



Receiver: **Assigned contact person (SPOC) for communication with e-VIS**

September 2025

Annual Flat Fee 2026

By this letter e-VIS notifies all companies (MAH/Representative of MAH), with a signed Co-Operation agreement, the amount of the annual fee for 2026, decided by the e-VIS Board, in accordance with section 5.1 Fees in the agreement.

Annual flat fee per MAH for 2026: SEK 63 000 (currency: Swedish krona)

Fee exclusive of value added tax (VAT)

(Fee remains unchanged since 2022)

Important dates

- Deadline to apply for a **reduced fee 2026**, note that an application needs to be done each year, - **14 November 2025**
- Deadline to provide a **Purchase Order Number**, if required on invoices, - **14 November 2025**, send to administration@e-vis.se
- The **invoice** will be issued in **December 2025** (Payment term is thirty (30) days net from the date of the invoice). **Note** that the email sender of the invoice is: noreply@xledger.net

Fee model per MAH - National fee SMVS

The costs of the repositories system shall be borne by the manufacturers of medicinal products bearing the safety features, in accordance with Article 54a(2)(e) of Directive 2001/83/EC.

Section 5.1 in the Co-Operation Agreement between e-VIS and the Company regulates the fee to e-VIS.

e-VIS charges an adjusted flat fee model per MAH. There are two ways in the agreement to indicate the number of MAHs valid for each contracting party:

- a) A single MAH = one (1) flat fee
Co-Operation agreement, section 17. Appendices: N/A
- b) More than one (1) MAH = one (1) flat fee per MAH
Co-Operation agreement, section 17. Appendices: Appendix/Amended Appendix 1
List of marketing authorisation holders represented by the company

Reduced fee

MAH's with pharmaceuticals within scope for FMD, Rx, OTC and vaccines, on the Swedish Market and with a registered net sales* less than SEK 1 000 000 (one million) can apply for a reduced fee for 2026.

Note: Reduction in fee does not apply for MAH's within the same group.

| Net Sales * (Swedish Market, within scope for FMD) | Discount offered | Actual Fee 2026 (currency: SEK, Swedish krona) |
|--|------------------|--|
| > 1 000 000 SEK | 0% | 63 000 |
| 500 000 - 999 999 SEK | 25% | 47 250 |
| 100 000 - 499 999 SEK | 75% | 15 750 |
| 0 - 99 999 SEK | 95% | 3 150 |

*** Moving Annual Total during a 12-month period before September 2025**

All fees expressed are exclusive of value added tax (VAT)

How to apply

To apply for a reduced fee, notify e-VIS at administration@e-vis.se

Note that an application needs to be done each year

e-VIS may ask for an additional proof such as sales statistics, annual report, and financial statement. By signing the application for reduced fee MAH accept to provide these proofs.

It is the responsibility of the MAH to give notice if they meet the criteria for a reduced fee **at the latest 14 November 2025**.

New/change/transfer of MAH

Make sure that e-VIS has up to date information about your company.

If a company intends to transfer, add or delete an MAH (when no longer will act as an MAH in Sweden) stated in the agreement or in the Appendix, notify e-VIS at administration@e-vis.se

Find information in the Co-Operation agreement sections:

4. Obligations of the Company (iii), (vii) and 13. Term and Termination.

Change/transfer of MAH during the current year – the net sales are inherited from the former MAH.

New MAH - the product/s will be expected to be sold on the Swedish market and be a part of the e-verification system.

For further information visit our website at:

<https://e-vis.se/en/mah/>

<https://e-vis.se/en/about-us/>

On behalf of e-VIS

DocuSigned by:

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Kristina von Sydow
General Manager