



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

September 2023

## Annual Flat Fee 2024

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 2024, decided by the e-VIS Board, in accordance with section 5.1 Fees in the agreement.

The annual flat fee for 2024: SEK 63 000 (currency: Swedish krona)

### 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 registered net sales\* less than SEK 1 000 000 (one million) can apply for a reduced fee for 2024.

Net Sales * (Swedish Market, within scope for FMD)	Discount offered	Actual Fee 2024 (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 2023**

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

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

### How to apply

To apply for a reduced fee, notify e-VIS at [administration@e-vis.se](mailto:administration@e-vis.se)

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 17 November 2023**.

### 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](mailto: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.

## Important dates and Purchase Order Number

- Deadline to apply for a reduced fee 2024 - **17 November 2023**
- If a Purchase Order Number is required on the invoice send to [administration@e-vis.se](mailto:administration@e-vis.se) at the latest **1 December 2023**
- The invoice will be issued in **Mid December 2023**

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