2.2.2022

**Rules on reduction of fees according to Tariff no. 133/2022**

According to Article 18 of Tariff no. 133/2022 for marketing authorisations, annual fees and other licence fees for medicinal products and related products, collected by the Icelandic Medicines Agency, the Agency may reduce tariff fees under special circumstances. The Agency shall lay down rules regarding prerequisites and arrangements concerning this matter, to be published on the Icelandic Medicines Agency’s website.

**1) Fees for medicinal products for which a purely national marketing authorisation was granted before 1 January 2000, including additional pharmaceutical forms and strengths of these products, which have been granted a purely national marketing authorisation after 1 January 2000.**

In these cases the Icelandic Medicines Agency collects the same fee as collected when Iceland is a CMS in DCP or MRP, on the condition that it will be confirmed in the application’s cover letter that an identical application has been submitted in another EEA member state – normally a member state which shares the packages of the product with Iceland – and the applicant requests that the application will not be addressed by the Icelandic Medicines Agency until the application has been finalised in the other member state. Furthermore, the cover letter must state that the applicant will send the Icelandic Medicines Agency a copy of the approval from the other member state, as well as a copy of any additional documentation submitted in that member state.

The heading of the cover letter shall contain the following text: “An identical application has been submitted in <name of the EEA member state> <which shares package(s) of the product with Iceland>”.

The cover letter shall contain the following text:

“An identical application has been submitted in <name of the EEA member state> <which shares package(s) of the product with Iceland>. The applicant kindly requests that the Icelandic Medicines Agency does not address the application until it has been finalised in <name of the other EEA member state>. In due course of time the Icelandic Medicines Agency will be informed of the conclusion in the other EEA member state by submitting a copy of the conclusion letter and any additional documentation submitted in <name of the other EEA member state>.

**2) Products that have been granted a purely national marketing authorisation after 1 January 2000.**

Until 31st of January 2023, the Icelandic Medicines Agency will collect the same fee as collected when Iceland is a CMS in DCP or MRP.

**3) Products which have been granted a marketing authorisation when Iceland is a CMS in a DCP/MRP**

For type IA and IB variations which do not affect the Icelandic marketing authorisation, no fee will be collected by the Icelandic Medicines Agency.

For grouped variations there will be a 10% discount of the total amount for the application.

**4) Increase in the number of medicinal products marketed in Iceland**

The Icelandic Medicines Agency has been working for several years to increase the number of marketed products in Iceland, for both human and animal use. The aim has primarily been to fill gaps in the pharmaceutical market and reduce the risk of supply problems while increasing competition.

Icelandic Medicines Agency provides the following resources, that applicants can apply to receive, to support this:

*0 day process:*

A request for a simpler application process for a medicinal product can be submitted. Each request is examined separately with regard to whether the medicinal product in question is approved to undergo a simpler application process and a possible reduction in fees. The request shall be sent to the Icelandic Medicines Agency@lyfjastofnun.is

*Administrative/shortened renewal: Generic medicinal products*

When an application for a shorter renewal process is submitted and all applicable conditions are met, a 20% discount on fees can be requested. The application is submitted by writing, the following in the “free text field” of the cover letter for the application:  “For this administrative renewal we apply for a  20% discount”.

*Annual fees:*

It is possible to apply for a medicinal product to be exempt from the annual fee if it meets the following conditions:

* Information about the medicinal product must have been included in the pharmacopoeia on the previous 31 December.
* No medicinal product marketed in Iceland can replace the medicinal product in question.
* The total turnover (wholesale price w/o VAT) of all pharmaceutical form/strengths of the medicinal product in the previous year is less than ISK 1,800,00.

To apply for the above resource, applicants must fill out a [form: „Application for reduction of annual fee“.](https://www.lyfjastofnun.is/utgefid-efni/eydublod/#q=ums%C3%B3kn%20um%20l%C3%A6kkun%20%C3%A1rgjalds)

A completed form together with the applicant's cover letter must be sent to the Icelandic Medicines Agency af between 1 January and 20 January each year. No exemption from the annual fee will be granted for applications received by the Icelandic Medicines Agency after that time.

Each cover letter may be accompanied by application forms for medicinal products from the same marketing authorisation holder. Each form may cover all strengths of a single pharmaceutical form.

The application must include information on the turnover of the medicinal product in the previous 2 years. Turnover refers to the total wholesale value of all packages of all pharmaceutical forms and strengths of the pharmaceutical form in question, excluding VAT.