March 2025
EMA/90567/2025
European Medicines Agency

Regulation (EU) 2024/568: Q&A clinic for the Veterinary Industry stakeholders

Questions and Answers

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

New fee regulation: published questions and answers

- New fee regulation: General questions and answers for all applicants
- Annex II questions and answers – Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- Annex III questions and answers – Annual fees and remuneration
- Annex IV questions and answers – Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices

Disclaimer: *The information provided in this document is for general informational purposes only and should not be considered legally binding. It is based on the Q&A clinic that was hosted, where answers were provided live. While efforts were made to ensure accuracy, due to the live format, discrepancies may arise. In case of any conflict or inconsistency, the applicable legislation and Fee Regulation Working Arrangements shall take precedence over the content of this document.*

For further clarification or more detailed responses, additional Q&A resources are available for each Annex. We encourage reviewing these resources to ensure a comprehensive understanding of the topics discussed.

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1. General questions

1.1. Is the remuneration included in the fee, or does it classify as an additional cost?

The total amount payable includes the fee and remuneration. Please note that remuneration to rapporteurs is not payable by applicants, but it is paid by EMA. Hence, no additional fee is payable.

1.2. How does the new regulation affect maximum residue limit (MRL) fees being deducted from the marketing authorisation application fee?

We have noted this discrepancy and have requested clarification from the European Commission. We are currently awaiting a response, and once received, we will update the Q&A accordingly.

1.3. Is it correct that fee reductions specified in Annex V are automatically applied?

Yes, fee reductions are applied automatically based on the provisions in Annex V.

1.4. Are the fees within the new regulation subject to value-added tax VAT?

No, the agency is exempt from VAT as per provision of Article 3 of the Protocol (No 7) on the privileges and immunities of the European Union. Such VAT exemption is clearly stated within a foot note on all invoices for reference in case of tax authority inquiries.

1.5. Where can we find details of all fee amounts?

The official fee amounts are listed in the new regulation EU 2024/568. This document contains all applicable fees categorised by procedure.

1.6. Is it possible to make partial payments over time?

For services requiring prepayment (e.g., scientific advice certificates, parallel distributions), full payment must be made before the service is provided. However, for other fees, payment extensions and instalment plans can be arranged upon request, subject to fulfilment of the conditions foreseen by the Agency's financial regulation. Interest for late or delayed payments may apply.

1.7. Is there any fee reduction for veterinary biological products in the annual fee?

No, there is no fee reduction for veterinary biological products.

2. Certificates of Pharmaceutical Products (CPP)

2.1. Regarding Certificates Processing System (CPS), what is the delivery time for standard and urgent procedures of the CPP after the invoice has been paid?

The current target handling time for urgent requests is within 2 working days, starting on the following working day after the receipt of payment in full of relevant fees. Choose 'Standard' for the standard procedure: the current target handling time for standard requests is within 10 working days, starting on the following working day after the receipt of payment in full of relevant fees. Typically, allocation of received payments will happen automatically. If the automatic allocation of payment fails, for example because of unclear payment reference; and/or missing remittance advice; and/or unmatching amounts, the EMA's accounting team will contact the financial contact point requesting a confirmation of the payment reason i.e. the invoice number. In this case, manual intervention will be required, and it might take longer for EMA to confirm that the payment has been received and successfully allocated.

2.2. What confirmation notifications are included as part of the CPP process?

Confirmation emails will be delivered at each step: when the request is submitted, when the invoice is issued, when the payment is successfully allocated to the request and when the CPP is processed.

2.3. How will the certificates be delivered, and will other members of the organisation be able to download the information?

The certificates will be sent via email to the address provided in the request, and all relevant information will be included. These can then be circulated after receiving.

3. Pharmacovigilance (PhV)

3.1. When will EMA send the invoice for the annual fee for products in the Union Product Database (UPD)? Does the marketing authorisation holder (MAH) need to create a customer account?

Invoices will be generated based on data extracted from the UPD database. Missing customer data will be created to facilitate invoice processing. Companies should ensure that financial contact details are up to date by the end of June.

3.2. Can EMA invoice the pharmacovigilance annual fee to a different legal entity within the same company instead of the MAH?

Yes, EMA can invoice a different legal entity within the same company. However, the invoice will still be issued under the MAH, with an alternative billing address if requested.

3.3. Is there a reduction for micro, small and medium-sized enterprises (SME) for the annual PhV fee for veterinary products?

Yes, SMEs receive a 40% reduction, applied automatically if the SME status is valid as of 1st July. Micro entities receive a 100% reduction, resulting in a zero fee.

4. Micro, small and medium-sized enterprises (SME)

4.1. Regarding new molecules in the EU, does an SME receive a fee reduction at application?

Fee reductions apply at the SME level, not at the new molecule level. Specific reductions depend on the type of procedure (e.g., a 90% reduction for scientific advice, but no reduction for initial applications—only a deferral).

4.2. Does SME classification reduce the overall fee?

Fee reductions for SMEs come from the SME Regulation. Additional reductions outlined in Annex V, point 1 apply only to specific fees, particularly for initial marketing authorisation applications, the fee is only deferred until the opinion stage.

4.3. Regarding initial marketing applications, is any fee applicable if the applicant is classified as a micro entity?

Yes, the fee still applies. However, SMEs benefit from a payment deferral until a final decision on marketing authorisation is made. Additional reductions (e.g., 50% for immunological veterinary products and limited markets) are detailed in Annex V.

4.4. Does the classification as a micro entity reduce the application fee to zero?

For some applications, micro entities may receive a 100% fee reduction, effectively making the fee zero. However, this depends on the type of application.

4.5. Are their specific requirements for micro-size entities applying for new marketing authorisation?

The Support to SMEs page on the EMA website provides information on SME status requirements and application processes.

5. Vaccine Antigen Master File (VAMF)

5.1. Is there any reduction for multiple VAMFs?

No, but a cap exists for multiple submissions, as detailed in Annex II.

5.2. Regarding VAMF, is there a discount for centralised procedures?

No, as the certification provided by the Agency can also be used at the national level.

6. Annual Fee & administrative charges

6.1. Regarding products that are not on the market, are annual fee payments still required?

Yes, as long as the marketing authorisation is valid, the annual fee remains payable.

6.2. If the annual fee for a registered product has not been paid, will this influence sales?

The annual fee payment is managed separately from sales and marketing processes, so they are not directly connected.

6.3. When are annual fee invoices generated and sent, and when will this process first take effect?

Annual fees are calculated on 1st January each year, but invoices are issued and sent to the marketing authorisation holder on the product's European birthdate anniversary. The first issuance under this process will occur in 2025.

6.4. Is an administrative fee payable for delays in submission beyond 60 days?

Yes, administrative fees apply to initial marketing authorisation applications if submission is delayed beyond 60 days from the initial letter of intent date.

6.5. If a variation submission for a centralised procedure is delayed beyond the notified letter of intent date, does this incur additional fees?

No, late submission fees apply only to initial marketing authorisations. However, delays may impact rapporteurship appointments and procedure processing. It is advisable to notify EMA early for better planning.

6.6. Regarding adapted fees in Italy, as per EMA fees should we expect an invoice for national registration annual fee payments?

This is a national legal adaptation managed separately from EMA's processing. Companies should contact Italian authorities for further information.

6.7. In Annex V, point 6, how is a limited market classified?

The limited market classification aims to provide predictability for eligibility under Article 23. More details are available on the EMA veterinary limited market webpage.