

Financial model change

From 2021, REKS' financial model is changing according to which the annual fees for MAH's will decrease from 2021. As an important change, the payment will no longer be made in the form of advances for the following year, as was necessary when the system was launched, but for the current year. Thus, **REKS will issue invoices for 2021 in the second quarter of 2021**. In 2020, no invoices will be issued to MAH's.

In order to receive an **exception for 2021**, REKS will ask MAH's to provide the turnover of 2020 in the first quarter of 2021. **Exception requests must be provided by March 31st. Late applications will not be accepted, and flat fee will automatically apply.**

MAH annual fee for 2021

MAH annual serialised medicines turnover* (euro) in Estonia	Annual fee for 2021 (without VAT)
over 100 000	<i>(flat-fee)</i> 6000 euro
50 000 – 99 999	(exception 1) 3000 euro
8 000 – 49 999	(exception 2) 1500 euro
3 000 – 7 999	(exception 3) 500 euro
0 – 3 000	(exception 4) 100 euro

*For the purpose of calculating the annual turnover of the MAH's, the turnover generated from sales to wholesalers is used. Upon request of REKS, the Company is obliged to submit proof of turnover.

MAH contract change

Due to the before mentioned financial model change, REKS is required to renew all contracts with MAH's in order to reduce the level of some annual fees below the minimum currently set in the contract (for exceptions).

In the main body of the contract the following points were changed:

- 6.1.3 The procedure for determining the annual fee upon the entry of a new company into the Estonian market
- 6.1.4 The procedure for calculating turnover in the case of a new company, making it possible to establish an exception in annual fee if the company has been operating less than 12 months
- 6.1.5 Regulating that upon termination of the contract, there is no right to recover the annual fee that has already been paid
- 6.1.6 The text of the agreement on invoicing has been simplified
- 6.1.7 The procedure for the annual fees and exceptions for the following year are approved by the Supervisory Board of REKS at the end of the previous year and they are published on REKS website
- 6.2.2 The right to set a default interest of 0.05% of the invoiced amount for each day overdue was added

- 6.2.3 The contract was supplemented with a clause that the company is obliged to pay the invoice in one instalment

In appendix 1, the publications of exceptions and flat fees was changed and the annex has been aligned with the new financial mode, which sets the maximum possible flat-fee in the contract, but does not set the limits on the flexibility of the levels of exceptions.

In addition, in appendix 2 REKS clarified who is meant under the “authorised MAH contact person” – an additional person to the contract signed who is responsible for FMD questions. This person can also contact REKS for inquiries regarding the products uploaded to EtMVS (does not need an additional POA for it). Important notice is that a company should not be listed here, but a juridical person.

To operate alert handling with MAH’s more efficiently, REKS also added MAH alert handling contact information to fill in appendix 2. This will ensure that in an alert investigation, REKS will contact the right person and hence the alert investigation will be quicker and smoother.

If there are any additional questions that are not answered here, please contact REKS info@reks.ee or by phone +372 656 5973