Lyfjastofnun
Icelandic Medicines Agency

22. April 2020

Rules concerning reduction of fees collected in accordance with Tariff No 1142/2019

According to Article 12 of Tariff No 1142/2019 for marketing authorisations, annual fees and other licence fees for medicinal products and other related products, collected by the Icelandic Medicines Agency, the Agency can reduce 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 pure national marketing authorisation was granted before 1 January 2000, including additional pharmaceutical forms and strengths of these products, which have been granted a pure 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. Additionally, it must be stated in the cover letter 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 there."

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

Until 31st of January 2020, 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.