Lyfjastofnun
Icelandic Medicines Agency

15/3/2023

Rules on reduction of fees according to Tariff no. 1554/2022

According to Article 18 of Tariff no. 1554/2022 for marketing authorisations, annual fees and other licence fees for medicinal 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 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 packaging 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 packaging 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 packaging 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>."

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

Until 31st of January 2024, 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) Discount for RMS registrations with no CMS and the medicinal product is marketed

When a marketing authorisation is granted and Iceland is registered as RMS and no CMS is registered in the process, the Icelandic Medicines Agency collects a registration fee as in the case of a nationally registered medicinal product. Granting of a discount in accordance with this provision is conditional on the relevant medicinal product or products being marketed in this country. A condition for this is that this is stated in the cover letter when applying for changes in variations for these marketing authorisations.

5) 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 medicinal 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.

The 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 lyfjastofnun@lyfjastofnun.is

Fee for marketing authorisation for a medicinal product in a 0-day process:

If the medicinal product that is the subject of the application is listed in the tariff as an exempt medicinal product (or a comparable medicinal product; same active ingredient, pharmaceutical form and strength (formulation)) and has been approved for marketing authorisation through a 0-day process, a discount of 30% is granted on expense item 2.17 which applies to a 0-day process in the tariff.

Fee for changes in variations of a medicinal product that has been granted marketing authorisation in a 0-day process: Fees for changes in variations for medicinal products that are granted marketing authorisation in a 0-day process and have been in use in the exemption system will be independent of the number of strengths within the marketing authorisation, i.e. only one fee will be collected for the change even if it has an effect on more than one strength of the marketing authorisation. This applies while the medicinal product is the only one of its kind on the market. If another comparable medicinal product is put on the market this ceases to apply.
The 0-day process fee only applies to the strengths of the medicinal products that are marketed.

Administrative/shortened renewal: Generic medicinal products
In cases where an application is made for a shorter renewal process and all conditions regarding such process are met, a 20% discount on fees may be requested. Such request is submitted by writing "For this administrative renewal we apply for 20% discount" in the free text field in the cover letter with the application.

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 forms/strengths of the medicinal product in the previous year is less than ISK 1,800,000.
- The pharmaceutical form/strength for which a reduction of the annual fee is requested was on the market (available) in this country for the entire previous year.

To apply for the above resource, applicants must fill out the form: "Application for reduction of annual fee".

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A completed form together with the applicant's cover letter must be sent to the Icelandic Medicines Agency 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 means the total wholesale value of all packaging within the marketing authorisation number of the relevant medicinal product, VAT excluded.

This document is a translated version of the Icelandic Reglur um lækkun gjalda samkvæmt gjaldskrá nr. 1554/2022. If there are any discrepancies between versions, the Icelandic document should be considered valid.