March 2025
EMA/90568/2025
European Medicines Agency

Regulation (EU) 2024/568: Q&A clinic for the Human 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 I questions and answers – Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use
- 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.

Table of contents

1. General questions 4

1.1. What happens to the dormant products that still have United Kingdom (Northern Ireland) (UK (NI)) as the State of Origin after the removal deadline? 4

1.2. Regarding procedures that no longer require payment (e.g., a renewal), what should the sponsor include in the cover letter? 4

1.3. Regarding PSUR, the basic fee will be divided between marketing authorisation holders (MAHs) participating in the Procedure). "The remuneration for the rapporteur is half of the amount". Please confirm if the remuneration amount is "withdrawn" from the basic fee? 4

1.4. Will there be an overview table on the EMA webpage where fees and reductions per activity can be consulted? 4

1.5. Regarding submission of Repeat Use Procedure (RUP), is it necessary to pay the old CMS too? 4

1.6. When is the annual fee for medicinal products invoiced? 5

2. Payment methods and fee calculation 5

2.1. Regarding urgent procedures, are alternative payment method, such as a provision (deposit) by the organisation, considered? 5

2.2. Regarding Scientific Advice (SA) payments, does EMA consider the wire transfer notification email or only the payment's actual receipt? 5

2.3. With no separate fee for minor Type IA & IB variations moving forward, how will the annual fee be calculated per product? 5

2.4. Which procedures have changed regarding fee payment, and how much is required for initial marketing authorisation applications or reactivation of dormant products? 6

2.5. Regarding SEPA being suitable for low-value transactions, is there a plan to restrict SEPA to pre-payment procedures (SA, Certificates of Pharmaceutical Products (CPP), etc.), or does EMA have a longer-term plan for broader applications? 6

3. Certificates of Pharmaceutical Products (CPP) 6

3.1. Is the Certificates Processing System (CPS) platform already mandatory? 6

3.2. Is the start date of the CPS procedure the date of payment receipt or the date of request submission? 6

3.3. Are CPS requests trackable on a dashboard within the account page? 7

3.4. If a CPP is issued incorrectly by EMA, how will the replacement certificate be managed for both standard and urgent CPPs? Will a new invoice be issued before a replacement certificate is issued? 7

3.5. Is it possible to withdraw the CPP request prior to payment of the fee? 7

3.6. Regarding CPS, what is the delivery time for standard and urgent procedures of the CPP after the invoice has been paid? 7

4. Scientific Advice (SA) 7

4.1. Will the process for SA fees that are calculated during validation, requiring payment within 5 days, be revised to allow more time? 7
4.2. Regarding SA procedures planned in March, when will EMA issue the invoice, and what is the payment deadline? 8
4.3. Regarding SA requests on paediatric-only products, will sponsors receive a fee waiver document at validation?....8
4.4. Regarding SA validation, can the request for fee payment and validation confirmation be provided in a single message? 8
4.5. Will the reduction of invoice issuance timelines for SA also be reflected in SA package validation timelines? Will this be reflected in SA timetables? 8
4.6. Regarding the waived fees on SA products developed solely for the paediatric population, will the sponsor receive a fee waiver document at validation time instead of an invoice? 8
5. Extensions and Variations 8
5.1. Regarding Annex I Section 4 of Regulation 2024/568, which states that the fee covers a single pharmaceutical form and strength, are additional strengths/presentations included in the same extension application subject to additional fees?....8
5.2. Regarding extension fees, does the "replicated" fee structure mean that for multiple strengths the fee would be charged multiple times? 9
6. Pharmacovigilance (PhV) 9
6.1. How can a MAHs calculate PhV fees for planning purposes? 9
6.2. What fee reductions are available for micro, small and medium-sized enterprises (SMEs) developing non-orphan products? 9
6.3. Regarding the PhV Fee for Periodic Safety Update Report (PSUR), has it remained unchanged since 2023 in accordance with Article 57 database? Will the fee remain the same before the 2025 fee changes? 9
6.4. What happens if the PSUR fee paid is from last year's fee? Will this cause a delay in the review of the PSUR? Will EMA request the correct fee (additional amount)? 9
7. Marketing Authorisation Applications (MAA) and Clinical Trial Applications (CTA) 10
7.1. If an applicant changes the intended submission date by more than 60 days, does the additional charge of EUR 4,200 apply only to initial marketing authorisation applications? 10
7.2. Regarding the reviewing of CTA for medicines, are there both fees and SME reductions? 10
7.3. Regarding an initial marketing authorisation application (iMAA) submitted in 2024 for a procedure start date in January 2025, which fee framework applies? 10

1. General questions

1.1. What happens to the dormant products that still have United Kingdom (Northern Ireland) (UK (NI)) as the State of Origin after the removal deadline?

For centrally authorised products, there is no longer a requirement to have a fee for UK (NI) as the State of Origin. If a procedure is a pharmacovigilance procedure and a chargeable unit related to UK (NI) was included in the calculation, it has now been removed. However, for nationally authorised products, the UK (NI) chargeable unit remains applicable. If the removal occurred before the fee due date, no fee will be charged. If it happened after the due date, the fee would still apply.

In the context of parallel distribution, dormant notices with UK(NI) as country of origin/destination, applicants are required to activate them by submitting an Update of parallel distribution notice status notification in order to be able to report removal of UK(NI) in the annual update submission. Both activation process and placing a notice in dormancy are free of charge. As communicated to all parallel distributors, Agency will enforce the compliance by removing UK(NI) after the deadline.

1.2. Regarding procedures that no longer require payment (e.g., a renewal), what should the sponsor include in the cover letter?

Sponsors should indicate either "Not Applicable" or "No Fee Payment" in the cover letter. Both formats are acceptable.

1.3. Regarding PSUR, the basic fee will be divided between marketing authorisation holders (MAHs) participating in the Procedure). "The remuneration for the rapporteur is half of the amount". Please confirm if the remuneration amount is "withdrawn" from the basic fee?

Yes, the basic fee would include the remuneration share. Please note that remuneration to rapporteurs is not payable by applicants, but it is paid by EMA. Hence, no additional fee is payable.

1.4. Will there be an overview table on the EMA webpage where fees and reductions per activity can be consulted?

No, an overview table will not be available. All the amounts are listed in the relevant Annexes of the Fee Regulation text. Detailed information on fees calculation and applicable reductions can be found in the legal framework and the question-and-answer documents linked on the first page. Additionally, information events per activity are available for further reference.

1.5. Regarding submission of Repeat Use Procedure (RUP), is it necessary to pay the old CMS too?

This is outside the scope of the regulation on fees applicable to EMA, as it is a nationally authorised procedure. It is a repeat use procedure within the framework of recognition concerning member states. This is handled at the national level, and the submitter will need to check with the relevant national competent authority where they plan to submit it.

1.6. When is the annual fee for medicinal products invoiced?

The annual fee for centrally authorised products is invoiced on the anniversary of the European birth date of the product. The process has not been changed from the production of the invoice point of view. What has changed is the calculation of the fee. Previously, it was calculated at the time of the European birth date together with the relevant reduction and fee applicable date calculation. Now, the fee applicable date has been moved to 1 January. The fee for each medicinal product is computed on 1 January, but the invoice is not sent until the European birth date, when it is triggered and issued.

2. Payment methods and fee calculation

2.1. Regarding urgent procedures, are alternative payment method, such as a provision (deposit) by the organisation, considered?

A deposit system, where a lump sum is paid in advance and EMA withdraws amounts as needed, is under consideration. However, existing legislation does not currently support this payment method. Implementation would require consultation with the European Commission. Additionally, EMA is evaluating the introduction of a Single Euro Payments Area (SEPA) direct debit system, expected to roll out no earlier than Q2 2025.

2.2. Regarding Scientific Advice (SA) payments, does EMA consider the wire transfer notification email or only the payment's actual receipt?

For SA payments (and all payments in general) the date on which the full amount of the payment is received in the bank account held by the Agency shall constitute the date on which the payment has been made (Article 7.4 Regulation (EU) 2024/568). The remittance advice sent to EMA AR team helps us to identify the payment and allocate it to the correct procedure in case of missing or incorrect reference quoted in the bank transfer. For further information on receiving and paying Agency’s invoices please refer to EMA guidance on how to pay fees and charges levied by EMA.

2.3. With no separate fee for minor Type IA & IB variations moving forward, how will the annual fee be calculated per product?

The annual fee is a fixed fee as per the new fee regulation. There will be no calculation based on submission volumes. All minor variations (Type IA & IB) are

included in the relevant annual fee, which is determined by the legal basis of the product.

2.4. Which procedures have changed regarding fee payment, and how much is required for initial marketing authorisation applications or reactivation of dormant products?

The fees for initial marketing authorisation applications have significantly increased to reflect the true cost of assessment. The specific amount depends on the legal basis of the application. Previously, fees were calculated based on the number of strengths, pharmaceutical forms, and presentations, but this has now been replaced with a flat fee structure. If an authorisation is surrendered, the annual fee will no longer be charged from the date of surrender but calculated pro-rata daily since the last annual fee due date (European Birth date).

As well, the fees for initial notifications for parallel distribution are outlined in the regulation and the Q&A documents found on the EMA website.

You are kindly advised to refer to the legal framework and the question-and-answer documents linked on the first page. Regarding dormancy and the activation of dormant notices, applicants are required to activate them by submitting an updated distribution notification. Both the activation process and placing a notice in dormancy are free of charge.

2.5. Regarding SEPA being suitable for low-value transactions, is there a plan to restrict SEPA to pre-payment procedures (SA, Certificates of Pharmaceutical Products (CPP), etc.), or does EMA have a longer-term plan for broader applications?

Initially, SEPA will be intended to facilitate prepayments, but it may later be expanded to other procedures, such as pharmacovigilance annual fees, depending on transaction limits set by the EMA payment service providers (banks).

3. Certificates of Pharmaceutical Products (CPP)

3.1. Is the Certificates Processing System (CPS) platform already mandatory?

Yes, the platform is mandatory.

3.2. Is the start date of the CPS procedure the date of payment receipt or the date of request submission?

Processing of certificates begins the next working day after full payment is received. The official request date is when payment is confirmed, and a formal request number is assigned.

3.3. Are CPS requests trackable on a dashboard within the account page?

Currently, there is no dashboard available for tracking CPS requests. Status updates are provided via email notifications at various stages, including request submission, processing, and invoice creation.

3.4. If a CPP is issued incorrectly by EMA, how will the replacement certificate be managed for both standard and urgent CPPs? Will a new invoice be issued before a replacement certificate is issued?

If a Certificate is issued incorrectly by EMA, the applicant should contact the Certificate inboxes since it needs to be investigated (certificate_urgent@ema.europa.eu or certificate@ema.europa.eu). If a correction is made after investigation due to an error made by EMA, then a new invoice is not applicable.

3.5. Is it possible to withdraw the CPP request prior to payment of the fee?

Although for CPP the concept of withdrawal prior to payment is not available, it is possible for the requestor to decide not to proceed with the CPP request. To do so, the requestor should simply not pay the invoice and let said invoice expire. After 30 days, the invoice will be cancelled, and the applicant/requester will receive a notification of the cancellation along with the cancellation document.

However, as indicated in the Annex IV Q&A document, if your request is withdrawn after the Agency has received the payment of the applicable charge, the amount paid will not be returned to the applicant.

3.6. Regarding CPS, what is the delivery time for standard and urgent procedures of the CPP after the invoice has been paid?

The target handling time is as follows: urgent procedures require 2 working days, while standard procedures take 10 working days. Please note that the timeline begins from the receipt of payment, not from the date of application submission.

4. Scientific Advice (SA)

4.1. Will the process for SA fees that are calculated during validation, requiring payment within 5 days, be revised to allow more time?

EMA has already revised the process and where possible shortened the validation timeline to issue invoices earlier, providing a longer payment window.

4.2. Regarding SA procedures planned in March, when will EMA issue the invoice, and what is the payment deadline?

Invoices are expected to be issued between the last week of February and March 3 at the latest. Payments must be received by March 10 for the request to be included in the March procedure; otherwise, it will be moved to the April round.

4.3. Regarding SA requests on paediatric-only products, will sponsors receive a fee waiver document at validation?

EMA issues an invoice with a zero value as a reference document, which is sent to the standard financial email address in the database.

4.4. Regarding SA validation, can the request for fee payment and validation confirmation be provided in a single message?

Currently, the process is designed so that validation confirmation and the invoice are issued simultaneously but sent separately. Validation notifications are sent through the IRIS system, while invoices are issued via EMA's SAP financial system to the email address(es) of the company designated financial contact(s) point(s) held on the Agency's file. For further information on receiving and paying Agency's invoices please refer to EMA guidance on how to pay fees and charges levied by EMA.

4.5. Will the reduction of invoice issuance timelines for SA also be reflected in SA package validation timelines? Will this be reflected in SA timetables?

No, SA timetables will not change, as they already state "at the latest." However, requests that are simpler may be validated sooner, while more complex requests may take longer, hence the range.

4.6. Regarding the waived fees on SA products developed solely for the paediatric population, will the sponsor receive a fee waiver document at validation time instead of an invoice?

EMA issues an invoice with a zero amount for reference. This zero-value invoice is sent to the email address(es) of the company designated financial contact(s) point(s) held on the Agency's file. Any applications receiving a 100% fee waiver or incentive will always receive a zero-value invoice for documentation purposes.

5. Extensions and Variations

5.1. Regarding Annex I Section 4 of Regulation 2024/568, which states that the fee covers a single pharmaceutical form and strength, are additional strengths/presentations included in the same extension application subject to additional fees?

Yes, with additional strengths or pharmaceutical forms the field will be replicated and will incur additional fees. However, additional presentations do not multiply the fee.

5.2. Regarding extension fees, does the "replicated" fee structure mean that for multiple strengths the fee would be charged multiple times?

Correct. The extension application fee is applied per strength.

6. Pharmacovigilance (PhV)

6.1. How can a MAHs calculate PhV fees for planning purposes?

The calculation method is detailed in the published Q&A documents and annexes (EMA´s fee website). Specifically, Section 14 of Annex 1 outlines how chargeable units are determined. Various factors, including, but not limited to, product name, marketing authorisation holder, Member State, and pharmaceutical form and applicable reductions, contribute to the final fee calculation. Since PhV fees depend on the number of chargeable units involved, the exact amount is known only when the invoice is generated.

6.2. What fee reductions are available for micro, small and medium-sized enterprises (SMEs) developing non-orphan products?

SMEs benefit from fee deferrals for initial marketing authorisations. The SME incentives from the existing SME regulation remain valid, and additional fee reductions introduced under the new regulation are applied in addition to other procedures. This is varying according to the type of procedure and explained in detail in the published Q&A documents and annexes (EMA´s fee website)

6.3. Regarding the PhV Fee for Periodic Safety Update Report (PSUR), has it remained unchanged since 2023 in accordance with Article 57 database? Will the fee remain the same before the 2025 fee changes?

The pharmacovigilance fee, previously regulated under the pharmacovigilance fee regulation, remains valid until 31 December 2024. All procedures starting from 1 January 2025 will follow the new fee regulation but still subject to inflationary decrease or increase.

6.4. What happens if the PSUR fee paid is from last year's fee? Will this cause a delay in the review of the PSUR? Will EMA request the correct fee (additional amount)?

If a fee was charged under last year's regulations, the PSUR procedure will follow the transition measures of the old PhV fee regulation. This will not cause delays in the timetable or require a correction of the fee. According to Article 17 of the new fee regulation, the applicable fee is determined based on when the procedure starts. If the procedure falls under the previous regulation, that fee applies, even if the assessment is conducted in 2025. Likewise, from 1 January 2025 onwards, the new fees apply, and no retroactive corrections between the two regulations will be made.

7. Marketing Authorisation Applications (MAA) and Clinical Trial Applications (CTA)

7.1. If an applicant changes the intended submission date by more than 60 days, does the additional charge of EUR 4,200 apply only to initial marketing authorisation applications?

Yes, this additional charge applies only to initial marketing authorisation applications.

7.2. Regarding the reviewing of CTA for medicines, are there both fees and SME reductions?

Currently, there are no Clinical Trial Application fees. If the review is part of a Scientific Advice Request, the corresponding advisory request fee applies, with SME reductions available as specified in the scientific advice framework.

7.3. Regarding an initial marketing authorisation application (iMAA) submitted in 2024 for a procedure start date in January 2025, which fee framework applies?

This situation falls under transition measures. Please refer to Q&A section 2.6 of Annex I for detailed guidance on applicable fees.