15 November 2024
EMA/536797/2024 – *Revision 1*
European Medicines Agency

Annex II to Regulation (EU) 2024/568

Question & 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.*

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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1. Scientific Advice

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

Yes, EMA charges a fee for Scientific Advice.

The amount payable will be calculated at the point of validation of your request. For the applicable fee levels and the scopes applicable for each request, please refer to Annex II, Section 1, to the Fee Regulation and Chapter 1.1 of the Fee Regulation Working arrangements.

There are no differences in the amount of fees between initial requests for Scientific Advice and requests which follow a previous scientific advice (i.e. follow-up requests). In both cases, the fees specified in the above-mentioned Annex II will apply.

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 90% fee reduction will apply to requests related to medicinal products submitted by SMEs.

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 scientific advice request.

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.

SME regulatory consultancies may seek to benefit from the provisions of the SME Regulation on behalf of non-EEA based clients only if both they and the client meet the SME criteria (i.e. fall below headcount and financial thresholds). In this case, both the regulatory consultant and the non-EEA based company should submit SME declarations. If successful, the regulatory consultant would receive an SME notification, and the non-EEA based company would be listed in annex to that notification as an SME client company. It is not possible for an SME regulatory consultant to be considered eligible if they are acting on behalf of non-SME clients, as this would be contrary to the objectives of the SME Regulation.

Both the regulatory consultant and the non-EEA based company 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 scientific advice request.

The invoice will be sent to the company acting as the applicant.

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

Entities not engaged in economic activities

A 100% fee reduction is applicable to certain entities and requests for scientific advice. In order to grant the fee reduction, the Agency has to verify compliance with section 1.8 of the Fee Regulation Working Arrangements. Said verification is carried out on request from the applicant, which shall be submitted to the Agency. The verification must be completed with a positive outcome (i.e. compliance verified) by the time of submission of the request for Scientific Advice, at the latest. Therefore, the request for verification has to be submitted at least 5 weeks before the submission of the request for

Scientific Advice. Late requests may not be processed in time, in which case it will not be taken into consideration when determining the fee for Scientific Advice.

For more information on the above-referred verification, please refer to the Academia Overview page.

Immunological products

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

Limited Market classification confirming eligibility under Article 23

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.

1.3. How do I pay for my request for Scientific Advice?

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

Once your request is submitted, the request will be validated and the fee will be calculated upon the notification of the validation, including any possible fee reduction.

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

The invoice shall be paid by the payable date indicated on the invoice (deadline for payment).

For your request of Scientific Advice to be included in the next available start of procedure date (cut-off date), EMA recommends that you pay the invoice promptly upon receipt, as the amount needs to be received by this date.

For additional information on deadlines' requests for Scientific Advice including suggested cut-off dates for payments, please refer to the Scientific Advice for Veterinary medicines page.

Should the payment not be received by the deadline specified on the invoice, your request will be considered rejected following the conclusion of the administrative validation and an administrative charge will apply.

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

1.4. Can I withdraw my request/application for Scientific Advice?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request is withdrawn within 24 hours from your submission in the IRIS portal, the withdrawal will be free of charge.

If your request is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises, the administrative charge shall be waived.

If your request is withdrawn after the Agency has received the payment of the applicable fee, the amount paid will not be returned to the applicant.

1.5. What happens if my request is rejected following administrative validation?

If your request is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge as laid down in section 6.1, Annex IV of the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

1.6. 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 requests validated in 2024, fees and fee reductions will be applied according to Council Regulation (EC) No 297/95 (previous Fee Regulation). The provisions outlined in Regulation (EU) 2024/568 (new Fee Regulation) will apply to all requests validated and starting in 2025.

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative fee will be charged for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

2. Request for classification of a veterinary medicinal product as intended for a limited market and for consideration for eligibility for authorisation

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

Yes, there is a charge for a request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation (LM classification).

For the applicable amounts, please refer to Annex II, Section 2, to the Fee Regulation.

2.2. Which reductions are applicable?

Immunological veterinary products

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

2.3. 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)?

For requests started in 2024, fees and fee reductions will be applied according to Council Regulation (EC) No 297/95 (previous Fee Regulation). The provisions outlined in Regulation (EU) 2024/568 (new Fee Regulation) will apply to all requests starting in 2025.

3. Establishment, modification or extension of a maximum residue limit (MRL) for active substances contained in veterinary medicines

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

Yes, EMA charges a fee for a request for the establishment, modification or extension of an MRL.

The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

For the applicable amounts, please refer to Annex II, Section 3, to the Fee Regulation.

3.2. 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 90% fee reduction is applicable for SMEs.

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 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. For more information, refer to the EMA SME user guide.

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

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, for the establishment, modification or extensions of an MRL.

A 100% 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, for the extension of a MRL, when such extension does not require assessment of data.

3.3. Can I withdraw my request/application for establishment, modification or extension of an MRL?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request is withdrawn within 24 hours from your submission, the withdrawal will be free of charge.

If your request is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises, the administrative charge is waived.

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.

3.4. What happens if my request/application is rejected following the conclusion of the administrative validation?

If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

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, which is the day before the procedure starts, 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.

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative fee will be charged for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

4. Authorisation to market veterinary medicinal products

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

Yes, EMA charges a fee for marketing authorisation applications for veterinary medicinal products.

The amount payable depends on the legal basis and your claim as to the type of active substance (i.e. new active substance or known active substance) in your application for marketing authorisation. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

For the applicable amounts, please refer to Annex II, Section 4, to the Fee Regulation.

All strengths, pharmaceutical forms and presentations submitted in the same application are covered in the applicable fee, irrespective of the target species.

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

4.2. Which reductions and deductions 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) ***Rev. June 2025***

A fee deferral will apply to marketing authorisation applications submitted by a SME.

A fee deferral for a SME applicant means that the time of payment of the fee for a marketing authorisation (MA) application 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. Said fee must be paid within 45 calendar days of the date of the notification of the final decision on the marketing authorisation, or within 45 calendar days of the date of notification of withdrawal of the application.

For the impact of contractual arrangements and mergers and acquisitions between SME and non-SME entities on fee incentives, see section 4.1 and 4.2 of General Q&As 00 – Important information to all Applicants.

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 marketing authorisation application.

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. For more information, refer to the EMA SME user guide.

A conditional fee exemption of the fee for the evaluation of a Marketing Authorisation application may be given where the scientific advice provided by EMA was taken into account by the applicant for the development of the product and a Marketing Authorisation is not granted (due to negative outcome or withdrawal of the MA application). To benefit from the conditional fee exemption, 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 marketing authorisation application. For additional details, refer to the Support to SMEs page.

A subsequent change to the SME status (i.e. expiration of the SME status) after the applicable fee level date (i.e. at the time of submission of the marketing authorisation application) will not be taken into account for the application of the SME fee incentives. 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 due will no longer be subject to fee deferral and shall be payable.

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

Immunological veterinary products

A 50% fee reduction is applicable for initial marketing authorisation application for immunological veterinary medicinal products.

Veterinary medicinal products for limited markets

A 50% fee reduction is applicable for initial marketing authorisation application for a veterinary medicinal product submitted under Article 23 of Regulation (EU) 2019/6.

Maximum Residue Limits *Rev. June 2025*

The fee paid for an application to set an initial MRL for a given substance pursuant to Annex II, section 3.1, to the Fee Regulation shall be deducted from the respective fee payable for an application for a marketing authorisation for the medicinal product containing the substance for which the MRL has been set, where such applications are submitted by the same applicant.

4.3. How do I pay for my application for a marketing authorisation?

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

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

If the applicant changes during an ongoing marketing authorisation application, any fee invoiced since the start of the procedure (i.e. fee for initial marketing authorisation and pre-authorisation inspection fee) will be credited to the original applicant and re-invoiced to the new applicant. This will include changes, if any, relating to micro, small or medium-sized enterprises applicants.

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

4.4. Can I withdraw my application for a marketing authorisation?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn within 24 hours from your submission, it is free of charge.

If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises, the administrative charge is waived.

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.

4.5. What happens if my application is rejected following administrative validation?

If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

4.6. 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, that is the day before the procedure start, is before 01/01/25, the applicable fee will be under Council Regulation (EC) No 297/95 (please refer to the published procedural timetables to determine the date).

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

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative fee will be charged for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

5. Re-examination of a marketing authorisation for limited markets

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

Yes, EMA charges a fee for re-examination of a marketing authorisation for limited markets pursuant Article 24(3) of Regulation (EU) 2019/6.

For the applicable amounts, please refer to Annex II, Section 5, to the Fee Regulation.

5.2. Which reductions are applicable?

There are no reductions applicable to this fee.

5.3. Can I withdraw my request/application for re-examination of a marketing authorisation for limited markets?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn within 24 hours from your submission, the withdrawal will be free of charge.

If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises, the administrative charge is waived.

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.

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

If your request/application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

6. Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6

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

Yes; EMA charges a fee for variations requiring assessment (VRAs) and a charge for work-sharing applications.

The amount payable depends on the scope of the VRA application. There are three levels of fees for an application for VRA. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions.

In order to determine the applicable fee for VRAs, the Agency will take into account the classification of changes and length of timetable specifically set out in the 'Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations' available here. Agreement to exceptionally run the procedure on a timetable different from the one set out in said Guidance will not affect the determination of the payable amount.

For VRAs grouped in a single application under Article 64 of Regulation (EU) 2019/6, a reduced fee applies to the third and subsequent VRA.

The charge for a work-sharing shall apply to each variation of the second and subsequent centrally authorised product included in the application.

For the applicable fee levels, determined at submission, please refer to Annex II, Section 6, to the Fee Regulation and the Appendix to the Fee Regulation Working arrangements.

6.2. 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 or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the application.

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.

The SME fee reductions are not applicable to the charge for each variation of the second and subsequent centrally authorised product included in the work-sharing application.

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

Immunological veterinary products

A 50% fee reduction is applicable for variations requiring assessment (VRAs) related to a marketing authorisation for immunological veterinary medicinal products.

Veterinary medicinal products for limited markets

A 50% reduction is applicable for variations requiring assessment (VRAs) related to veterinary medicinal products authorised pursuant to Article 23 of Regulation (EU) 2019/6.

Variations requiring assessment with scope G.I.18

A 50% fee reduction is applicable for variations requiring assessment (VRAs) falling under the scope G.I.18 for non-immunological veterinary medicinal products.

6.3. Can I withdraw my request/application for VRA?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn within 24 hours from your submission, it is free of charge.

If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises the administrative charge is waived.

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.

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

If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

6.5. 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, 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 (please refer to the published procedural timetables to determine the date).

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

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative fee will be charged for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

7. Referrals and arbitration procedures

7.1. Do I have to pay a fee and if so, how do I calculate it? Rev. June 2025

Yes, EMA charges a fee for certain types of referrals and arbitration procedures, while for other types (Articles 54(8), 70(11) and 141(1)(c,e)[1] of Regulation (EU) 2019/6) the fee is waived.

For the procedures for which a fee shall be paid, the amount payable depends on the legal basis of the referral/arbitration. There are two level of fees linked the legals basis. Fees will be determined after the start of the procedure based on the total number of chargeable units included in the procedure.

An advice note will be sent to the Qualified Person for Pharmacovigilance (QPPV) at the start of the procedure with the list of chargeable units in scope.

[1] For Article 141(1)(i) of Regulation (EU) 2019/6 please refer to Q&A Annex IV, section 5.1 – "Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices"

For the applicable fee levels, please refer to Annex II, Section 7, to the Fee Regulation and the Appendix to the Fee Regulation Working arrangements.

7.2. 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 or have submitted the renewal of the SME status (i.e. before its expiry) at the time of notification of referral.

The fee reduction shall not be granted to SMEs acting as marketing authorisation holder 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 or exclusions

No other fee reductions are envisaged for these types of procedures. They are also excluded from the possibility to request ad-hoc fee reduction in accordance with Article 6.5 of the Fee Regulation.

7.3. What is a chargeable unit? How will they be determined?

A 'chargeable unit' in relation to veterinary medicinal products means a unit defined by a unique combination of the following data fields contained in the Union Product database (UPD) 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.

7.4. 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 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 UPD for the relevant product(s) authorised for each marketing-authorisation holder.

This should be performed in liaison with the marketing-authorisation holder at the earliest opportunity and no later than 30 calendar days from the date of the advice note.

In absence of any action by the given deadline, the Agency will regard the information in UPD as agreed by the marketing-authorisation holder and consistent with the marketing authorisation holder's obligations as defined in Article 18 of Commission Implementing Regulation (EU) 2021/16.

7.5. 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) after the start of the procedure.

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 UPD for the respective product entry.

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

- the QPPV details present in 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 UPD 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 UPD. For veterinary medicinal products, marketing authorisation holders should refer to Article 18 of Commission Implementing Regulation (EU) 2021/16.

7.6. 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 start date of the referral or arbitration procedure, following notification of the procedure, is before 01/01/2025, the applicable fee will be under Council Regulation (EC) No 297/95.

If the start date of the referral or arbitration procedure, following notification of the procedure, is after 01/01/2025, the applicable fee will be under Regulation (EU) 2024/568 (Fee Regulation).

8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)

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

Yes, EMA charges a fee for a certification of compliance with Union legislation for vaccine antigen master files (VAMF) for veterinary applications.

There are two types of fees for certifications of compliance with Union legislation for a VAMF. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions. For the applicable fee amounts, determined at submission, please refer to Annex II, Section 8, to the Fee Regulation:

- A fee shall apply to an application for review of a VAMF and its initial certification submitted simultaneously with an initial application for a veterinary marketing authorisation containing the named antigen.
- Multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application will be charged the fee listed above, up to a set ceiling amount.

- A fee shall apply to an application for review of a VAMF and its initial certification submitted as a separate application for an antigen already authorised under the centralised, decentralised or mutual recognition procedure.

For the applicable amounts to a variation to a VAMF, refer to Annex II, Section 6, to the Fee Regulation.

8.2. 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 or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the application.

The fee reduction shall not be granted to SMEs acting as applicant 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 products

A 50% fee reduction is applicable for a VAMF related to immunological veterinary medicinal products.

Veterinary medicinal products for limited markets

A 50% fee reduction is applicable to VAMF related to veterinary medicinal products holding a Limited Market classification confirming eligibility under Article 23 of Regulation (EU) 2019/6, to requests submit simultaneously with initial marketing authorisation for a veterinary medicinal product submitted under Article 23 of Regulation (EU) 2019/6 and veterinary medicinal products authorised pursuant to Article 23 of Regulation (EU) 2019/6

8.3. Can I withdraw my request/application for a VAMF?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn within 24 hours from your submission, it is free of charge.

If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises the administrative charge is waived.

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.

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

If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

8.5. 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, 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.

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative fee will be charged for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)

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

Yes, EMA charges a fee for a certification of compliance with Union legislation for vaccine platform technology master files (vPTMF) for veterinary applications.

There are two types of fees for certifications of compliance with Union legislation for a vPTMF. The applicable amount will be calculated after the submission of your application, in conjunction with the related fee reductions. For the applicable fee amounts, determined at submission, please refer to Annex II, Section 9, to the Fee Regulation:

- A fee shall apply to an application for review of a vPTMF and its certification submitted simultaneously with an initial application for a veterinary marketing authorisation containing the named platform.
- A fee shall apply to an application for review of a vPTMF and its certification submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual recognition procedure.

For the applicable amounts to a variation to a vPTMF, refer to Annex II, Section 6, to the Fee Regulation.

9.2. 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 or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the application.

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 products

A 50% fee reduction is applicable for a vPTMF related to immunological veterinary medicinal products.

Limited markets

A 50% fee reduction is applicable to vPTMF related to veterinary medicinal products holding a Limited Market classification confirming eligibility under Article 23 of Regulation (EU) 2019/6, to requests submit simultaneously with initial marketing authorisation for a veterinary medicinal product submitted under Article 23 of Regulation (EU) 2019/6 and veterinary medicinal products authorised pursuant to Article 23 of Regulation (EU) 2019/6

9.3. Can I withdraw my request/application for vPTMF?

Yes; however, depending on when you decide to withdraw your request/application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related request/application, or the withdrawal may be free of charge.

If your request/application is withdrawn within 24 hours from your submission, it is free of charge.

If your request/application is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises the administrative charge is waived.

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.

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

If your application is rejected following the conclusion of the administrative validation, the Agency will issue an invoice for an administrative charge laid down in section 6.1, Annex IV, to the Fee Regulation.

For registered micro, small or medium sized enterprises, the administrative charge is waived.

9.5. 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, 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.

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative will be charged fee for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

10. Post-marketing surveillance studies

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

Yes, EMA charges a fee for an assessment of post-marketing surveillance studies (PMSS) pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member State.

Please refer to Annex II, Section 10, to the Fee Regulation for the applicable amounts.

The fee is paid in two parts:

- First instalment for the assessment of the draft study protocol;
- Second instalment for the assessment of the final study report.

In principle, a PMSS should involve a single study report and therefore, would trigger a single fee.

However, in cases where several study reports are submitted separately, the different study reports may be subject to a separate fee, depending on the nature of the study and the description of the protocol.

When several marketing authorisation holders have the obligation to conduct a joint PMSS, the amount of the fee shall be divided equally amongst the marketing authorisation holders involved.

The applicable amount will be calculated after the submission of the draft study protocol (for the first fee instalment) or of your study report (for the second fee instalment), in conjunction with the related fee reductions.

10.2. Which reductions are applicable?

There could be one or several fee reductions applicable. Please note that if multiple reductions apply, only 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 or have submitted the renewal of the SME status (i.e. before its expiry) at the time of submission of the application.

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 products

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

Veterinary medicinal products for limited markets

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

Other fee reductions or exclusions

No other fee reductions are envisaged for this procedure. They are also excluded from the possibility to request ad-hoc fee reduction in accordance with Article 6.5 of the Fee Regulation.

10.3. Can I withdraw an application for assessment of post-marketing surveillance studies referred to in Point 10 of Annex II to Regulation (EU) 2024/568?

In principle, an application for an assessment of PMSS pursuant to Article 76(3) of Regulation (EU) 2019/6 conducted in more than one Member State could be withdrawn, but you may wish to consider enquiring the Agency about your specific case. Depending on when you decide to withdraw your application, the Agency may apply the administrative charge laid down in section 6.1 of Annex IV to the Fee Regulation, or the fee for the related application, or the withdrawal may be free of charge.

If your request is withdrawn within 24 hours from your submission, the withdrawal will be free of charge.

If your request is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. For micro, small or medium sized enterprises, the administrative charge shall be waived.

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.

10.4. 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 procedures starting in 2024, there are no fees or charges to be applied according to Council Regulation (EC) No 297/95.

For procedures starting in 2025, the provisions of Regulation (EU) 2024/568 (new Fee Regulation) will apply.

If the date of your request to withdraw your application before the start of procedure is before 01/01/2025, no administrative will be charged fee for the withdrawal; however, if the date of your request to withdraw your application before the start of the procedure (and 24 hours after its submission) is on or after 01/01/2025, the new Fee Regulation applies with an administrative charge applicable.

11. Scientific opinions in the context of cooperation with international organisations for animal health for the

evaluation of veterinary medicinal products intended exclusively for markets outside the Union

11.1. Do I have to pay a fee and if so, how do I calculate it? Rev. June 2025

Yes, EMA charges a fee for an application for a scientific opinion following the evaluation of a veterinary medicinal product intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6. The applicable amount will be calculated after the submission of your application.

The fee will be applicable to the procedures specified in sections 1, 3, 4 and 6 of Annex II (Scientific advice, establishment, modification or extension of a maximum residue limit (MRL), initial applications and variations requiring assessment) and in sections 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 of that Annex (inspections, pre-submission, re-examination and other scientific services) and points 6.1, 6.2 and 6.4 (certificates). Please refer to Section 11, Annex II, to the Fee Regulation, and the relevant sections of Annexes II and IV, for the applicable amount.

11.2. Which reductions are applicable? Rev. June 2025

There could be one or several fee reductions applicable. Please note that if multiple fee reductions are applicable, only the most favourable reduction will be applied, as reductions are not cumulative.

Please refer to the relevant sections of Annexes II and IV to the Fee Regulation, for additional information on the applicable fee reductions.

11.3. Fee deferrals and conditional fee exemptions shall not apply to scientific opinions in the context of cooperation with international organisations for animal health for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. Can I withdraw my request/application?

Yes, please refer to the Q&A of the applicable procedure.

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

Please refer to the Q&A of the applicable procedure.

11.5. 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)?

Please refer to the Q&A of the applicable procedure.