Information on the annual fee for LiiV

In November 2016 the Swedish eHealth Agency took over responsibility for compiling and administering suppliers' medicinal product information from the Swedish Medical Products Agency. The information is registered in the LiiV system (Supplier Information in the VARA Register). LiiV is funded through an annual fee paid by suppliers of medicinal products.

The annual fee for LiiV is based on a forecast for operating, administration, development and overhead costs based on cost coverage.

The Ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products encompass the Swedish eHealth Agency's fee for the system for collecting medicinal product information (LiiV).

Link to Ordinance (2010:1167) | Svensk författningssamling (svenskforfattningssamling.se)

The annual fee has been adjusted from 1 January 2022 and is set to SEK 1,500 per medicinal product[1]. For parallel-imported medicinal products the annual fee is set to SEK 750 per product.

This applies to approved medicines[2], traditional herbal medicinal products and stock preparations with a national licence.

Management of deregistrations and applications for reduction of or exemption from the annual fee

Withdrawals

For medicinal products that are to be withdrawn and therefore not subject for an annual fee, the application for withdrawal must be submitted to the Swedish Medical Products Agency no later than 31 October the year before the next annual fee begins to apply. This is to allow the application for withdrawal to be processed before annual fees are invoiced.

Application for reduction of or exemption from the annual fee

In order to allow an application for reduction of or exemption from the annual fee for the coming year to be considered before invoicing, a joint application to the Swedish

[1] Per medicinal product, i.e. per NPL id.
[2] For medicinal products for which an application for marketing authorisation is being or has been assessed under Regulation (EC) No 726/2004 of the European Parliament and of the Council an annual fee may not be charged.

Medical Products Agency and the Swedish eHealth Agency should be made no later than 31 October the year before the next annual fee begins to apply.

Reduction or exemption cannot be granted for parallel imports and generics and for centrally authorised products under the Ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products.

Application is made on a joint application form for the Swedish Medical Products Agency and the Swedish eHealth Agency and is sent to the Swedish Medical Products Agency. Following this, a consideration is made at the Swedish Medical Products Agency and the Swedish eHealth Agency.

Fees | Swedish Medical Products Agency (lakemedelsverket.se)

If the Swedish eHealth Agency agrees that special reasons apply, the annual fee can be partly or fully reduced. Such reasons can apply if a medicinal product is or can be expected to become of great importance for medical treatment, but hard to make profitable.

Invoicing

The annual fee for LiiV is paid to the Swedish Medical Products Agency, which then transfers it to the Swedish eHealth Agency. This is done in connection with the collection of the annual fee paid to the Swedish Medical Products Agency.

If you have any questions concerning the Swedish eHealth Agency's fees, please contact registrator@ehalsomyndigheten.se