57 database’ (for medicinal

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<sup>1</sup> Including in case of withdrawal and revocation of the marketing authorisation.

products for human use) or the 'Union Product Database' (for veterinary medicinal products) on 1 July of said year.

The annual pharmacovigilance fee applies only for valid marketing authorisations at the time of the due date.

If the concerned marketing authorisation ceases to be valid<sup>2</sup> before or on 1 July of a given calendar year, no annual pharmacovigilance fee will be charged for said year. If, on the other hand, the marketing authorisation ceases to be valid after 1 July, no annual fees will be reimbursed for the remaining period of said year.

## **1.4. Inspections (Annex IV.1)**

This section applies equally to inspections performed on site and to inspections conducted remotely.

Regulation (EU) No 2024/568 provides for a fee per distinct inspection. The section below sets out the criteria for a distinct inspection per type. Therefore, multiple distinct inspections can apply per inspection request.

### **1.4.1. Good manufacturing practices (GMP)**

A distinct GMP inspection is established by the following cumulative criteria:

- a specific manufacturing site, and
- relates to a medicinal product which is the subject of a particular application/authorisation (or for which the prospective applicant has submitted to EMA a "letter of intent to submit"), 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 during a specified period.

In the above scope:

- a manufacturing site is a physical location that may comprise an individual building or complex of buildings in which a manufacturing activity or activities are carried out;
- a medicinal product is distinguished by its unique EMA product number<sup>3</sup>;
- 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
- manufacturing operations are distinguished one from another as follows:
  - manufacture of sterile products
  - manufacture of non-sterile products

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<sup>2</sup> Including in case of withdrawal and revocation of the marketing authorisation.

<sup>3</sup> Unique identification number assigned by EMA at the time of eligibility request to each medicinal product under the centralised procedure.

Fee calculations for inspections of Vaccine Antigen Master File (VAMF) manufacturers shall be done by analogy to the calculation of inspections for active substances.

### **1.4.2. Good clinical practices (GCP)**

A distinct GCP inspection is established by the following cumulative criteria:

- a medicinal product which is the subject of a particular application/authorisation (or for which the prospective applicant has submitted a “letter of intent to submit”), 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, as defined below), and
- involves the same inspection team and is conducted during a specified period.

In the above scope:

- a medicinal product is distinguished by its unique EMA product number<sup>4</sup>;
- a specific clinical trial is distinguished by its unique protocol number<sup>5</sup>;
- a specific clinical trial related site is a physical location identifiable by a distinct address;
- activity groups 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, audit activities and/or computerised system.

For the purposes of Annex IV, points 1.1.3. and 1.1.4., the “leading authority” is the reporting authority, which takes the responsibility for organising, planning and reporting the GCP inspection(s), acting as the main communication point between the inspection team and the Agency and writing and co-signing the integrated inspection report summarising the critical and major findings of the inspection of several sites.

### **1.4.3. Plasma master file (PMF)**

A distinct PMF inspection is established by the following cumulative criteria:

- includes up to 4 specific blood establishment sites, and
- relates to a specific PMF dossier, and

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<sup>4</sup> Unique identification number assigned by EMA at the time of eligibility request to each medicinal product under the centralised procedure.

<sup>5</sup> Unique number or character sequence assigned by the clinical trial sponsor to uniquely identify the investigational protocol..

- is conducted in the same tour, by the same inspection team and during a specified period.

Consecutive PMF inspections are inspections performed in the same tour as the distinct inspection, and they are established by the following cumulative criteria:

- each consecutive PMF inspection includes up to 4 additional blood establishment sites different to those included in the distinct inspection. Any further up to 4 blood establishment sites will constitute an additional consecutive PMF inspection, and
- relates to the same PMF dossier as the distinct inspection, and
- is conducted in the same tour, by the same inspection team and during the same period as for the distinct PMF inspection.

In the above definition:

- a blood establishment site is a physical location that may comprise an individual building or complex of buildings in which a specific blood/plasma activity (e.g. collection, processing, testing) related to the production of a plasma pool defined by the PMF dossier is carried out.
- a PMF dossier is distinguished by its unique EMA PMF number.

#### **1.4.4. Good laboratory practices (GLP)**

A distinct GLP inspection is established by the following cumulative criteria:

- a medicinal product which is the subject of a particular application/authorisation (or for which the prospective applicant has submitted a "letter of intent to submit"), and
- relates to a single test facility, which has carried out non-clinical safety and/or toxicological and/or pharmacological studies proposed in an application for marketing authorisation for either medicinal products for human use or veterinary medicinal products, which is subject to either a specific GLP study inspection covering studies performed at the test facility to assess issues raised during the assessment of the non-clinical part of the dossier, or to general GLP compliance verification of the studies supporting the non-clinical part of the dossier, and
- involves the same inspection team and is conducted during a specified period.

#### **1.4.5. Pharmacovigilance inspections**

A distinct pharmacovigilance inspection is established by the following cumulative criteria:

- a pharmacovigilance system described in a specific pharmacovigilance system master file (PSMF) that covers one or more medicinal product(s) which are the subject of a particular application/authorisation (or for which the prospective applicant has submitted a "letter of intent to submit"), and
- is carried out at a specific pharmacovigilance site, and
- involves the same inspection team and is conducted during a specified period.

In the above scope:

- a specific pharmacovigilance system master file (PSMF) describing a specific pharmacovigilance system is distinguished by its unique reference;
- a specific pharmacovigilance site is a physical location identifiable by a distinct organisation name and address.



#### **1.4.6. Cancellation of an inspection**

The term 'reasons attributable to the applicant' is to be understood as an action or an absence of action ascribable to the applicant that results in the cancellation of a scheduled inspection.

The following are examples of reasons attributable to the applicant for the cancellation of a scheduled inspection, as referred to in Annex IV, point 1, to the Fee Regulation:

- withdrawal of either the marketing authorisation or the application for a marketing authorisation (or for other scientific opinion or assessment by the applicant);
- the notification of the non-submission of the intended application by the prospective applicant, for cases where the inspection was requested on the basis of a "letter of intent to submit" (i.e. prior to the actual submission of an application for a marketing authorisation or for other scientific opinion or assessment);
- 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 for a marketing authorisation or for rolling review, the prospective applicant and the marketing authorisation holder to the scope of the application or submitted data, or access to, changes to the ownership of, or location of facilities (e.g. manufacturing facilities) or data necessitating a cancellation of the inspection.

#### **1.4.7. Travel expenses relating to inspections**

Annex IV, point 1.4, to the Fee Regulation sets out the charges for travel expenses.

Travel expenses for changes made to notified inspection arrangements by parties other than the applicant (e.g. change in travel arrangements for the inspectors) shall not be charged to the applicant.

The Agency and the concerned inspecting authority will not be liable for any financial loss and/or damage suffered by the applicant due to a failure to conduct a notified inspection or a consequential need to rearrange that inspection.

### ***1.5. Certificates of medicinal products (Annex IV.6.2)***

A certificate of medicinal product is composed of one original electronic certificate (eCPP) for a medicinal product with a distinct marketing authorisation number, addressed to an importing country, issued in one or a combination of more official language(s) of the European Union and a set of Annexes.

The Agency will issue certificates within 10 working days under the standard procedure, and within 2 working days under the urgent procedure.

### ***1.6. Notifications of parallel distribution (Annex IV.6.3)***

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 use or veterinary medicinal products.

3. **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:
  - i. a change in the name and/or
  - ii. address of a parallel distributor and/or
  - iii. addition or deletion of a re-packager and/or
  - iv. a change in the name and/or address of a re-packager.
4. **Annual update notification:** submission of a notification due on the first and each subsequent anniversary after the initial notification, if applicable.
5. **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.

### ***1.7. Timetable for variations requiring assessment to the terms of a marketing authorisation (Annex II.6)***

The type of changes and length of timetable for variations to the terms of a marketing authorisation requiring assessment pursuant to Annex II, point 6, are understood to be those set out in the 'Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations' available [here](#).

### ***1.8. Entity not engaged in an economic activity (Annex V.2)***

For the purposes of Annex V.2 to the Fee Regulation, the entity shall demonstrate that it

- is by its form non-profit-making or has a legal or statutory obligation not to distribute profits to its shareholders, owners or members, and
- is not owned or controlled directly or indirectly<sup>6</sup> by any private profit making organisation (PPO), nor has concluded any agreements with any such organisation concerning their sponsorship or participation to the specific research project for which this fee incentive would apply.<sup>7</sup>

In addition, the entity shall be located in the EEA.

The entity shall provide evidence to demonstrate compliance with the above, including the entity's founding documents (e.g. deed, statutory articles) and a declaration of not being owned or controlled by any PPO, nor having concluded any agreements with any PPO concerning their sponsorship or participation to the specific research project to which the fee waiver under Annex V.2 to the Fee Regulation would apply.

Further to the above, to benefit from the fee waiver laid down in Annex V.2 to the Fee Regulation, applicants shall provide scientific arguments supporting the foreseen practical impact of the advice on the planned research as well as on improving its potential for addressing public health priorities.

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<sup>6</sup> Including (i) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the applicant, or of a majority of the voting rights of the shareholders or associates of that applicant; or (ii) the direct or indirect holding, in fact or in law, of decision-making powers in the applicant or in the scientific results of the subject directly resulting from the incentivized procedure.

<sup>7</sup> Material transfer agreements conferring to the provider less than 50% of the ownership of the results directly obtained from the research in relation to which the advice is requested shall not be considered as an agreement with an PPO concerning their sponsorship or participation to the specific research project for which this fee incentive would apply.

The reasoning on the impact should cover all aspects applicable to the research, including but not limited to the concerned public or veterinary health priority, funding not permitting to carry fees for regulatory services, critical-to-quality factors of a clinical trial, a multi-national clinical trial(s), generation of information on proof-of-principle and medical plausibility of a product with a view to a marketing authorisation application or modification thereof, development tools or methodologies addressing either regulatory science research needs, accelerating or strengthening medicines evaluation, or enabling the research to involve international researchers.

### **1.9. Services rendered by National Competent Authorities**

For services rendered by NCAs through (co-)rapporteurs, inspectors and scientific advice coordinators as set out in the Appendix to these working arrangements, the appointment of the responsible NCA is handled by the respective scientific committee before the actual application is validated at the Agency.

## **2. Scientific services**

None

## **3. Fee reductions (Article 6.4)**

### **3.1. Applications for designated orphan medicinal products**

Pursuant to the provisions of Article 7(2) of Regulation (EC) No 141/2000 on the use of the special contribution from the European Union, the following shall apply for designated orphan medicinal products:

- 75% fee reduction for protocol assistance (scientific advice on orphan medicinal products) pursuant to point 1 of Annex I to the Fee Regulation, and  
100% fee reduction for paediatric-related protocol assistance (scientific advice on orphan medicinal products) pursuant to point 1 of Annex I to the Fee Regulation; restricted to the development of an orphan medicinal product for the paediatric population, where the advice requested excludes the adult population,
- 10% fee reduction for initial marketing authorisation applications pursuant to point 2 of Annex I to the Fee Regulation,
- 100% fee reduction for pre-authorisation inspections pursuant to point 1 of Annex IV to the Fee Regulation.

However, if the application is submitted by a micro, small and medium-sized enterprise, the following shall apply:

- 100% fee reduction for protocol assistance (scientific advice on orphan medicinal products) pursuant to point 1 of Annex I to the Fee Regulation,
- 100% fee reduction for initial marketing authorisation applications pursuant to point 2 of Annex I to the Fee Regulation,
- 100% fee reduction for the post-authorisation activities referred to in points 4, 5, 6, 14 and 15 of Annex I, point 1 of Annex III and points 2, 4 and 6.2 of Annex IV to the Fee Regulation up to the 1<sup>st</sup> anniversary date of the Commission Implementing Decision granting the marketing authorisation,

- 100% fee reduction for pre-authorisation inspections pursuant to point 1 of Annex IV to the Fee Regulation.

### **3.2. Applications for certain medicinal products for human use that are used for stockpiling in preparation of a bioterrorism health threat**

For the post-authorising activities in relation to authorised medicinal products for human use that are used for stockpiling in preparation of a bioterrorism health threat, 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>8,9</sup>, the following shall apply:

- 50% fee reduction for annual fee pursuant to point 1 of Annex III to the Fee Regulation.
- 50% fee reduction for extension of a marketing authorisation related to the preparedness pursuant to point 4 of Annex I to the Fee Regulation.
- 50% fee reduction for transfer of a marketing authorisation pursuant to point 2 of Annex IV to the Fee Regulation.
- 50% fee reduction for major type II variations pursuant to point 5 of Annex I to the Fee Regulation.

However, such reduction shall not apply to any variation to the terms of the marketing authorisation of said medicinal products to authorise a therapeutic indication unrelated to preparedness against biological agents that might be used as weapons of bioterrorism.

If such a variation is granted, all fee reductions for the concerned medicinal product shall stop applying as of the date of the Commission Implementing Decision authorising the concerned indication.

The above-mentioned fee reductions will apply upon request to the Agency by the marketing authorisation holder justifying the fulfilment of the above-described criteria (e.g. only authorised for preparedness for bioterrorism health treat and used for stockpiling).

The fee reductions will be granted on an annual basis.

The reductions shall not apply if the concerned medicinal product is also authorised for a therapeutic indication unrelated to preparedness against biological agents that might be used as weapons of bioterrorism.

### **3.3. Variations requiring assessment with scope G.I.18**

For non-immunological<sup>10</sup> veterinary medicinal products, the following shall apply:

- 50% fee reduction for variations requiring assessment pursuant to point 6.2 of Annex II to the Fee Regulation with classification G.I.18.<sup>11</sup>

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<sup>8</sup> i. e. anthrax, plague, tularaemia, smallpox, viral haemorrhaging fever, botulism, brucellosis, Q-fever, glanders and melioidosis and other infectious diseases.

<sup>9</sup> CPMP/4048/01 16.01.2002 as last amended.

<sup>10</sup> Reference is made to veterinary medicinal products not falling within the definition of "immunological veterinary medicinal product" provided for in Article 4(5) of Regulation (EU) 2019/6 (i.e., veterinary medicinal products referred to in Sections II and IIIa of Annex II to the same Regulation).

<sup>11</sup> See the '[Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation \(EU\) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations](#)'.

### **3.4. Pharmacovigilance inspections related to veterinary medicinal products**

For each distinct pharmacovigilance inspection, the following shall apply:

- 30% fee reduction for post-authorisation pharmacovigilance inspections related to veterinary medicinal products.

## **4. Payment modalities**

### **4.1. Payment terms for fees and charges**

#### **4.1.1. Due date pursuant to Article 9 of the Fee Regulation and applicable fee and charges level**

Fees and charges for which a due date is not laid down in the Fee Regulation shall be due in accordance with the rules set out in the Appendix to these working arrangements and shall be payable pursuant to the terms specified in sections 4.1.2 and 4.1.3 below.

The payable fee or charge shall be calculated on the basis of the applicable fee or charge level in force on the due date set out in the Appendix.

In addition, to determine the applicable fee or charge to be paid, the Agency shall take into account the criteria (e.g., status of the applicant, product type, product status, etc.) that apply on the date when the fee or charge becomes due, in accordance with the Appendix.

Any change to the applicable criteria that occurs after the due date shall not be considered for the fee determination and, therefore, will have no impact on the total fee or charge due that has already been determined.

#### **4.1.2. Prepayment of fees and charges**

The following services shall be provided only after the fee or charge has been paid in its entirety in accordance with Article 71 of the Agency's Financial Regulation and Article 7(3) of the Fee Regulation:

- Parallel distribution (Annex IV, point 6.3 of the Fee Regulation)
- Certificates of medicinal products (Annex IV, point 6.2 of the Fee Regulation)
- Scientific advice (Annex I, point 1 and Annex II, point 1 of the Fee Regulation)

#### **4.1.3. Fees and charges not subject to prepayment**

Without prejudice to other provisions in the Union legislation, the fees and charges for services that are not listed under section 4.1.2 above shall be payable in their entirety in accordance with Article 7(3) of the Fee Regulation within 30 days from the date of the request for payment (invoice) issued by the Agency, in accordance with the Appendix of this document.

### **4.2. Operational implementation of transfer to the bank account of the Agency**

Pursuant to Article 7(3) of the Fee Regulation, the payment of the fees and charges shall be made by means of a transfer to the bank account of the Agency specified in the request for payment.

Payments must be made net of all bank charges, withholding taxes and any other deductions.

A transfer to the bank account of the Agency is understood as either

- SEPA or non-SEPA Credit Transfer initiated by the payer; or
- a transfer made by the payer via an online payment platform made available by the Agency; or
- a transfer made within a SEPA direct debit system.

Payments by cheque and/or cash shall not be accepted.

In the case of payments processed via an online payment platform made available by the Agency, for the purposes of Article 7(4) of the Fee Regulation the date on which the payer receives confirmation of the approval of the online payment shall constitute the date on which the payment has been made.

### ***4.3. Disagreement on fees and charges and other queries***

Any disagreement on the invoice shall not suspend the payment period for said invoice and, therefore, the invoice shall still be paid by its due date.

Should the disagreement lead to a correction of the contested invoice, any amount overpaid in connection with said invoice shall be reimbursed by the Agency or offset against a future invoice of the same entity, in agreement with the debtor.

A limitation period of 5 years shall apply to credits owed by the Agency in respect of third parties, in accordance with Article 70 of the Agency's Financial Regulation.

The Agency will not accept disputes on the grounds that a purchase order number is not provided in the invoice, as the use of the purchase order system is an internal control process of the applicant and it is not binding on the Agency.

## **5. Mechanisms for financial compensation of NCAs**

### ***5.1. Remuneration for assessment activities of scientific committees and inspection services***

The Fee Regulation establishes the applicable amounts of remuneration for the services provided by the (co-)rapporteurs (or), appointed as committee members by the NCAs, and by persons performing other roles considered as equivalent for the purposes of that Regulation as referred to in the Annexes to said Regulation.

According to Article 5(3) of the Fee Regulation, said remuneration shall be paid in accordance with the written contract referred to in Article 62(3), first subparagraph, of Regulation (EC) No 726/2004. The cooperation agreements regulating the services provided by the NCAs to the Agency (Cooperation Agreements) constitute such written contracts and detail the terms governing said remuneration. The Agency shall not pay the remuneration for said services directly to the individuals conducting the tasks, unless specifically agreed in advance by the Agency and the concerned NCA.

The monthly service statement prepared for each NCA, stating all procedures assigned to that NCA in the previous month, as well as the related budget commitments/purchase orders, constitutes a specific contract based on the conditions of Annex II of the Cooperation Agreements.

The timetable establishing the remuneration dates is provided in the Appendix.

The remuneration for the services provided by the (co-)rapporteur (and other roles considered equivalent under the Fee Regulation) will be paid to the NCA formally appointed to undertake such role. The foregoing will apply also in cases where the assessment work is conducted by a different NCA on the basis of a bilateral agreement with the NCA formally appointed as (co-) rapporteur.

Where for a certain procedure subject to remuneration the NCA of the rapporteur and the NCA of the co-rapporteur agree to formally swap their roles (of rapporteur and co-rapporteur), they shall immediately notify the Agency about said agreement through the relevant channel(s) in writing, so that the remuneration to be paid is recalculated accordingly.

Where multinational assessment teams are established, the leading NCAs can request the Agency, in writing, to distribute the corresponding remuneration for the specific assessment directly to each of the participating NCAs. Such notification shall be made through the relevant channel(s) in writing before the validation of the application for the specific procedure and of the allocation of resources, and shall indicate either the percentage or directly the amount to be paid to each of the participating NCAs.

With regards to the annual fee, the applicable amount of remuneration payable to the NCA for medicinal products authorised under the centralised procedure covers a period of one year. If a marketing authorisation ceases to be valid<sup>12</sup>, the remuneration payable to the NCA as share of the annual fee shall be calculated by the Agency in proportion to the period elapsing from the latest anniversary date up to the date of the relevant Commission decision withdrawing or revoking the marketing authorisation at issue.

For inspections involving more than one supporting supervisory authority, the payment to the participating authorities shall be calculated by dividing equally the amount for the supporting authority established in Annex IV, point 1 of the Fee Regulation by the number of supporting supervisory authorities participating in the inspection (i.e. for two supporting supervisory authorities, the amount of remuneration for the supporting authorities is to be split in two), unless a different apportionment of the applicable remuneration amount has been agreed by all parties involved in the inspection and notified in writing to the Agency before the inspection takes place.

In exceptional situations where there is no supporting supervisory authority available, the inspection may only involve one authority (the leading authority) who will have to take on additional tasks to compensate for the absence of a second authority. In these specific and duly documented cases, the amount of remuneration for the supporting authority established in Annex IV, point 1, to the Fee Regulation, will be paid to the leading authority for the additional exceptional workload and related costs incurred by the leading authority for assuming the additional supporting inspectorate role work.

## ***5.2. Common format for national competent authorities and experts contracted for the work of experts panels on medical devices to provide performance and financial information***

### **5.2.1. Common format to submit performance information**

In accordance with Article 10(2) and Annex VI to the Fee Regulation, performance information per calendar year shall be provided to the Agency per type of pertinent procedure on the number of working hours spent by the rapporteur, the co-rapporteur or persons performing other roles considered as equivalent for the purposes of this Regulation, including hours spent by experts and others employed by the competent authorities of the Member States to assist them, and number of working hours spent by experts contracted for the work of the expert panels on medical devices. The

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<sup>12</sup> Including in case of withdrawal and revocation of the marketing authorisation.

types of procedure for which said working hours apply, will be provided in a separate Decision of the Management Board , in accordance with Annex VI (6) to the Fee Regulation.

To that end, the Agency will, at a defined frequency, as set out in the above Management Board decision, provide the competent authorities of the Member States and experts contracted for the work of experts panels on medical devices with a prefilled form concerning the relevant procedures finalised in the corresponding period. The Agency may make available a data system to submit said performance information, in which case the corresponding link to said system will be facilitated in due time to the competent authorities of the Member States and above-mentioned experts.

## **5.2.2. Common format to submit financial information**

Pursuant to Article 10(4) of the Fee Regulation, the Agency shall provide the competent authorities of the Member States and experts contracted for the work of the expert panels on medical devices with the common format that shall be used to provide the Agency with financial information on significant changes in the costs of services rendered to the Agency, in line with the Management Board decision referred to in section 5.2.1.

The Agency may make available a data system to submit said financial information, in which case the corresponding link to said system will be facilitated in due time to the competent authorities of the Member States and above-mentioned experts.

**DocuSigned by:**  
  
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Lorraine Nolan  
Chair of the Management Board

02 July 2024



## Appendix – List of fee (due) dates and deadlines for payments of remuneration to National Competent Authorities

### Terminology used in the Appendix

1. **Applicable fee level date:** As set out in the Fee Regulation, date which determines the fee amount, the legal entity to be charged and the applicable fee incentive(s).
2. **Fee due date:** the date when a fee becomes payable.
3. **Recovery (sales) order/commitment date:** the date by when a recovery (sales) order and, where applicable, a commitment shall be completed in respect of a due fee and, where applicable, a payment for a service.
4. **Date of payment due for National Competent Authorities (NCA):** date from which the time-limit for payment shall be calculated within the meaning of Article 116(1)(c) of Regulation (EU, Euratom) 2018/1046.
5. **Letter of intent:** notification of intention to submit an application.

## 1. Medicinal products for human use – Annex I of Fee Regulation

Activity	Reference to Fee Regulation - Annex I	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Scientific Advice	Point 1	Receipt of submission date	Validation notification	By the date of Validation notification	Validation date in Core Business Application	Day 30 following the start date
Authorisation to market a medicinal product	Point 2	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date (or Day 60 if a shorter timetable applies)
Scientific opinion and assessment prior to potential submission of an application for marketing authorisation	Point 3	Receipt of submission date of 1 <sup>st</sup> rolling review application	Day 1 (start) of 1 <sup>st</sup> rolling review cycle	By day 30 following start of 1 <sup>st</sup> rolling review cycle	Receipt of fee cover note at the start of 1 <sup>st</sup> rolling review cycle	Adoption of interim CHMP opinion at end of 1 <sup>st</sup> rolling review cycle
Extension (Annex I applications)	Point 4	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date
Major variations of Type II	Point 5.1	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Validation date in Core Business Application	Day 60 following the start date
Major variations of Type II	Point 5.2	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Validation date in Core Business Application	Day 30 following the start date
Referrals and scientific opinions pursuant Art. 5(3)	Point 6	Date of notification of referral of procedure	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 90 following the start date
Evaluation of traditional herbal medicines (scientific advice)	Point 7	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Confirmation of start of procedure	Day 90 following the start date

Activity	Reference to Fee Regulation - Annex I	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Certification of compliance for Plasma Master Files (pursuant to part III of Annex I)	Point 8	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Confirmation of start of procedure	Day 90 following the start date
Certification of compliance for Vaccine Antigen Master Files (pursuant to part III of Annex I)	Point 9	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Confirmation of start of procedure	Day 90 following the start date
Certification of quality and non-clinical data relating to ATMPs by SMEs	Point 10	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date
Paediatric applications	Point 11	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date
Orphan designation	Point 12	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date
Scientific opinion to market outside EU	Point 13	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date
Periodic safety update reports	Point 14	EURD Data lock point date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date
Post-authorisation safety studies	Point 15	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date of each phase

## 2. Veterinary medicinal products – Annex II of Fee Regulation

Activity	Reference to Fee Regulation – Annex II	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Scientific Advice	Point 1	Receipt of submission date	Validation notification	Date of Validation notification	Validation date in Core Business Application	Day 30 following the start date
Limited Market classification	Point 2	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Receipt and start date confirmation to the company	n/a
Establishment, modification or extension of MRL	Point 3	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date (or Day 60 if a shorter timetable applies)
Authorisation to market a medicinal product	Point 4	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date (or Day 60 if a shorter timetable applies)
Re-examination of a marketing authorisation for limited markets	Point 5	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core business application	Day 60 following the start date
Variations requiring assessment Level 1 – 3	Point 6	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 60 following the start date
Referrals, and arbitration and scientific opinions	Point 7	Date of notification of referral procedure	Day 1 (start) of procedure	By day 60 following the start date	Day 1 (start) date in Core Business Application	Day 90 following the start date

Activity	Reference to Fee Regulation – Annex II	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Certification of compliance for Vaccine Antigen Master Files	Point 8	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date confirmation to the company	Day 60 following the start date if submitted as stand-alone procedure; day 120 if submitted with an application for a marketing authorisation
Certification of compliance for Platform technology master file	Point 9	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date confirmation to the company	Day 60 following the start date if submitted as stand-alone procedure; day 120 if submitted with an application for a marketing authorisation
Post-marketing surveillance studies	Point 10	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date confirmation to the company	Day 60 following the start date of each phase
Scientific opinion for int. organisations outside EU	Point 11	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date

### 3. Annual fees – Annex III of Fee Regulation

Activity	Reference to Fee Regulation – Annex III	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Annual fee for medicinal products for human use and veterinary medicinal products	Points 1 and 2	1st of January of the applicable year	Anniversary of the date of Commission decision on marketing authorisation or Commission decision date on withdrawal of marketing authorisation	By 1 <sup>st</sup> of February of the applicable year	Report generated from data of the relevant business applications	Within 30 calendar days from of the date of the marketing authorisation decision of the European Commission or the date of the Commission decision withdrawing the marketing authorisation
Annual pharmacovigilance fee for medicinal products for human use and veterinary medicinal products	Point 3	1 July of the applicable year		By 15 September of the applicable year	Report generated from data of the relevant business applications	n/a

#### 4. Other fees and charges – Annex IV of Fee Regulation

Activity	Reference to Fee Regulation – Annex IV	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Inspections	Point 1.1	Receipt of inspection report	Receipt of inspection report	By day 30 following notification of receipt of inspection report	Date of insertion of receipt date of inspection report in Core Business Application	Validation of inspection report
Inspection cancellation	Point 1.2	Cancellation date	Cancellation date	By day 30 following insertion of cancellation date in Core Business Application	Date of insertion of cancellation date in Core Business Application	Date of insertion of cancellation date in Core Business Application
Inspection cancellation	Point 1.3	Cancellation date	Cancellation date	By day 30 following insertion of cancellation date in Core Business Application	n/a	n/a
Transfer of marketing authorisation	Point 2	Receipt of submission date	Receipt of submission date	By day 30 following receipt of submission date	n/a	n/a
Pre-submission request	Point 3.1	Receipt of submission date of letter of intent or, if letter of intent is not submitted, receipt of submission date of application for marketing authorisation	Receipt of submission date of letter of intent or, if letter of intent is not submitted, receipt of submission date of application for marketing authorisation	By day 30 following receipt of submission of letter of intent or, if letter of intent is not submitted, receipt of submission date of application for marketing authorisation	Date of insertion of receipt date of Letter of Intent in Core Business Application (for Recovery Order) Date of insertion of Rapporteurs in Core Business Applications (for Commitments)	Date of closure of appointment of Rapporteurs in Core Business Application

Activity	Reference to Fee Regulation – Annex IV	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Change of intended submission date	Point 3.2	Receipt of submission date of request for change	Receipt of submission date of request for change	By day 30 following receipt of submission date for request for change	Receipt of submission date of request for change	Day 30 following receipt of submission date of request for change
Re-examination of an opinion	Point 4	Receipt of submission date of grounds for re-examination (start date of re-examination phase)	Receipt of submission date of grounds for re-examination	By day 30 following receipt of grounds for re-examination	Start date of re-examination phase in core business application	Day 30 following the start date of re-examination phase
Scientific Services	Point 5	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	By day 120 following the start date
Administrative charges	Point 6.1	Date of negative validation or date of withdrawal prior to validation	Date of negative validation or date of withdrawal prior to validation	By day 30 following Date of negative validation or date of withdrawal prior to validation	n/a	n/a
Certificates of medicinal products	Point 6.2	Receipt of submission date	Receipt of submission date	Receipt of submission date	Date of receipt registered in Core business application.	n/a
Parallel Distributions	Point 6.3	Receipt of submission date	Receipt of submission date	Receipt of submission date	Date of receipt registered in Core business application.	n/a



Activity	Reference to Fee Regulation – Annex IV	Applicable fee level	Fee due	Recovery (Sales) Order/Commitment		Date of payment due for NCA
		Date	Date	Date	Supporting trigger	
Administrative services	Point 6.4	Receipt of submission date	Receipt of submission date	By day 30 following receipt of submission date	Date of receipt registered in Core business application.	n/a
Consultation on ancillary medicinal substances in a Medical device	Point 7.1	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date
Consultation on Substance based Medical devices	Point 7.2	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 120 following the start date
Consultation on companion diagnostics	Point 7.3	Receipt of submission date	Day 1 (start) of procedure	By day 30 following the start date	Day 1 (start) date in Core Business Application	Day 30 following the start date