15 November 2024
EMA/534613/2024 - *Rev. June 2025*
European Medicines Agency

General Q&As – Important information to all Applicants

Question & Answers (Q&As)

Legal framework

- Regulation (EU) 2024/568 of the European Parliament and the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency
- Commission Regulation (EC) No 2049/2005 on 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
- Regulation (EC) No 141/2000 on orphan medicinal products
- Regulation (EC) No 1901/2006 on medicinal products for paediatric use
- Regulation (EC) No 1394/2007 on advanced therapy medicinal products
- Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Disclaimer: *The information provided in the Q&As' sections is for general informational purposes only and is not legally binding. While we strive to ensure accuracy, in case of discrepancy or conflict the applicable legislation and Fee Regulation Working Arrangements take precedence over the information in these Q&As.*

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1. Do I have to pay a fee or a charge, and if so, how can I calculate it?

All the applicable fees and charges are listed per type of procedure in the Annexes to Regulation (EU) 2024/568 (Fee Regulation):

- Annex I – Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use
- Annex II – Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- Annex III – Annual fees and remuneration
- Annex IV – Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices
- Annex V - Fee reductions and deferrals

The total amount payable depends on the scope of your request/application, procedure or annual fee, and it will be calculated in conjunction with the related fee or charge reductions.

The applicable fee level is determined in accordance with the "Applicable fee level date" as listed, by type of procedure, in the Appendix to the Fee Regulation Working arrangements. The applicable fee level date is the date which determines the applicable fee and charge amounts, and the relevant criteria for the application of fee and charge incentives. Fee reductions criteria therefore must be met by the applicable fee date for the incentive to apply.

Fees and charges become payable at the fee due date that is set out in the same Appendix of the Working arrangements.

For more detailed information, please refer to the dedicated Q&A of each procedure.

2. When is the fee or charge charged by the Agency?

The Agency charges fees and charges in accordance with the provisions of the Fee Regulation and Working arrangements, as well as the provisions of the Agency's Financial Regulation.

The Fee Regulation Working arrangements establish the fee due dates, i.e. the date when fees and charges become payable.

When a fee or a charge becomes due, and in accordance with the relevant procedure/application, the Agency issues an invoice to the applicant's billing address held on file by the Agency.

Scientific advice, Parallel distribution and Certificates services are subject to pre-payment, meaning that services are provided only after the fee and charges have been paid in its entirety.

For more detailed information on fees or charges, refer to the dedicated Q&A of each procedure.

For additional information on receiving and paying Agency's invoices, please refer to the How to pay page.

3. When do I pay the fee or charge and what are the payment modalities?

The Agency's invoices shall be paid by the payable date indicated on the invoice i.e. within 30 calendar days from the date of the invoice.

If the invoice relates to services subject to pre-payment (i.e. Scientific Advice, Parallel Distribution and Certificates), ensure that the deadline for payment is respected.

With respect to Scientific Advice services, the Agency recommends that the invoice is paid as soon as possible upon receipt, for the request to be included in the next available start of procedure date.

If the invoice relates to services not subject to pre-payment, ensure that the deadline for payment is respected to avoid enforced recovery and additional late payment charges on your account.

For more detailed information about when to pay and payment modalities, please refer to the dedicated Q&A of each procedure.

For additional information on receiving and paying Agency's invoices, please refer to the How to pay page.

4. Which fee reductions are available, if eligible?

Reductions may apply depending on the types of applications/requests/procedures and annual fees and according to the applicant's and product's status. For details on the incentives and their eligibility, refer to Annex V to the Fee Regulation and section 3 of the Working arrangements, and to the applicable legal provisions provided by the following legal acts:

- Commission Regulation (EC) No 2049/2005 on 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;
- Regulation (EC) No 141/2000 on orphan medicinal products;
- Regulation (EC) No 1901/2006 on medicinal products for paediatric use;
- Regulation (EC) No 1394/2007 on advanced therapy medicinal products;
- Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

For more detailed information about fee reductions, please refer to the dedicated Q&A of each procedure.

4.1 What is the impact of contractual arrangements between SME and non-SME entities on fee incentives? *Rev. June 2025*

The SME reductions shall not be granted to SMEs acting as applicant or marketing authorisation holder for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity, where said non-SME legal entity would benefit from the SME incentives.

Such contractual arrangements shall be declared to the Agency ahead of any service. This includes agreements for regulatory consultancy services between a non-SME legal entity and a SME regulatory

consultancy, and out-licencing agreements by which an SME grants licencing rights for a medicinal product to a non-SME.

Where the contractual arrangement is declared to the Agency only after a request for service, the Agency will proceed to recover any SME incentive unduly granted after the date of signature of the arrangement, if any.

With effect from the signature date of the arrangement, there will be no further access to SME incentives for future services and any fee due for ongoing services shall no longer be subject to a fee deferral. This will apply also in cases where the contractual arrangement envisages a future transfer of the marketing authorisation for the concerned medicinal product to a non-SME.

4.2 What is the impact of mergers and acquisitions between SME and non-SME entities on fee incentives? *Rev. June 2025*

If a registered SME merges with or is acquired by another company and the SME criteria are no longer met by the newly formed company or the group which acquired the SME, with effect from the date of the change of ownership, the company will have no further access to the SME incentives and any fee due for ongoing services shall no longer be subject to a fee deferral.

The SME Office at EMA should be informed immediately of the merger or acquisition of a registered SME with or by another company. Where EMA has not been informed immediately, the Agency will proceed to recover any SME incentive unduly granted after the date of the change of ownership, if any.

5. What is the ad hoc fee reduction that can be granted by the Executive Director? *Rev. June 2025*

For certain types of procedures, applicants may consider requesting the Executive Director to grant a total or partial ad-hoc fee reduction under the provisions of Article 6.5 of Regulation (EU) 2024/568, if they consider that there are exceptional circumstances and imperative reasons of public or animal health.

To apply for such ad-hoc fee reduction, please send your request to the Executive Director of the Agency, who will consider the request on a case-by-case basis.

The applicant should cite Article 6, paragraph 5, of Regulation (EU) 2024/568 and provide details of the product, procedure type and applicable fee, and the reason(s) for the request that justify exceptional circumstances and imperative reasons of public or animal health in a detailed and factual report. Justification of financial nature will not be considered and will be rejected.

The Agency shall make information on such reductions, including the reasons for the reductions, publicly available on its website, after deletion of all information of a commercially confidential nature.

Applicants are required to make their request at least one month before the date of submission of the relevant application for which the reduction is being requested or one month before the anniversary of the European Birth date of the Marketing Authorisation for Annual fees. Applicants are advised that late requests may not be processed in time and may not be taken into consideration when determining the fee.

Applications for ad hoc fee reductions under Article 6, paragraph 5, of Regulation (EU) 2024/568 submitted after the applicable fee level date of the relevant service or procedure will not be processed.

Each request must cover one fee reduction for one specific procedure; a request pertaining to multiple procedures will be rejected. Requests submitted after the receipt of an invoice for the procedure for which the reduction is being requested will not be considered.

For more information on how to apply, please refer to the relevant standard operating procedure.

6. Did you find the information you need on the EMA fee page or Q&As?

For specific fee related queries which are not answered in the ´fee regulation: questions and answers documents ´such as fee codes, application numbers and procedures, please submit the EMA Fees Query Form.

Important: Dynamic forms, such as the 'EMA fees query form', do not open in your browser. As a workaround, please download the file on your computer and open it using the PDF desktop app.

7. Which procedures are applicable under the fee Regulation (EU) 2024/568?

The fee Regulation applies to the Agency managed procedures (e.g. for Centrally Authorised Medicines or CAPs), including nationally authorised ones (or NAPs), when they are included in pharmacovigilance procedures, pharmacovigilance annual fee or referrals.

8. Is the remuneration to the (Co) Rapporteurs, Leading authorities and Coordinators as established under Regulation (EU) 2024/568 for the evaluation services provided, already included in the fees?

Yes, the fee already includes remuneration costs. The Agency is responsible for the remuneration to the relevant National Competent Authorities.

9. Will the annual fee / annual pharmacovigilance fee for Centrally Authorised Products (CAPs) be charged once or will this be charged for each individual country in which the product is marketed?

For the centrally authorised products (CAP) a maintenance annual fee is levied; each CAP pays one annual fee. The annual fee charged for CAPs includes the maintenance of pharmacovigilance activities.

10. Is it correct that there will be no fees for Variations requiring assessment (VRAs) with a reduced timetable (30 days)?

Yes, it is correct. Costs for VRAs with a reduced timetable are now absorbed by the annual fee. As per Recital 16 of Regulation (EU) 2024/568, the annual fee also includes the cost for minor variations of Type I and renewals and activities contributing to a continuous follow-up of the benefit-risk balance of authorised medicinal products.

To note in cases in which the timetable may be shortened to 30 days from a longer original timetable, the fee will be the one associated to the original timetable as indicated in the Classification guidance.

E.g. a VRA with standard timetable of 60 days (as assigned in the Classification Guidance), if shortened to 30 days, will carry the fee of the original timetable (i.e. the 60 days).

11. Is it correct that human type IA/B variations will be free of charge from January 2025?

Yes, it is correct. As per Recital 16 of Regulation (EU) 2024/568, the annual fee also includes the cost for minor variations of Type I and renewals and activities contributing to a continuous follow-up of the benefit-risk balance of authorised medicinal products.