e-VIS
e-Verifikation i Sverige

September 2020

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 2021 in accordance with section 5.1 in the agreement.

Please see point 6 for the updated fee 2021.

1. The Falsified Medicines Directive 2011/62/EU:

The European Falsified Medicines Directive (FMD) prescribes mandatory, harmonised European safety features on all prescription medicinal products (with certain risk-based exceptions) and hence applies to most of the pharmaceutical companies.

The purpose of the FMD is to secure the legal pharmaceutical supply chain in Europe to better protect patients from falsified medicines, the supply chain for dispensing medicines to patients in Europe will become even safer.

The Medicines verification system went live across EU on 9 February 2019.

2. The Swedish Market and Swedish Medicines Verification Organisation:

The responsibility for the implementation is by legislation with each country's non-profit governance organisation, the NMVO:s.
The non-profit organisation in Sweden is e-VIS (e-Verification in Sweden), whose sole responsibility is to establish and manage the Swedish Medicines Verification System (SMVS).

Members of e-VIS are five professional associations in the pharmaceutical distribution chain:

- the Swedish Association of the pharmaceutical industry (LIF Sweden)
- the Swedish Generic Medicines and Biosimilars Association
- the Swedish Association of Pharma Traders
- the Swedish Association of Pharmaceutical Wholesalers
- the Swedish Pharmacy Association

MAH Obligations:

- As of 9 February 2019, Marketing Authorised Holders (MAH) are obliged to place safety features to all packs covered by the FMD
- Contract with the European Medicines Verification Organisation (EMVO) and connect to the EU Hub to upload master and product data as required by the Delegated Regulation (EU) 161/2016.
- Each MAH which markets at least one product within a national territory must sign an agreement with the National Medicines Verification Organisation (NMVO) and pay the national fee.

  For further information: https://e-vis.se/en/pharmaceutical-companies-mahs/

3. SMVS - National fee:

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 in the Co-Operation agreement section **17. Appendices** Appendix 1 (or Amended Appendix 1) List of marketing authorisation holders represented by the company.

4. Co-Operation agreement Section 5. Financing of the SMVS:

Section 5.1 in the Co-Operation Agreement between e-VIS and the Company regulates the fee to e-VIS as an annual fee per each represented MAH for the development, testing, implementation, operation, maintenance, and update of the SMVS.

The annual fee shall be paid to e-VIS as and from 2019. An invoice for the annual fee will be issued in December each year and will be due for payment in accordance with section 5.2 Payment terms in the Co-Operation agreement.

The amount of the annual fee for any given year will be notified by e-VIS to the Company in writing no later than 30 September during the previous calendar year.

e-VIS is notifying all Companies regarding the annual fee for 2021 by this letter.

5. Invoice

The invoice for the annual fee year 2021 will be **issued in December 2020** 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 send the PO number by email to administration@e-vis.se at the latest **on 16 November 2020**

6. Annual Fee 2021

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

1. The adjusted flat fee per MAH will be reduced by 30 percent compared to the 2020 fee. The annual fee for 2021 is SEK **70 000**

2. Adjusted flat fee: Companies with registered net sales* less than SEK 1 000 000 (one million) for combined MAHs can apply for a reduced fee for 2021.

Net Sales*	Discount offered	Actual fee 2021
> 1 000 000 SEK	0%	70 000 SEK
500 000 - 999 999 SEK	25%	52 500 SEK
100 000– 499 999 SEK	75%	17 500 SEK
0– 99 999 SEK	95%	3 500 SEK

* Moving annual total during a twelve months period before September 2020

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.

It is the responsibility of the company to give notice if they meet the criteria for a reduced fee **at the latest November 16, 2020**.

7. Principles fee

3. Change/transfer of MAH (medicinal products covered by the FMD) during the current year the sales are inherited from the former MAH.
   Principles 1 and 2 will apply.

4. New MAH (in Europe). The product/s will be expected to be sold on the Swedish market and be a part of the e-verification system. The flat 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.

8. Change of MAH

If a company intends to transfer, add or delete an MAH stated in the agreement or in the Appendix. Please contact administration@e-vis.se.

Find information in the Co-Operation agreement section: 4. Obligations of the Company (iii), (vii) and in section13. Term and termination.

On behalf of e-VIS,

Kristina von Sydow
General Manager