



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

General Q&As – Important information to all Applicants

Question & Answers (Q&As)

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 and deferrals. 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 prepayment, 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.

5. What if I am not eligible to any of the applicable fee and charge reductions?

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.

In view of the internal administrative procedure in order to reach a decision, 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.

Each request must cover one fee reduction for one specific procedure, a request pertaining to multiple procedures will be rejected. Applicants are also informed that 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?

If not, contact us: NFR@ema.europa.eu