

## 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](mailto: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](mailto: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 \(ima.is\)](https://www.ima.is/Withdrawals)
- 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 Catalogue 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 can a product be marketed?**

It is allowed to market a product when information about the product have been published in both the Medicinal Product Information Database and the Price Catalogue: The Database is updated in the beginning of every month. The Price Catalogue is published two working days before the 1st of each month, and takes effect on the 1st of every month. List with the main changes between publications and specific reimbursement is published in addition.

The second Catalogue every month is published two working days before the 15th of each month, takes effect the 15th of every month, and contains only new information about new exchange rates and new exemption medicines. No new marketed drugs or changes are in the second Catalogue of every month. However, there is a possibility to correct the Catalogue if needed.

Exemptions from the above mention requirements will only be granted in cases of medicine shortages in opinion of the IMA and no equivalent medicine is available. In those cases, a reasoned request should be sent to [lyfjastofnun@lyfjastofnun.is](mailto:lyfjastofnun@lyfjastofnun.is) and state whether the matter is urgent.