14 November 2024
EMA/534612/2024
European Medicines Agency

# ANNEX III to Regulation (EU) 2024/568

Questions & 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. Annual fee for medicinal products for human use authorised through the centralised procedure

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

Yes, EMA charges an annual fee for each marketing authorisation for medicinal products authorised under the centralised procedure falling within the scope of Regulation (EC) No 726/2004.

The amount payable depends on the legal basis of the application for marketing authorisation, in conjunction with the related fee reductions which are applicable. The total payable amount is calculated on the basis of the information recorded in the Agency's systems on 1st January of each year. The fee will relate to the preceding year from the anniversary date of the Commission implementing decision granting the marketing authorisation.

There are three levels of annual fees. For the applicable amount for each fee level, please refer to Annex III, Section 1, to the Fee Regulation.

It should be noted that for duplicate marketing authorisations, the same annual fee as described above applies.

Regardless of the applicable fee level, all strengths, pharmaceutical forms and presentations as part of the marketing authorisation are covered by the respective annual fee.

For withdrawn or revoked marketing authorisations, a pro-rata annual fee will be calculated from the period elapsing from the latest anniversary date up to the date of the relevant Commission decision withdrawing or revoking the marketing authorisation. Please refer to Chapter 1.3.1 of the Fee Regulation working arrangements.

## *1.2. Which reductions are applicable?*

There could be one or several fee reductions applicable. 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% fee reduction is applicable for small or medium-sized enterprises.

A 100% fee reduction is applicable for a micro sized enterprise.

A 100% fee reduction is applicable for annual fees of marketing authorisations for designated orphan medicinal products if the Marketing Authorisation Holder (MAH) is a micro, small or medium sized enterprise on the 1st of January of the first anniversary date of the Commission decision granting the marketing authorisation.

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 on the 1st January or have submitted the renewal of the SME status (i.e. before its expiry) before the 1st of January.

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.

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

**Medicinal products for paediatric use**

A 50% fee reduction for annual fees relating to a paediatric use marketing authorisation (PUMA) in the first year from granting of a marketing authorisation.

**Pandemic core dossier vaccines**

A 100% fee reduction is applicable for annual fees relating to core dossier marketing authorisations for pandemic vaccines until the human pandemic situation is duly recognised either by the World Health Organisation or by the European Commission.

**Orphan medicinal products**

A 100% fee reduction is applicable for annual fees of marketing authorisations for designated orphan medicinal products if the MAH is a micro, small or medium sized enterprise on the 1st of January of the first anniversary date of the Commission decision granting the marketing authorisation.

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 time of submission of the marketing authorisation application. A positive COMP opinion on orphan designation is not sufficient for eligibility to the orphan fee 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 fee 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% fee reduction is applicable to an annual fee related to marketing authorisations for medicinal products for human use that are used for stockpiling in preparation of a bioterrorism health threat. For further details on applying for such fee reduction, please refer to Chapter 3.2 of the Fee Regulation working arrangements.

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

## *1.3. How do I pay for the annual fee for my marketing authorisation?*

EMA will issue an invoice to the applicant's billing address held on the Agency's file.

The applicable annual fee will be calculated on 1st January each year and an invoice will be issued on the 1st anniversary of the marketing authorisation and on each following anniversary thereafter. The fee will relate to the preceding year.

Payments must be made by the payable date indicated on the invoice.

If the marketing authorisation is withdrawn or revoked, the fee and invoice will be issued on the date of the European Commission's withdrawal or revocation decision.

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

### *1.4. 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)?*

The annual fee becomes due for each medicinal product on the anniversary of the marketing authorisation. Therefore, for the annual fees with anniversary date up until and including 31.12.2024 the applicable fee will be under Council Regulation (EC) No 297/95. The fee will relate to the preceding year.

For the annual fees with anniversary date from 1st January 2025, the fees according to Regulation (EU) 2024/568 apply. The same principles apply for pro-rata annual fee calculation for withdrawn or revoked products depending in which year the related Commission Decision was issued.

## 2. Annual fee for veterinary medicinal products authorised through the centralised procedure

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

Yes, EMA charges an annual fee for each marketing authorisation for medicinal products authorised under the centralised procedure falling within the scope of Regulation (EU) 2019/6.

The amount payable depends on the legal basis of the application for marketing authorisation, in conjunction with the related fee reductions which are applicable. The total payable amount is calculated on the basis of the information recorded in the Agency's systems on 1st January of each year. The fee will relate to the preceding year from the anniversary date of the Commission implementing decision granting the marketing authorisation.

There are two levels of annual fees. For the applicable amount for each fee level, please refer to Annex III, Section 2, to the Fee Regulation.

It should be noted that for duplicate marketing authorisations, the same annual fee as described above applies.

Regardless of the applicable fee level, all strengths, pharmaceutical forms and presentations as part of the marketing authorisation are covered by the respective annual fee.

For withdrawn or revoked marketing authorisations, a pro-rata annual fee will be calculated from the period elapsing from the latest anniversary date up to the date of the relevant Commission decision withdrawing or revoking the marketing authorisation. Please refer to Chapter 1.3.1 of the Fee Regulation working arrangements.

### *2.2. Which reductions are applicable?*

There could be one or several fee reductions applicable. 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% fee reduction is applicable for small or medium-sized enterprises.

A 100% fee reduction is applicable for a micro sized enterprise.

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 on the 1st January or have submitted the renewal of the SME status (i.e. before its expiry) before the 1st of January.

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.

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

**Immunological veterinary medicinal product**

50% fee reduction is applicable for annual fees for marketing authorisations for immunological veterinary medicinal products.

**Limited markets veterinary medicinal product**

A 50% reduction is applicable to veterinary medicinal products authorised pursuant to Article 23 of Regulation (EU) 2019/6

**Vaccines against certain major epizootic diseases**

100% fee reduction is applicable for annual fees related to marketing authorisations for vaccines against certain epizootic diseases (namely bluetongue virus (serotypes 1-24), highly pathogenic avian influenza, foot and mouth disease and classical swine fever) where the vaccine is authorised under normal circumstances and the product has not been marketed within the European Union at any time during the period covered by the fee.

**Other veterinary medicinal products**

25% fee reduction is applicable for annual fees related to marketing authorisations for veterinary medicinal products with the exclusion of those products already listed in sections above.

## *2.3. How do I pay for the annual fee for my marketing authorisation?*

EMA will issue an invoice to the applicant's billing address held on the Agency's file.

The applicable annual fee will be calculated on 1st January each year and an invoice will be issued on the 1st anniversary of the marketing authorisation and on each following anniversary thereafter. The fee will relate to the preceding year.

Payments must be made by the payable date indicated on the invoice.

If the marketing authorisation is withdrawn or revoked, the fee and invoice will be issued on the date of the European Commission's withdrawal or revocation decision.

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

## *2.4. 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)?*

The annual fee becomes due for each medicinal product on the anniversary of the marketing authorisation. Therefore, for the annual fees with anniversary date up until and including 31.12.2024 the applicable fee will be under Council Regulation (EC) No 297/95. The fee will relate to the preceding year.

For the annual fees with anniversary date from 1st January 2025, the fees according to Regulation (EU) 2024/568 apply. The same principles apply for pro-rata annual fee calculation for withdrawn or revoked products depending in which year the related Commission Decision was issued.

# 3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

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

Yes, EMA charges each marketing authorisation holder an annual pharmacovigilance fee only for nationally authorised medicines.

The total payable amount of the annual pharmacovigilance fee for each marketing authorisation holder is calculated by the Agency on the basis of the chargeable units which correspond to the information recorded on 1 July of each year. That amount shall cover the period from 1st January to 31 December of the year concerned.

## *3.2. Which reductions are applicable?*

**Micro, small and medium sized enterprises (SMEs)**

A 40% fee reduction is applicable for small or medium-sized enterprises.

A 100% fee reduction is applicable for a micro sized enterprise.

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 on 1st July or have submitted the renewal of the SME status (i.e. before its expiry) before 1st July.

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.

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

Other fee reductions

A fee reduction of 25 % shall apply to the annual pharmacovigilance fee for the following medicinal products:

- Generic and Well-established use medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;
- Homeopathic medicinal products for human use;
- Herbal medicinal products for human use;
- Veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;
- Homeopathic veterinary medicinal products;
- Homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.

**Fee reduction exclusions**

The annual pharmacovigilance fee is excluded from the possibility to request ad-hoc fee reduction in accordance with Article 6.5 of the Fee Regulation.

## *3.3. What is a chargeable unit? How will they be determined?*

A 'chargeable unit' for medicinal products for human use means a unit defined by a unique combination of the following dataset:

- name of the medicinal product, as defined in point 20 of Article 1 of Directive 2001/83/EC;
- marketing authorisation holder;
- the Member State in which the marketing authorisation is valid;
- active substance or a combination of active substances; except in the case of homeopathic medicinal products or herbal medicinal products (as defined in Article 1, points 5 and 30, respectively, of Directive 2001/83/EC).
- pharmaceutical form.

A "chargeable unit" in relation to veterinary medicinal products means a unit defined by the unique combination of the following data fields contained in the Union product database established pursuant to Article 55(1) of Regulation (EU) 2019/6:

- the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;
- the Product Identifier referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16.

## *3.4. What is the purpose of an advice note?*

The advice note provides information on the chargeable units that have been identified for validation at a given point in time within the 'Article 57 database' for medicinal products for human use and the Union Product database (UPD) for veterinary medicinal products. In order to have a reliable and complete list of medicinal products and related chargeable units, the Qualified Person for Pharmacovigilance (QPPV) is requested to review (and, if necessary, take action as required) the data in the 'Article 57 database' or UPD for the relevant product(s) authorised for each marketing-authorisation holder.

The review should be performed at the earliest opportunity and finalised no later than 30th June every year.

In absence of any action by the given deadline, the Agency will regard the information in the systems above as agreed by the marketing-authorisation holder and consistent with the marketing authorisation holder's obligations as defined in Article 57 (2) of Regulation (EC) No 726/2004 for medicinal products for human use or Article 18 of Commission Implementing Regulation (EU) 2021/16 for veterinary medicinal products.

## *3.5. To whom will the advice note be sent? Is it possible to send the advice note to another (additional) contact point?*

To support marketing authorisation holders, an advice note will be generated and sent out to the designated marketing-authorisation holder's Qualified Person for Pharmacovigilance (QPPV) before April each year.

As this is an automated process, the Agency is not able to send the advice note to any additional e-mail address or any other contact point other than the QPPV provided in 'Article 57 database' for medicinal products for human use or UPD for veterinary medicinal product for the respective product entry.

Please note that for medicinal products for human use, changing the QPPV (i.e.: different person taking the respective role) in EudraVigilance registration system does not lead to an automatic update of the respective authorised medicinal product entries in the Article 57 database. A dedicated update of product entries must be made to amend the QPPV referenced in each individual entry. However, changes of details for a particular QPPV (e.g.: amendments of contact details) will be automatically updated without any other further changes required at product level. For veterinary medicinal products, the change of QPPV needs to be submitted via a variation not requiring assessment.

There are several reasons why an advice note might not have been generated, for example:

the QPPV details present in 'Article 57 database' or UPD for the medicinal product are incorrect, therefore, the advice note might have been sent out to a different QPPV, or

the concerned medicinal product entries were not present in 'Article 57 database' for medicinal products for human use, or UPD for veterinary medicinal products, on the date of creation of the advice note.

The advice note is provided as an additional support to the marketing authorisation holder; the non-receipt of an advice note does not exempt from the receipt of an invoice or the proactive review of data in Article 57 database or UPD. Marketing authorisation holders for medicinal products for human use are obliged to maintain the submitted medicinal product information in Article 57 database and notify the EMA of any newly authorised medicines or variations to the terms of the marketing authorisation according to the requirements introduced by Article 57(2) of Regulation No 726/2004. For veterinary medicinal products, marketing authorisation holders should refer to Article 18 of Commission Implementing Regulation (EU) 2021/16.

## *3.6. By when and how do I pay for annual pharmacovigilance fees?*

The annual pharmacovigilance fee is due on 1st July every year.

EMA will issue an invoice to the applicant's billing address held on the Agency's file as of 1st July and it will be sent in the period from 1st July to 15th September.

Payments must be made by the payable date indicated on the invoice.

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