

Information on the annual fee for LiiV

In November 2016 the eHealth Agency took over responsibility for compiling and administering suppliers' medicinal product information from the Medical Products Agency. The information is registered in the new 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 fee will provide the expected cost coverage over time and the ambition is to keep the level of fees low and even from year to year.

The Ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products has been amended as of 1 June 2017 to also encompass the eHealth Agency's fee for the system for collecting medicinal product information (LiiV).

http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-20101167-om-avgifter-for-den_sfs-2010-1167

The annual fee will be SEK 1,590 per medicinal product¹. For parallel-imported medicinal products the annual fee will be SEK 795 per product. This applies to approved medicines², 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

According to the Medical Products Agency, time for processing a withdrawal is estimated to a maximum of three months. For medicinal products that are to be withdrawn and therefore not subject for an annual fee, the application for withdrawal must be submitted to the Medical Products Agency not later than 31st October the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.

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.

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 Medical Products Agency and the 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 Medical Products Agency and the eHealth Agency and is sent to the Medical Products Agency. Following this, a consideration is made at the Medical Products Agency and the eHealth Agency.

<https://lakemedelsverket.se/english/product/Medicinal-products/Fees--/>

If the 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 Medical Products Agency, which then transfers it to the eHealth Agency. This will be done in connection with the collection of the annual fee paid to the Medical Products Agency. However, the LiiV fee will be accounted for as a separate item in order to enable the transfer of the fee to the eHealth Agency.

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

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