10 December 2024
EMA/575969/2024
European Medicines Agency

Annex IV to Regulation 2024/568

Question and 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. Inspections

1.1. Do I have to pay a fee and if so, how do I calculate it?

Yes, EMA charges a fee for inspections, which varies depending on the type of inspection Good Manufacturing Practice inspections (GMP), Good Clinical Practice inspections (GCP), Good Laboratory Practice inspections (GLP), Plasma Master File inspections (PMF) and pharmacovigilance inspections (GVP) and site of the inspection whether it is within or outside the Union.

The amount payable will be determined by the date of receipt of the inspection report by the supervisory authorities as outlined in the Appendix to the Fee Regulation Working arrangements. For the applicable amount for each distinct or consecutive inspection, please refer to Annex IV, Section 1, to the Fee Regulation and chapter 1.4 of the Fee Regulation Working arrangements.

The criteria defining a distinct inspection per type are outlined in chapter 1.4 of the Working Arrangements.

Example scenarios fee calculations

The example scenarios shown below do not represent an exhaustive list.

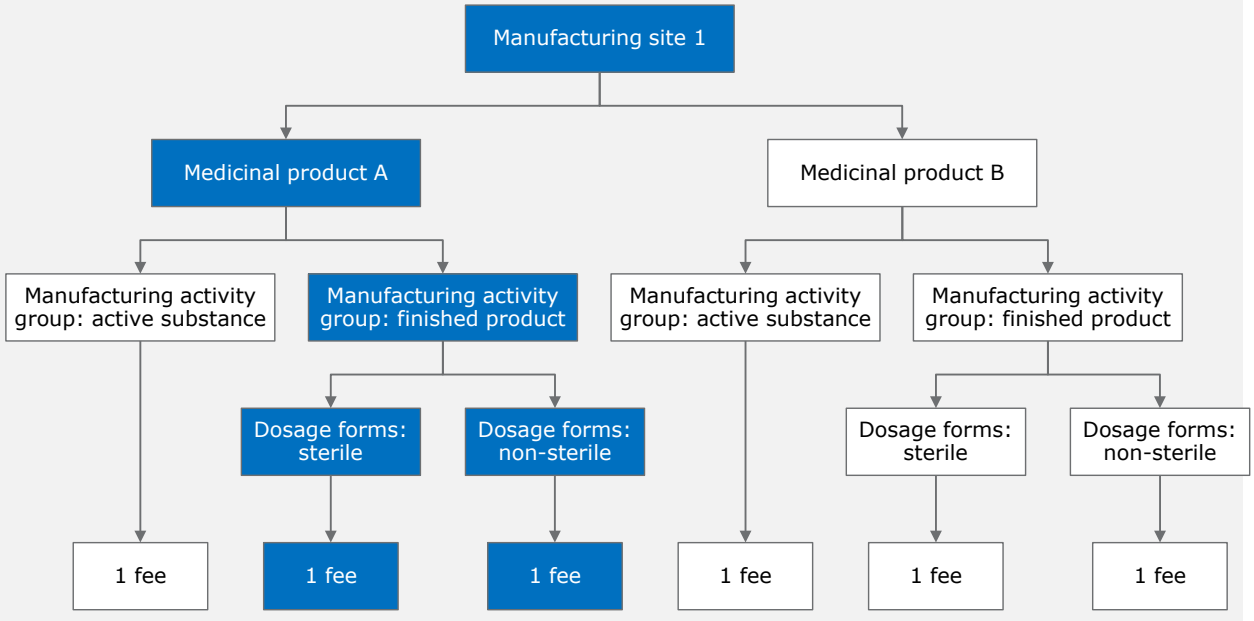
Scenario 1 Good Manufacturing Practice inspections (GMP):

GMP inspection of manufacturing site 1 for one medicinal product A and involving two pharmaceutical forms: capsules (non-sterile) and solution for injection (sterile). The manufacturing activity for the two pharmaceutical forms is the same, i.e. manufacture of the finished product.

Fee payable: 2 x distinct inspection fee

Rationale: there are two types of dosages forms (sterile and non-sterile) and each one attracts a fee.

The applicable fees to be paid are represented by the blue boxes in the flowchart below**.**



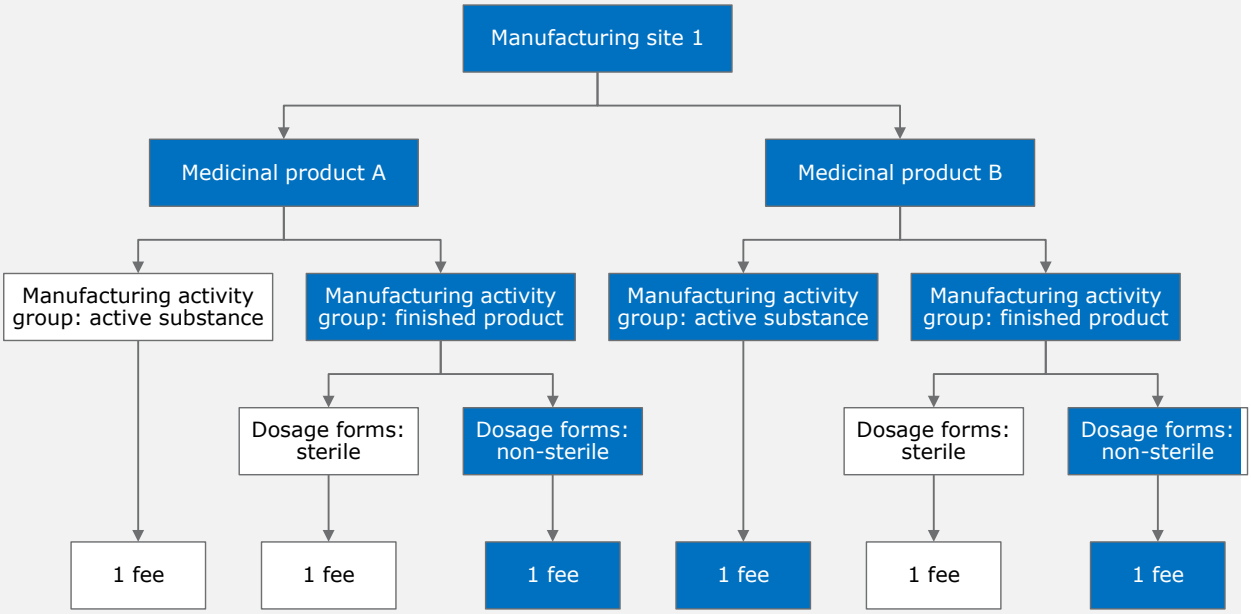
Scenario 2 Good Manufacturing Practice inspections (GMP):

GMP inspection of manufacturing site 1 for two medicinal products (A and B). Product A involves only one pharmaceutical form (capsules) and one pharmaceutical activity (primary packaging). Product B also involves one pharmaceutical form (tablets) and four manufacturing activities (manufacture of the active substance, quality control of the active substance, manufacture of the finished product and primary packaging).

Fee payable: 3 x distinct inspection fee

Rationale: Product A attracts only one fee because there is only one group of manufacturing activities (i.e. finished product) and one dosage form (non-sterile). Product B attracts two fees because there are manufacturing activities related to each group as follows:

- Group Active Substance: manufacture of the active substance and quality control of the active substance
- Group Finished Product: manufacture of the finished product and Primary Packaging

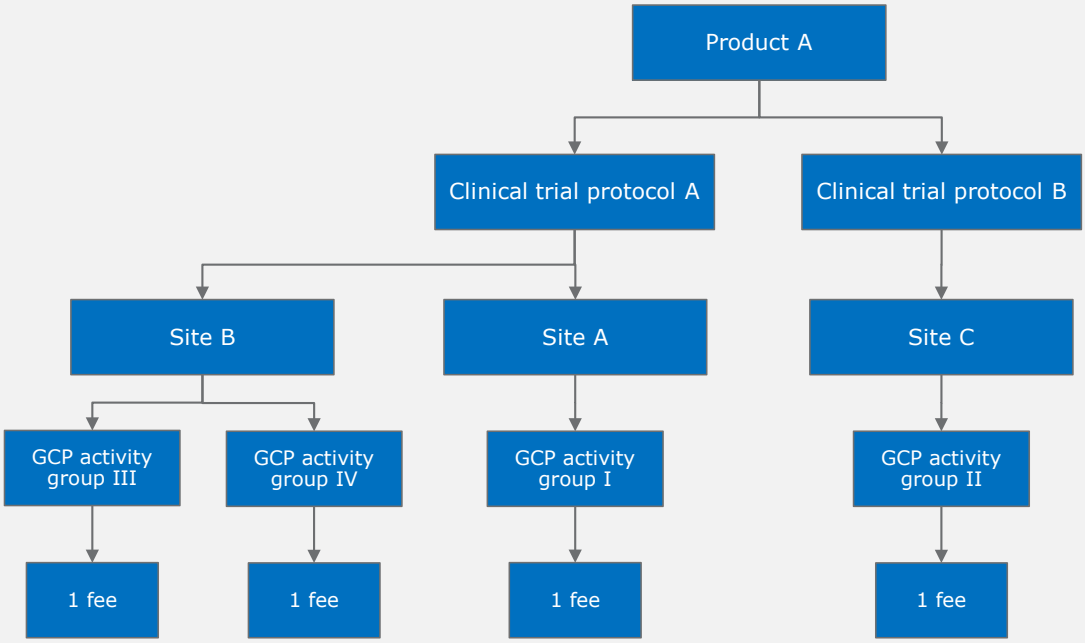


Scenario 3 Good Clinical Practice inspections (GCP):

GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol A at Site A (investigator site) for one clinical trial activity (Activity Group I) and at site B (sponsor site) for two clinical trial activities (Activity Group III and Activity Group IV). GCP inspection of clinical trial protocol B conducted at site C (Central laboratory) for one activity group (Activity group II);

Fee payable: 4 x distinct inspection fee

Rationale: there is one product A supported by two pivotal trials the conduct of which is inspected for clinical trial protocol A at Site A for one activity group (Activity Group I) and at site B for two activity Groups (Activity group III and Activity Group IV). The clinical trial protocol B is inspected at site C for one activity group (Activity Group II) and each activity group attracts a fee (Level I).

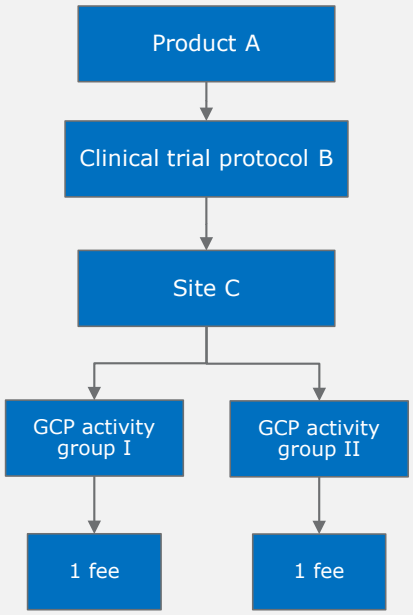


Scenario 4 Good Clinical Practice inspections (GCP):

GCP inspection request for Product A marketing authorisation application and the conduct of clinical trial protocol B at Site C (i.e. CRO site including clinical and bioanalytical facility) for two clinical trial activities (Activity Group I) and (Activity Group II).

Fee payable: 2 x distinct inspection fee

Rationale: there is one product A supported by one pivotal trial the conduct of which is inspected for clinical trial protocol B at Site C for two activity groups (Activity Group I and Activity Group II) and each activity group attracts a fee (Level I).



1.2. Which reductions are applicable?

There could be one or several fee reductions applicable linked to an inspection. Please note that the most favourable reduction to the applicant will be applied, as reductions are not cumulative. Moreover, please note that reductions only apply to the applicable fees; reductions do not apply to the cancellation charges referred to in point 1.3 of Annex IV to Regulation 2024/568.

Micro, small and medium sized enterprises (SMEs)

A 90% fee reduction and deferral is applicable to pre-authorisation inspections of marketing authorisation applications for non-orphan medicinal products submitted by micro, small or medium-sized enterprises.

A 90% fee reduction is applicable to post-authorisation inspections for non-orphan medicinal products.

A fee deferral for a SME applicant means that the time of payment of the inspection fee is deferred until the notification of the final decision (positive or negative outcome) on the MA is issued, or the application is withdrawn. The invoice issued at the time the fee is calculated will inform the applicant that the fee is deferred.

Applicants must be established in the EEA and fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. To benefit from

incentives, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at time of receipt of the inspection report by EMA.

The fee reductions shall not be granted to SMEs acting as applicant for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity. A subsequent change to the SME status (i.e. expiration of the SME status) taking place after the applicable fee level date (i.e. date of receipt of the inspection report) will not be taken into account for the application of the SME fee incentives. However, in case of a merger or acquisition impacting the applicant's SME status, or a product is subject to out-licensing to a non-SME legal entity, after the applicable fee level date, then the deferral will cease to apply from the date on which the merger/acquisition or out-licensing took place, and the applicable fees will no longer be subject to fee deferral and shall be payable.

For pre- and post-authorisation inspections, if there is a merger or acquisition impacting the applicant's SME status, or if a product is subject to out-licensing to a non-SME legal entity, before the applicable fee level date, then the SME fee reduction will not apply.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

Designated orphan medicinal products

A 100% fee reduction is applicable for pre-authorisation inspections related to designated orphan medicinal products.

To be eligible for orphan fee incentives, a decision of the European Commission granting the orphan designation must have been adopted (product entered in the Community Register of orphan medicinal products) at the time of submission of the scientific advice request. A positive COMP opinion on orphan designation is not sufficient for eligibility to the orphan fee reduction.

Please note that during a transfer of an orphan designation, eligibility for fee incentives lies with the initial sponsor (orphan designation holder) until the transfer is complete. Once the transfer is completed, the new sponsor is eligible to fee incentives. The new sponsor must be a different person/legal entity.

For more information on how to receive an orphan designation for a medicinal product, please refer to the Orphan Designation Overview page.

Medicinal products for paediatric use

A 50% fee reduction is applicable for pre-authorisation inspections related to a paediatric use marketing authorisation application (PUMA) and to post-authorisation inspections in the first year from granting such marketing authorisation, if the advice requested does not include the adult population.

Pharmacovigilance inspections related to veterinary medicinal products

A 30% fee reduction is applicable for each distinct post-authorisation pharmacovigilance inspection related to veterinary medicinal products.

1.3. Can an inspection be cancelled fully or partially and in what conditions?

Yes; however, depending on when you decide to cancel the inspection, a different amount is charged as laid down in section 1.2 or 1.3 of Annex IV to the Fee Regulation.

If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the full inspection fee will be applicable.

If a scheduled inspection is cancelled more than 30 calendar days before the first day of the inspection for reasons attributable to the applicant, a cancellation charge is applicable.

The Agency and inspecting authorities are not liable for any financial loss or damage the applicant may incur due to a failure to conduct a scheduled inspection or the need to reschedule it.

An inspection is considered to be scheduled once the specific dates for the actual inspection have been decided by the inspecting NCAs and provided to the EMA Inspection office.

The cancellation date (as referred to in the Appendix to the Fee Regulation Working Arrangements) will be determined as follows:

- the date of receipt by EMA of a formal letter from the MAH/applicant/PMF Holder requesting the cancellation of an inspection for one or more products, including a valid justification (e.g. a site will be removed from the dossier/ongoing evaluation of a procedure); please note that a request simply made in an e-mail is not considered sufficient to cancel an inspection.
- The date of submission of withdrawal of an initial marketing authorisation application or withdrawal of a variation.
- The date of submission of a variation.

Upon cancellation of the inspection, EMA will issue the corresponding cancellation fee or charge as applicable. In case of doubts as to the applicability of an administrative charge or fee, please contact the Agency before submitting your cancellation request.

If following the cancellation of the inspection the applicant/MAH/PMF Holder does not remove the site from the dossier as communicated to EMA and, consequently, an inspection is needed, a new inspection will be requested by EMA and the full applicable fees will be charged. As a result, in such cases, both the cancellation fee of the initial inspection and a full fee for the following inspection will be charged.

Cancellation fees are charged when a product or a site is fully removed from the scope of an inspection, following the Annex IV of the Working Arrangements. In case of the partial deletion of the manufacturing operations of a product in scope, no cancellation fees will be charged. In these cases, EMA will readjust the number of fees applicable to that product based on the manufacturing operations left in scope.

1.4. What about travel and accommodation expenses?

The supervisory authorities will charge the applicant the travel and accommodation expenses separately from the fees levied by EMA; travel and accommodation charges and their payment are dealt with between the supervisory authorities and the applicants.

In case of a cancelled inspection, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.

1.5. Which fee will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the inspection report is received by EMA before 01/01/25 (in 2024), the applicable fee will be under Council Regulation (EC) No 297/95.

If the inspection report is received by EMA on or after 01/01/2025, the fees according to Regulation (EU) 2024/568 apply.

Concerning partial or full cancellations, the applicable fees are calculated considering the date of receipt by EMA of the formal letter from the MAH/Applicant/PMF Holder to request to cancel an inspection. If the receipt of the formal request for cancelation is before 01/01/25 (i.e. in 2024), the applicable cancellation fee will fall under Council Regulation (EC) No 297/95

If the receipt of the formal request for cancelation is on or after 01/01/2025, the cancellation fees will be calculated according to Regulation (EU) 2024/568.

2. Transfer of a marketing authorisation

2.1. Do I have to pay a fee and if so, how do I calculate it?

Yes, there is a charge applicable for a transfer of a marketing authorisation.

For the applicable amount, please refer to Annex IV, Section 2, to the Fee Regulation.

2.2. Which reductions are applicable?

There could be one or several charge reductions applicable linked to a transfer of marketing authorisation. Please note that the most favourable reduction to the applicant will be applied, as reductions are not cumulative.

Micro, small and medium sized enterprises (SMEs)

A 40% charge reduction is applicable to a marketing authorisation transfer from a small or medium-sized enterprise to another SME.

A 100% charge reduction is applicable to a marketing authorisation transfer from a micro sized enterprise to another SME.

To benefit from incentives, the transferor and the transferee must be established in the EEA and fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. In addition, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the transfer request.

The reductions shall not be granted to SMEs acting as applicant for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

Designated orphan medicinal products

A 100% charge reduction is applicable for designated orphan medicinal products when the applicant is a micro, small or medium-sized enterprise at the time of submission. This is applicable up to the first anniversary date of the Commission decision granting the marketing authorisation.

To be eligible for orphan incentives, a decision of the European Commission granting the orphan designation must have been adopted (product entered in the Community Register of orphan medicinal products) at time of submission. A positive COMP opinion on orphan designation is not sufficient for eligibility to the orphan charge reduction.

Please note that during a transfer of the orphan designation from the currently approved sponsor (orphan designation holder) to a new sponsor which is a different person/legal entity, eligibility lies

with the initial sponsor until the transfer is completed. Once completed, the new sponsor is eligible to incentives.

For more information on how to receive an orphan designation for a medicinal product, please refer to the Orphan Designation Overview page.

Bioterrorism health threat related medicinal products

A 50% charge reduction is applicable for a transfer of a marketing authorisation in relation to authorised medicinal products for human use that are used for stockpiling in preparation of a bioterrorism health threat.

For further details on applying for such reduction, please refer to Chapter 3.2 of the Fee Regulation working arrangements.

For more information, refer to the Biological and chemical threats page.

2.3. Can I withdraw my request/application for a transfer of a marketing authorisation?

Yes; however, in case of withdrawal of request for transfer of marketing authorisation, the applicable charge will be payable in full.

2.4. *Which charge will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?*

If the submission is before 01/01/2025, the applicable charge will be under Council Regulation (EC) No 297/95.

If the submission is on or after 01/01/2025, the charge laid down in Regulation (EU) 2024/568 applies.

3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure

3.1. Do I have to pay a fee and if so, how do I calculate it?

Yes, EMA charges a fee for pre-submission requests and a fee for notifications of change of the intended submission date which may apply cumulatively. For the applicable amount of each fee, please refer to Annex IV, Section 3, to the Fee Regulation.

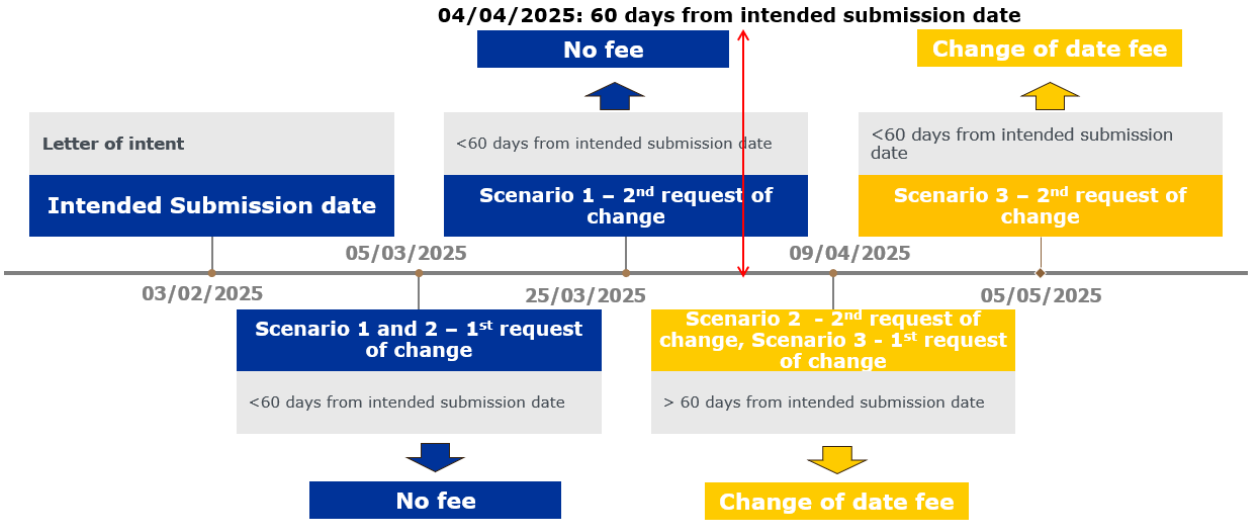
The applicable fee outlined below will be calculated after the submission of your request, in conjunction with the related fee reductions:

- A fee shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation under the scope of the centralised procedure. The fee covers any costs related to pre-submission activities up to the submission of the marketing authorisation application.
- An additional fee(s) shall apply for any changes of the intended submission date, if the change is more than 60 days from the initially notified intended submission date.

If the initially notified submission date is changed several times beyond 60 days from the initially notified date, the fee for change will be charged as many times as the date is changed.

A list of example scenarios on fee(s) applicable for changing the intended submission date is given below:

Scenario 1: no fee for changes of the intended submission date, cumulative changes less than 60 days in total	Scenario 2: fee for changes of the intended submission date, cumulative changes with second change more than 60 days	Scenario 3: fee(s) for changes of the intended submission date, cumulative changes more than 60 days
Intended submission date is 03.02.2025 as declared in the letter of intent	Intended submission date is 03.02.2025 as declared in the letter of intent	Intended submission date is 03.02.2025 as declared in the letter of intent
Delay of 30 days to 05.03.2025 is requested: no fee applicable	Delay of 30 days to 05.03.2025 is requested: no fee applicable	Delay of more than 60 days to 09.04.2025 is requested: 1 fee for change is applicable
Further delay of 20 days to 25.03.2025 is requested: no fee applicable	Further delay of 35 days to 09.04.2025: 1 fee for change, as there are more than 60 days between the initially notified intended submission date (05.03.2025) and the final submission date (i.e. 09.04.2025).	Further delay of 32 days to 05.05.2025 is requested: 1 additional fee for change is applicable (in total 2 fees)



3.2. Which reductions are applicable?

There could be one or several fee reductions applicable linked to a pre-submission request. Please note that the most favourable reduction to the applicant will be applied, as reductions are not cumulative.

Pandemic core dossier vaccines

A 100% fee reduction is applicable if the request is related to a pre-submission for a marketing authorisation of a pandemic core dossier vaccine until the human pandemic situation is duly recognised, either by the World Health Organization or by the Commission. Please refer to Annex V, Section 3.2 (a), to the Fee Regulation.

Immunological veterinary products

A 50% fee reduction is applicable to requests related to immunological veterinary medicinal products.

Veterinary medicinal products for limited markets

A 50% fee reduction is applicable to requests related to veterinary medicinal products holding a Limited Market classification confirming eligibility under Article 23 of Regulation (EU) 2019/6.

3.3. Can I withdraw my pre-submission request?

Yes; however, in case of withdrawal of your request, the applicable fee will be payable in full and irrespective of whether a marketing authorisation application for a concerned product is subsequently submitted.

3.4. Which fee will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

For pre-submission requests or notification of change of intended submission date received in 2024, there are no fees to be applied according to Council Regulation (EC) No 297/95.

If the receipt date of your pre-submission request or notification of change of intended submission date is on or after 01/01/2025, the relevant fee laid down in Regulation (EU) 2024/568 applies.

4. Re-examination of an opinion of the Committees

4.1. Do I have to pay a fee and if so, how do I calculate it

Yes, EMA charges a fee for a re-examination of an opinion, upon receipt of submission of grounds for re-examination.

The fee for re-examination of an opinion of any of the committees shall be 30 % of the fee applicable to the initial opinion in accordance with Sections 2, 4, 5 and 6 of Annex I and Sections 3, 4, 6 and 7 of Annex II to the Fee Regulation.

4.2. Can I withdraw my request/application?

Yes; however, in case of withdrawal of request after the submission of grounds for re-examination, the applicable fee will be payable in full.

5. Additional Scientific services referred to in Article 4(1) of Regulation (EU) 2024/568

(fees not yet applicable as these scientific services are not yet established)

6. Administrative services

6.1. Administrative charges

6.1.1. When do I have to pay an administrative charge?

The administrative charge for:

- an application that withdrawn after 24 hours of its submission and prior to completion of the administrative validation;
- an application that has been rejected following the conclusion of the administrative validation;

is further clarified in the relevant Q&A sections of Annex I and II, where applicable.

The same administrative charge will also apply when a marketing authorisation holder or an applicant is claiming, or has claimed, to be entitled to a fee reduction but fails to demonstrate that it is entitled to such a reduction. The full administrative charge will be applied also to SMEs, where applicable. Please ensure that your claim to the entitlement of a fee reduction can be demonstrated at the time of the applicable fee level as per Appendix of the Fee Regulation Working arrangements, for Annex I, II and III.

For the applicable amount for the charge, please refer to Annex IV, Section 6.1, to the Fee Regulation.

6.2. Certificates of medicinal products

6.2.1. Do I have to pay a fee and if so, how do I calculate it?

Yes, EMA applies a charge for certificates of medicinal products as referred to in Article 127 of Directive 2001/83/EC and in Article 98 of Regulation (EU) 2019/6.

There are two levels of charges for certificates:

- For each certificate request using the standard procedure;
- For each certificate request using the urgent procedure.

The charge will be determined at the point of submission of your request for the certificate, in conjunction with the applicable calculation of related charge reduction. For the applicable amount for each charge level and the scopes applicable for each request, please refer to Annex IV, Section 6.2,to the Fee Regulation and Chapter 1.5 of the Fee Regulation Working arrangements.

6.2.2. Which reductions are applicable?

Micro, small and medium sized enterprises (SMEs)

A 100% charge reduction is applicable for micro, small or medium-sized enterprises.

Applicants must be established in the EEA and fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. To benefit from

incentives, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the application.

The reductions shall not be granted to SMEs acting as applicant for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

6.2.3. How do I pay for my request for a certificate?

In accordance with Article 71 of the Agency's Financial Regulation and Article 7(3) of the Fee Regulation and its working arrangements, certificates for medicinal products will be provided only after the applicable charge has been paid in its entirety.

Upon sending of a request for certificate(s), the requestor will receive an email acknowledging their intention to submit a request for certificate(s), followed by an invoice issued to the marketing authorisation's billing address held on the Agency's file.

We recommend that you pay the invoice as soon as possible upon receipt and at the latest by the payable date indicated on the invoice (deadline for payment).

Should the payment not be received by the deadline specified in the invoice, your request will be cancelled, and the service will not be delivered.

6.2.4. Can I withdraw my request for a certificate?

Yes; however, 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.

6.2.5. Which fee/charge will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the submission is before 01/01/2025, the applicable fee will be under Council Regulation (EC) No 297/95.

If the submission is on or after 01/01/2025, the charge laid down in Regulation (EU) 2024/568 applies.

6.3. Notification of parallel distribution in accordance with Article 57(1), point (o), of Regulation (EC) No 726/2004

6.3.1. Do I have to pay a charge and if so, how do I calculate it?

Yes, EMA applies charges for notifications of parallel distribution. There are three levels of charges for parallel distribution. The applicable amount will be calculated at the point of submission of your notification for parallel distribution. For the applicable amount of the charge, please refer to Annex IV, Section 6.3, to the New Fee Regulation and Chapter 1.6 of the Fee Regulation Working arrangements.

6.3.2. How do I pay for a notification of parallel distribution?

In accordance with Article 71 of the Agency's Financial Regulation and Article 7 of the Fee Regulation and its working arrangements, parallel distribution services will be provided only after the invoice is paid in its entirety.

Following the completion of the submission process in IRIS, the parallel distributor will receive an automated notification acknowledging their intention to submit a notification for parallel distribution, followed by an invoice issued to the applicant's billing address held on the Agency's file.

We recommend that you pay the invoice as soon as possible upon receipt and at the latest by the payable date indicated on the invoice (deadline for payment).

The charge for parallel distribution notification is calculated at submission, based on the type and scope of said notification.

Upon receipt of payment by the Agency, the parallel distributor will receive a notification acknowledging that the invoice has been paid and the regulatory check will start.

Should the payment not be received by the deadline specified in the invoice, your intention to submit will be cancelled and the service will not be delivered.

For additional information, please refer to the Frequently asked questions about parallel distribution page

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

6.3.3. What happens with the charge if I wish to withdraw my request/application for parallel distribution?

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.

6.3.4. Which fee/charge will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the submission is before 01/01/2025, the applicable fee will be under Council Regulation (EC) No 297/95.

If the submission is on or after 01/01/2025, the charge laid down in Regulation (EU) 2024/568 applies.

6.4. Additional administrative services referred to in Article 4(2) of Regulation (EU) 2024/568

(Charges not yet applicable as these administrative services are not yet established)

7. Consultation on medical devices

7.1. Ancillary substances incorporated in medical devices

7.1.1. Do I have to pay a fee and if so, how do I calculate it? *Rev. Jan. 2025*

Yes, EMA charges a fee for a consultation on one or more ancillary medicinal substances. The amount payable depends on the type of consultation.

The fee for consultations regarding a change with respect to an ancillary medicinal substance incorporated in a device referred to in Annex IV, Section 7.1.3, to the Fee Regulation applies to one consultation, regardless of the number of changes and ancillary medicinal substances covered in said consultation.

The medical device manufacturer that requested the assessment of conformity of the medical device for which the notified body is consulting the Agency, will be charged.

There are two levels of fees for a consultation on one or more ancillary medicinal substances. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

For the applicable fee levels, determined at submission, please refer to Annex IV, Section 7.1, of the Fee Regulation and the Appendix to the Fee Regulation Working arrangements.

For additional procedural information, please refer to the Medical Devices Page

7.1.2. Which reductions are applicable?

Micro, small and medium sized enterprises (SMEs)

A 90% fee reduction is applicable for medical device manufacturers which are a small or medium-sized enterprises.

A 100% fee reduction is applicable for a medical device manufacturer which is a micro sized enterprise.

The medical device manufacturer must fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. To benefit from incentives, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the request.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

7.1.3. Can I withdraw my request/application for consultation on one or more ancillary medicinal substances?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may charge the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn before the start of the procedure, it is free of charge.

If your request is withdrawn after the start of the procedure, the applicable fee as per invoice issued at the start of the procedure is to be paid.

7.1.4. What happens if my request/application is rejected following administrative validation?

If your application is rejected following the conclusion of the administrative validation, it will be free of charge.

7.1.5. Which fee/charge will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the end of the administrative validation date, which is the day before the procedure start, is before 01/01/2025, the applicable fee will be under Council Regulation (EC) No 297/95.

If the start of procedure date is in 2025 the fees under Regulation (EU) 2024/568 apply.

7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose

7.2.1. Do I have to pay a fee and if so, how do I calculate it?

Yes, EMA charges a fee for a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances that are absorbed by or locally dispersed in the human body. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

The medical device manufacturer that requested the assessment of conformity of the medical device for which the notified body is consulting the Agency, will be charged.

For the applicable amount, please refer to Annex IV, Section 7.2, of the Fee Regulation and the Appendix to the Fee Regulation Working arrangements.

For additional procedural information, please refer to the Medical Devices Page

7.2.2. Which reductions are applicable?

Micro, small and medium sized enterprises (SMEs)

A 90% fee reduction is applicable for medical device manufacturers which are a small or medium-sized enterprises.

A 100% fee reduction is applicable for a medical device manufacturer which is a micro sized enterprise.

The medical device manufacturer must fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. To benefit from incentives, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the request.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

7.2.3. Can I withdraw my request/application for a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may charge the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn before the start of the procedure, it is free of charge.

If your request is withdrawn after the start of the procedure, the applicable fee as per invoice issued at the start of the procedure is to be paid.

7.2.4. What happens if my request/application is rejected following administrative validation?

If your application is rejected following the conclusion of the administrative validation, it will be free of charge.

7.2.5. Which fee will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the end of the administrative validation date, which is the day before the procedure start, is before 01/01/2025, the applicable fee will be under Council Regulation No (EC) 297/95.

If the start of procedure date is in 2025 the fees under Regulation (EU) 2024/568 apply.

7.3. Companion diagnostics

7.3.1. Do I have to pay a fee and if so, how do I calculate it? *Rev. Jan. 2025*

Yes, EMA charges a fee for a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product.

There are two levels of fees for a consultation on the suitability of a companion diagnostic, depending if it an initial request or a request for a change affecting the suitability of the companion diagnostic. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

If your initial request for a consultation on the suitability of a companion diagnostic is related to more than one concerned medicinal product, a reduced fee applies to the second and subsequent medicinal product, up to a set ceiling amount.

The fee for consultations regarding a change affecting the suitability of a companion diagnostic in relation to one medicinal product applies per each of the concerned medicinal products.

The medical device manufacturer that requested the assessment of conformity of the medical device for which the notified body is consulting the Agency, will be charged.

For the applicable amounts and related reductions, please refer to Annex IV, Section 7.3, of the Fee Regulation and Chapter 3.5 of the Fee Regulation Working arrangements.

For additional procedural information, please refer to the Medical Devices Page

7.3.2. Which reductions are applicable?

Micro, small and medium sized enterprises (SMEs)

A 90% fee reduction is applicable for medical device manufacturers which are a small or medium-sized enterprises.

A 100% fee reduction is applicable for a medical device manufacturer which is a micro sized enterprise.

The medical device manufacturer must fulfil the definition of a micro, small or medium-sized enterprise as set out in Commission Recommendation 2003/361/EC of 6 May 2003. To benefit from incentives, SMEs must hold a valid SME status with EMA or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the request.

To register as an SME with EMA or renew the SME status, please refer to the Support to SMEs page.

7.3.3. Can I withdraw my request/application for a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may charge the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn before the start of the procedure, it is free of charge.

If your request is withdrawn after the start of the procedure, the applicable fee as per invoice issued at the start of the procedure is to be paid.

7.3.4. What happens if my request/application is rejected following administrative validation?

If your application is rejected following the conclusion of the administrative validation, it will be free of charge.

7.3.5. Which fee will be applicable during the transitional provisions between Council Regulation (EC) No 297/95 (previous Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation)?

If the end of the administrative validation date, which is the day before the procedure start, is before 01/01/2025, the applicable fee will be under Council Regulation No (EC) 297/95.

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