Determining the maximum wholesale price of medicines

Procedure

The Icelandic Medicine Agency (IMA) determines the maximum wholesale price for prescription medicines and all the veterinary medicines, but the pricing of the over the counter (OTC) for humans is free. A condition for the marketing of prescription medicines for human is that the IMA has approved a maximum wholesale price that information about the medicine is published on the Icelandic Medicine Price Catalogue (IMPC).

IMA bases decisions on the pricing of the medicine on a cost-effective basis, which is intended to promote a balance between medicine prices and an adequate supply of necessary medicines, considering the uniqueness of the Icelandic medicines market.

Since the pricing of veterinary medicines is free in the Nordic countries, it is not possible to compare prices in this country with prices in reference countries. The IMA therefore accepts the requested price of veterinary medicines. These procedures cover medicines for humans.

Glossaries

- **Maximum wholesale price, without VAT:** The highest possible price at which relevant package can be sold wholesale. It is not permitted to give a discount from the maximum wholesale price except by notifying the IMA, which will publish the lower price in the next edition of the Icelandic Medicine Price Catalogue as the agent's wholesale price and pharmacy purchase price. Those in charge of the procurement of medicines for the public sector are also permitted to tenser and/or enter into agreements on the purchase price of medicines which the public sector pays in full or in part.
- **Representative discount price, without VAT:** Pharmaceutical wholesalers/agents/marketing license holders who wish to sell prescription medicines at a lower price than the maximum wholesale price must notify the IMA. IMA publishes such a reduced price as the so-called agent wholesale price.
- **Pharmacy purchase price, without VAT:** The price of the relevant package from the wholesaler to the retailer, in some cases it is the same price as the maximum wholesale price, yet of the wholesaler/agents/marketing licensee has decided to grant a discount on the medicine, it is the same price as the agent's wholesale price.

- **Reference price, with VAT:** In each reference price category is based on the cheapest unit price in the category.
- **Maximum retail price, with VAT:** Is the highest possible retail price of the package in question. A discount may be given on the maximum retail price. Information on the maximum retail price is also published in the special medicine register.
- **Reimbursement price with VAT:** If the price is the same as the maximum retail price of the package in question, except in the case if OTC medicines, it is equivalent to the price at which Icelandic Health Insurance (IHI) co-payment is based.

Rules for pricing and criteria

The pricing of medicines elsewhere in the Nordic countries is considered, as further stipulated in this procedure. If a medicine has not been marketed in the Nordic countries, the IMA may use prices in other countries within the European Economic Area as a reference. If the price of a medicine in one reference country is significantly below the price recorded in other reference countries, IMA has the authority to exclude that country when calculating the average price, e.g., in cases of temporarily abnormally low prices.

The reference countries are Denmark, Finland, Norway and Sweden. Information about prices in the countries is obtained from the Icelandic Medicine Price Catalogue of the respective country as well as other sources, which are detailed in the procedure for each category separately and on the website of the IMA. The Icelandic Medicine Price Catalogue rate on the application date is taken into account.

The IMA determines the maximum wholesale average price of the medicine in reference countries. When determining the maximum price of Specialty Care High Cost Medicines (SCHCM), the organization takes into consideration the lowest wholesale price in the reference countries yet is permitted to accept a higher wholesale price if price agreements have been reached with National University Hospital of Iceland that ensure that the purchase price lower than the lowest price in the reference countries. In special circumstances, IMA decides to accept the maximum wholesale price temporarily, e.g. if there is no standard or if there is a temporary severe shortage of medicine. A more detailed explanation is given below, divided into two main categories, one is medicines that are marketed and second is medicines that are not marketed.

MARKETED MEDICINES

General medicines – Reference medicine

- The price of the requested medicine is compared with the price of the same medicine in reference countries. The price of the requested medicine must not be higher than the average price of the medicine in the reference countries. If the price of a medicine in one reference country is significantly below the price recorded in other reference countries, the IMA is authorized to exclude that country from the calculation of the average price.

General medicines – Generic medicine

- The price of the requested drug is compared with the price of the same generic medicines on the market in reference countries. The average price of all generic medicine in each country is calculated and then the average of the countries is taken. The price of the requested medicine must not be higher than the average price of generic medicines in one reference country is significantly below the price recorded in other reference countries, the IMA is authorized to exclude that country from the calculation of the average price.
- If the generic medicine is the only generic medicine on the market in this country, the same rule applies as for the pricing of generic medicine, compare above here above, the price of the requested medicine is compared with the price of the same medicine from the same marketing authorization holder.
- If the generic medicine is the only generic medicine on the market in this country and is not available from the same marketing license holder in the Nordic countries, the requested price is accepted if there is no reason to compare with prices in other countries within the European Economic Area.

Specialty Care High-Cost Medicine - reference medicines & biologics

- The price of a medicine applied for is compared with the price of the same medicine from the same marketing authorization holder in reference countries. The price of the medicine applied for must not be higher than the lowest price of the medicine in the reference countries. Of the reference price of the medicine in the reference countries. If the reference price of a licensed medicinal product in one reference country is significantly below the price registered in other refence countries, the IMA may aim at the lowest price in the reference countries.

- The IMA is authorized to accept a higher price than the lowest price of the medicine in reference countries if National University Hospital of Iceland has confirmed a contract for the purchase of the relevant medicine that guarantees that the purchase price of the medicine is lower than the lowest price in reference countries. The higher price is published in the Icelandic Medicine Price Catalogue when the contract comes into effect.

Specialty Care High-Cost Medicine – Generic medicines & biosimilars

- The price of the requested medicines is compared with the price of the same generic medicines/biosimilar equivalent on the market in reference countries. The price of the requested medicine must not be higher than in the reference country with the lowest average price of generic medicines/biosimilars analogues. If the reference price of a Specialty Care High-Cost Medicine in one reference country is significantly below the price registered in other reference countries, the IMA may aim at the next lowest price in the reference countries.
- The IMA is authorized to accept a higher price, although not higher than the average price of the medicine in reference countries, if agreements have been reached with National University Hospital of Iceland for the purchase of the relevant medicine that ensure that the purchase price is lower than the lowest average price in the reference countries. The higher price is published in the Icelandic Medicine Price Catalogue when the contract comes into effect.
- If a generic medicine/biosimilar analogue is the only generic medicine/biosimilar on the market in Iceland, the same rules apply as for the pricing of licensed original medicine/biosimilar compare above, i.e., the price of the requested medicine is compared with the price of the same medicine from the same marketing authorization holder.
- If the licensed generic medicine/biosimilar is the only generic medicine/biosimilar on the market in this country and is not available from the same marketing license holder in the Nordic countries, and the IMA believes that other countries within the European Economic Area should not be targeted, the requested price is accepted.

Parallel imported medicines

- Parallel imported original product: Price of the parallel imported medicines should be lower than the original product in Iceland.
- Parallel imported generic medicine: The price of a parallel imported generic medicine must be lower than the price of the corresponding registered medicine in Iceland (on which the registration is based). If the corresponding medicine is not marketed, the price of the parallel

imported drug must be lower than the average price of the corresponding generic medicine in the respective reference price category in this country.

Over the Counter (OTC) with reimbursement

- For an OTC medicine to receive a reimbursement following an application, there must be approved price that appears in the Icelandic Medicine Price Catalogue in the column *reimbursement price* at the Icelandic Medicine Price Catalogue.
- The basis for determining the price of the requested medicine is a comparison of the price of the same medicine from the same marketing authorization in the reference countries. The price of the requested medicine must not be higher than the average price of the medicine in reference countries.
- The pricing of OTC medicines is free in the Nordic countries, so information on the websites of the largest pharmacy chains in each country is generally used as a basis.

Concession for low-turnover and cheap marketed medicines – New, comes into force on September 1st, 2023, which means that applications received after 1. September will take their rules into account. The applications received before that time follow the old procedure.

If the annual turnover of pharmaceutical package is estimated to be below 7 million ISK, then it is allowed to request up to 15% higher price than the IMA procedures states, provided that the annual turnover with surcharge does not exceed 7 million ISK. If the maximum wholesale price of the respective pharmaceutical package is 1.333 ISK or lower, it is permitted to request 200 ISK load, instead of a 15% higher price.

If a pharmaceutical package is already marketed, it is based on the annual wholesale turnover. In the case of a new medicine, it is based on the estimated sales given by the marketing authorization holder/agent.

Concession for marketed antibiotics, ophthalmic drugs, drugs mainly intended for children and other drugs that are in short supply and necessary on the market at any time - New, takes effect on September 1st, 2023, which means that the applications received after September 1 take this into account rules. The applications received before that time follow the old procedure.

For the following generic drugs (non- Specialty Care High-Cost Medicine), it is permitted to request up to a 20% higher price:

- Anti-infective medicines in ATC classification within J01
- Ophthalmic drugs within ATC category S
- Medicines in dosage forms mainly intended for children, e.g., oral and rectal styles

If there is a serious problem regarding access to a necessary medicine, it is allowed to request a higher price if the application is accompanied by justification and cost data supporting the requested price.

The IMA evaluates each application individually, i.e. considering the maximum wholesale price, annual turnover, shortage of medicines in Iceland as well as in reference countries and equality between parties on the market.

MEDICINES WITHOUT MARKETING (Exemption medicine)

Exemption medicine (Medicines sold without marketing authorization / medicines with marketing authorization but not marketed) – New, takes effect in September 2023, which means that the applications received after September 1, 2023, take these rules into account. The applications received before that time follow the old procedures.

For exemption medicines, the rule generally applies that it depends on the type of medicines (e.g. original product, generic medicine or biosimilar etc.), but in addition, the decision on the price of the exempt medicines depends on the whether the exempted medicine is intended to solve a temporary serious shortage of medicines or an urgent need at the need at the request of National University Hospital of Iceland and however, depending on estimated annual turnover.

A. The exemption medicine displaces temporary serious shortage of medicines in the opinion of the IMA and or is rapidly transported to the country following an urgent request from National University Hospital of Iceland and is not classified as a Specialty Care High-Cost Medicine.

Estimated turnover	
0 – 1.5 million ISK	The asking price is accepted if the estimated annual turnover is below 1.5 million. ISK.
1.5 – 5 million ISK	Prices up to 30% higher than in reference countries are accepted.
5 – 7 million ISK	Prices up to 20% higher than in reference countries are accepted.
>7 million ISK	If the estimated annual turnover is over 7.0 million ISK is allowed a 2% higher price than in the reference countries.

B. Exemption medicines other than those specified in point A. E.g. Medicine in regular sale and licensed medicines

Estimated turnover	

0 – 1.5 million ISK	The asking price is accepted if the estimated annual turnover is below 1.5 million ISK
1.5 – 7 million ISK	Prices up to 15% higher than in reference countries are accepted.
>7 million ISK	The same price as in the reference countries cf. regulations for marketed medicines

If the same/comparable exempt medicine is already on the Icelandic Medicine Price Catalogue, the requested price must follow the guidelines that apply at the time of application, except if the exempt medicine is in the price list is at a lower price than the standard, then the maximum price list applies.

The price of exempt medicines in the Icelandic Medicine Price Catalogue is re-evaluated regularly.

EXECUTION

Application

- **Application for Maximum wholesale price, without VAT (MWP) for a new medicine/price increase of a marketed medicine:** marketing authorization holders/agents apply for MWP to IMA on a form provided on the organization's website, with necessary information, and send to the email address: verd@lyfjastofnun.is. In the case of an application for concession, the applicant must justify the requested increase.
- **Notification of reduction of MWP:** The same form cannot be used for a new medicine and send it to the email address: verd@lyfjastofnun.is.
- **Notification of agent's wholesale prices:** Information can be sent about reduced prices (discounted by MWP) through the IMA electronic price access or by e-mail to the email address verd@lyfjastofnun.is. Price changes must be submitted in the period first 10 days of each month for prices to be published in the next month's Icelandic Medicine Price Catalogue.

Procedure / Application processing time

The IMA's decision on medicine price must be available and communicated to applicant no later than 90 days after the application has been received. If the applicant has not included the necessary information with the application, IMA informs what information is missing and the decision of IMA must be available and communicated to the applicant no later than 90 days after the necessary

additional information was received. If a decision is not made within this time limit, the applicant is permitted to market the medicine at the price applied for.

If an unusually large number of applications for price increases have been received by IMA, the deadline can be extended once by 60 days. The applicant must be notified of such an extension before the deadline set by the IMA for decision-making has passed. If a decision is not made within this time limit, the applicant may increase the price according to the application.

If IMA does not agree to the requested official price or price change, the agency must justify its decision and inform the applicant of his authority to take the agency's decision to court.

Publication of decisions on medicines prices

The Icelandic Medicine Price Catalogue includes, among other things, published information on the price of prescription-only medicines for humans and all veterinary medicines, see the section on glossaries above. In addition, Icelandic Medicinal Product Information Database contains information on the maximum retail price.

Other

Price freeze

The IMA is authorized to apply a price freeze. If a price freeze is applied to all medicines or medicines in special category, the decision must be reviewed at least once a year. An exemption from the price freeze may be granted in accordance with the application in certain cases.

Reassessment

The IMA can review previous decisions on the maximum price of medicines, either at the request of interested parties or on its or on its own initiative considering changed circumstances or added information. The IMA must reassess the assumptions for medicine prices in this country compared to the same drugs in reference countries regularly and no less often than every two years and make proposals for changes if the assessment warrants it. All decisions that lead to a reduction must always be announced at least months before they are implemented.

Consultation

When IMA makes general decisions on the maximum wholesale price of prescription medicines, the agency must consult with representatives of wholesale license holders. When IMA makes general decisions on the maximum price of veterinary medicine, the agency must consult with representatives of veterinary associations.

Legal basis

Paragraph 1 in Article 6, paragraph 1 in Article 11 and XV. section of the Medicines Act no. 100/2020. Regulation no. 1414/2020 on the pricing of medicines and co-payment of medicines.
