

Work procedure for issuing a Medicine Price Catalogue

The Icelandic Medicine Agency (IMA) is in charge of the edition and the publication of the Medicine Price Catalogue (MPC), where e.g., the information on the maximum price and contribution of prescribed medicine for the humans and maximum price of all veterinary medicines.

Commission – for agents, marketing authorization holders (MAH) and wholesalers

Publication of new marketed medicine

The publication of new medicines must be applied for one month in advance, i.e., the application is made before the 1st of each month for medicine that should appear in the MPC at the end of the following month.

- Guidelines: "<u>Publication of information in the Medicinal Product Information</u> <u>Database and the Medicine Price Catalogue"</u>.
- Application form: "<u>Request for publication in the Medicine Price Catalogue and the</u> <u>Product Information Database"</u>,
- Example: Publication is requested by November 30th at the latest if publication is to be January 1st.

Publication of new exemption medicine

To publish a new exemption medicine in the next MPC, a price application is required to have received at the latest 4 working days before the entry into force of the Medicine Price Catalogue, 1st or 15th of every month.

• Application form: <u>"Umsókn um hámarksheildsöluverð – undanþágulyf"</u>



Removed from Medicine Price Catalogue due to lack of stock

- On the 15th of each month, or the next business day before, a <u>list is published</u> on the Icelandic Health Insurance Institution (IHI) on the medicines that have been listed out of stock for longer than 90 days. The medicine in question will be removed from the MPC at the end of the month. During the period 15th to 17th of every month a <u>list is published</u> on the IMAs website of the medicine that will be removed form the next MPC due to lack of stock.
 Example: the Icelandic Health Insurance Institution list was taken out on November 15th and the medicine were removed from the Medicine Price Catalogue as takes effect on December 1st.
- Agents, MAH and wholesalers are asked to look at the packages of the medicines in their administration, yet it is possible to request that the packages not be removed from the MPC if the supplies are expected before the end of the month. Such a request should be sent to the email address: verd@lyfjastofnun.is. The request must be received no later than 4 business days before the MPC change takes effects on the first day of each month.

Republishing in the Medicine Price Catalogue

For the medicines that have been removed from the MPC due to a lack of stock, must apply for re-publication before the 6th of each month to be able to be published at the end of the following month. In an emergency, it is possible to request to sell before the republished publication appears in the MPC. Example: A re-publication is requested before December 6th if the republication is to be on January 1st.

 Application form: <u>"Application for the republishing of information in the</u> <u>Medicine Price Catalogue"</u>.



Price change in agent price

During the period 1st – 10th of each month, it is possible to enter a price change on the agent price, which should appear in next month's MPC. The price change is entered via electronic portal on the <u>IMAs website (price access)</u> or by sending an email to <u>verd@lyfjastofnun.is</u>.

Publication of the Medicine Price Catalogue

MPC is published twice a month:

- First file of every month: Two business days before the 1st of each month, the MPC is on the IMA website and in web services. In addition, a list is published with major changes, in Icelandic "Helstu breytingar" and <u>conditional co-</u> <u>payment</u>, in Icelandic "Skilyrt greiðsluþátttaka".
- Second file of every month: Two business days before the 15th of each month, the MPC is available on the IMAs website and web services. The second file is published with a new exchange rate and new exemption medicine. No new marketed drugs or changes are in the second file. However, there is a possibility to correct the file if needed.

Medicine Price Catalogue rate

- <u>The Exchange Rate of the Icelandic Price Catalogue is published</u> four working days before 1st and 15th of each month. The exchange rate is used to update the MPC that comes in effect 1st and 15th of each month.
- Guidelines: <u>"Description as to how the currency rate for the MPC is calculated"</u>



Publication list

 During the period 11th – 12th of each month, a list is published on the website, <u>under news</u> "Ný lyf til birtingar í verðskrá", of the IMA that has been requested to appear in the Medicine Price Catalogue on the 1st of the following month.

Definition/Legal basis

The Medicinal Products Act no. 100/2020:

Only medicines for which the IMA has granted a marketing license are allowed to be marketed in Iceland. In the case of prescript medicine for humans, it is also a condition that the IMA has approved the maximum wholesale and retail prices and that information about the medicine is published in the Medicine Price Catalogue. The same applies to all veterinary medicines [Paragraph 1 Article 11].

Retailers, i.e., medicines wholesalers and marketing license holders who want to sell prescription medicine at a lower price than the maximum price states must report that price to Lyfjastofnun, which will publish the reduced price in the next edition of the Medicine Price Catalogue. The retailer must sell the medicine at the same price at all its outlets [3. paragraph, 4 tl., art. 66].

IMA manages the edition and publication of a Medicine exchange catalogue where generic medicine, biosimilar medicine and medicine with similar therapeutic effects are classified together in reference price categories for the determination of co-payment [Article 69, paragraph 2].