9 June 2017

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. Medicinal product 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. In the work on determining the fee for LiiV, a dialogue has been conducted with the Ministry of Health and Social Affairs and the Medical Products Agency.

Annual fee for 2017

The annual fee has been set by the Ministry of Health and Social Affairs after a circulation for comment. In the Ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products it is stated that the annual fee will be SEK 1,590 per medicinal product[1]. For parallel-imported medicinal products it is stated that the annual fee will be SEK 795 per product. It has been set that the Ordinance is effective from 1 June 2017, which means that the fee will be lower this year, as it is payable only for seven months. For 2017 the fee will thus be SEK 1,590 x 7/12 = SEK 928 per medicinal product. For parallel-imported medicinal products the fee will be SEK 795 x 7/12 = SEK 464. The amendment will apply to approved medicines[2], traditional herbal medicinal products and stock preparations with a national license.

Invoicing

The annual fee for LiiV is paid to the Medical Product 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.
This year, the invoice for the LiiV fee will be sent separately in September by the Swedish Medicines Agency. For medicines which are approved after the summer a single invoice will be issued for both fees.

If you have any questions concerning this, please contact registrator@ehalsomyndigheten.se.

Best regards,
Ylva Andersén
Head of Unit, Master data
eHealth Agency

1 Per medicinal product, i.e. per NPL id

2 For medicines 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 will not be collected.