

September 2021

Dear Sir/Madam,

Receiver of this letter is the assigned contact person (SPOC) for communication with e-VIS.

By this letter e-VIS notifies all companies, with a signed Co-Operation agreement, regarding the annual fee for 2022 in accordance with section 5.1 Fees in the agreement.

For information on Background and About us visit our website at:

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

Annual Flat Fee 2022

The adjusted flat fee per MAH will be **reduced by 10 percent** compared to the 2021 fee.

The annual fee for 2022 is SEK 63 000

Companies with registered **net sales* less than SEK 1 000 000 (one million)** can apply for a reduced fee for 2022. **Please note** that reduction in fee does not apply for combined MAHs i.e. MAHs in the same group.

Net Sales *	Adjusted Flat fee 2022	Discount offered
> 1 000 000 SEK	63 000 SEK	0%
500 000 - 999 999 SEK	47 250 SEK	25%
100 000– 499 999 SEK	15 750 SEK	75%
0– 99 999 SEK	3 150 SEK	95%

* Moving Annual Total (MAT) during a twelve-month period before September 2021.

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

To apply for a reduced fee, notify e-VIS at administration@e-vis.se
e-VIS will then send an application form to be completed.

Please note: It is the responsibility of the company to **give notice** if they meet the criteria for a reduced fee **at the latest November 19, 2021**

Principles fee

Change/transfer of MAH (human medicinal products covered by the FMD) during the current year – the net sales 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. The fee will apply when the products is marked as 'On the market = yes' in the Supplier information in the VARA register at the Swedish e-Health Agency.

Change of MAH

If a company intends to transfer, add or delete an MAH stated in the agreement or in the Appendix. Please 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.

Fee model per MAH - National fee SMVS

The FMD requires the pharmaceutical industry to finance the system. e-VIS charges an adjusted flat fee model per MAH. There are two ways in the agreement to indicate the number of MAH:s 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 listed in the Appendix 1/ Amended Appendix 1
Co-Operation agreement, section **17. Appendices: Appendix/Amended Appendix 1**
List of marketing authorisation holders represented by the company

Invoice

The invoice for the annual fee year 2022 will be **issued in December 2021** and will be due for payment in accordance with section 5.2 Payment terms in the Co-Operation agreement.

For companies that require **Purchase Order number** (PO) on invoices, please provide and send the PO number to administration@e-vis.se **at the latest November 19, 2021**.

Background for Financing of the 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.

Important dates

- 19 November 2021 – deadline for providing Purchase Order number
- 19 November 2021 – deadline for applications of reduced fee
- Beginning of December 2021 – issue of invoice

On behalf of e-VIS,



Kristina von Sydow
General Manager