Publication of information in the Icelandic Medicinal Product Information Database and the Icelandic Medicine Price Catalogue

What is important to consider when applying for publication?

Filling the form:

When requesting publication of information about medicinal products in the Medicinal Product Information Database and the Medicine Price Catalogue, here after Medicine Catalogues (MCs), a specific application form shall be completed and sent by email to the Icelandic Medicine Agency (IMA) birting@lyfjastofnun.is

Timelines

- Request for publication shall be sent at least one month before the intended publication in the MCs. The same rule applies to changes which are to be published in the MCs, e.g. a new pharmaceutical form, new strength, new pack size/type, new Nordic article number etc. If a request is made with a shorter notice than one month, e.g. to prevent medicine shortage, arguments for a shorter notice is needed with the request.

Request for publication of the change from a prescription medicine (Rx) to an over-the-counter medicine (OTC)

If the Nordic article number is unchanged:

- The supplies of the Rx packages shall be recalled from pharmacies before the OTC packages are distributed to pharmacies. A confirmation shall be sent to ima@ima.is when the recall process is finalized.

If the Nordic article number is new:

- A request to withdraw information from the MCs about the Nordic article number of the Rx package needs to be sent to the IMA. At the same time, a request to publish the new Nordic article number in the MCs shall be sent to the IMA. Guidelines on withdrawals/deletion on the IMA website: Withdrawals - Icelandic Medicines Agency (ima.is)
- It is allowed to sell the Rx package, according to a prescription from a physician, for up to three months after a withdrawal request from the MCs has been sent to the IMA.

Request for a publication of a new product name

A. **The Medicinal Product Information Database** – When a Marketing Authorization Holder (MAH) applies for a changed name (application IB), it has to be decided when the change shall take effect, e.g. when the new name shall be published in the Database (implementation date), and estimated when the package with the prior name is out of stock. New name will

be published in the Database according to the implementation date stated in the application. If the MAH does not select an implementation date, then the new name will be published in the Database at the date of the approval of the application for a changed name (application IB).

B. **The Medicine Price Catalogue** – MAHs need to request for a publication in the Catalogue before a package with a new name is marketed. The option "New name of medicinal product" shall be selected in the application form „Application for publication in the Drug Cataloge and the Price List".

When can a product be dispensed?

To make it possible for retailers to have a new product on stock in the beginning of the month, it is allowed to distribute the new product to retailers if the marketing authorization is approved and a request for publication has been made in the Price Catalogue for the next month.

When may a medicinal product be marketed and sold at retail level?

Prescription medicine

The marketing of prescription medicinal products is permitted once information on the product has been published in the Icelandic Medicines Register (Sérlyfjaskrá) and in the current Medicines Price List, provided that the product complies with the conditions of the Icelandic marketing authorisation. New medicinal products, pharmaceutical forms, and pack sizes are published in the Medicines Register at the beginning of each month, and the Medicines Price List enters into force on the first day of each month.

In exceptional cases, it is possible to apply for an exemption from this provision:

• An exemption for advertising (promotion) may be granted once the Icelandic Medicines Agency has approved the maximum wholesale price (MWP) and can confirm that information on the medicinal product will be published in the next edition of the Medicines Price List.

• Exemptions from the requirements for authorisation to sell are granted only in cases of medicine shortages where no equivalent medicinal product is available.

• Application for exemption – a reasoned request must be submitted through the Icelandic Medicines Agency website: Contact us → Written inquiry → Pricing and reimbursement. It is important to specify if the request is urgent.

Non-prescription medicines

The pricing of non-prescription medicines is not regulated, pursuant to the Medicines Act and Regulation No 1414/2020.

The marketing authorisation holder is required to notify the Icelandic Medicines Agency of the date on which the actual marketing of the medicinal product commences in Iceland, pursuant to Article 81(1) of Regulation No 545/2018.

When submitting an application for the publication of a medicinal product in the Pharmaceutical Price List and the Specialities Register (marketing), the date on which the actual marketing of the non-prescription medicine commences must be provided in the **"Further comments"** field.

If this date changes after the application has been submitted, information on the revised date must be sent to **birting@lyfjastofnun.is**.

The sale of non-prescription medicines may commence before information on the medicinal product has been published in the medicinal product registers.