
# Icelandic Medicine Pricing and Reimbursement Committee

## Overview:

### The committee consists of five members

- The Chairman is appointed by the Minister of Welfare.
- One member is appointed by the Icelandic Health Insurance.
- One member is appointed by the Icelandic Medicines Agency.
- One member is appointed by the Directorate of Health.
- One member is appointed by the Ministry of Finance.

**Regular meetings of the committee are twice a month on Mondays:**

**When the committee makes general decisions concerning:**

- Wholesale price - Representative from the Association of Medicine Wholesalers takes a seat in the committee.
- Retail price - Representative from the Association of Pharmacists takes a seat in the committee.
- Retail price for veterinary medicine - Representative from the Icelandic Food and Veterinary Authority takes a seat in the committee.

### The committee's decisions are on:

- Reimbursements.
- Wholesale pricing.
- Specialty care high-cost medicines
- Joint application, Reimbursement and Price.
- Retail Pharmacy mark-up.
- The committee is also responsible for the Icelandic drug price catalogue, published every month.

In the pricelist are the maximum wholesale price, wholesale discount price, reference price and maximum retail price.

The price catalogue can be found on the committee website www.lgn.is

See: Guidelines concerning publication of information in the Drug Catalogue and the Price List

And also: Application for publishing in "Medicine Price Catalogue" and "Medicinal product information catalogue

### When reimbursements decisions are taken the following is evaluated:

- Safety of the drug.
- Clear indication and place in therapy.
- Price is relative to efficacy and in comparisons to already reimbursed drugs.
- Budget impact – how many patients for how long.
- Hospital drugs do not have general reimbursement and therefore are not applicable.

New application and decision process for Specialty care high-cost medicines was introduced in May with a clinical and economical evaluation done in co-operation with the University hospital and National Insurance.

### When decisions are taken for Specialty care High-cost medicines the following is evaluated

- Price is relative to efficacy and in comparisons to comparator
- Budget impact – how many patients for how long.
- Clinical and economical evaluation and decision done in co-operation with the University hospital and Icelandic Health Insurance

See: Application form for Specialty care high-cost medicines

Cover letter
1. part-Clinical-evaluation
2. part-Economic-evaluation

**Pricing decisions**

- Over the counter drugs (OTC) - pricing is not regulated.
- Prescription drugs (POM) - wholesale price is regulated. The committee sets a maximum wholesale and retail price. Discounts can be given from retail price but not from wholesale price.
- The law requires cost containment measures. Therefore POM prices are externally compared to prices in Denmark, Finland, Norway and Sweden. Hospital prices are compared to the lowest price in the same four countries.

**Cost containments responsibilities of the Committee**

- The Committee is to monitor the wholesale and retail pricing of medicines in the country and compare them with comparable medicines in the four other Nordic countries.
- The Committee may do a review of previously determined maximum wholesale and retail prices.
- The Committee may do a review of previously determined reimbursements of an individual drug or a therapeutic group.
- The Committee may do a review of the retail mark-up.

Price comparisons are done regularly on wholesale price and retail price.

Wholesalers' prices are reviewed and adjusted at least every two years.

Wholesale prices in the price list can be connected to a foreign currency and will change monthly accordingly.

The committee decisions cannot be altered by the Ministry of Welfare and any disputes have to be taken up in the court of law.

All of the committee decisions can be reviewed with due cause.

**See laws and regulation regarding the committee and its decisions:**

Medicinal Products Act, No. 93/1994

Rg. 353/2013 um lyfjagreiðslunefnd

**Price application and decisions:**

Importers and producers as well other representative's agents are required to apply for a maximum wholesale price to be able to sell pharmaceuticals in Iceland, see chapter XIV of the Law of Pharmaceuticals nr. 93/1994.

The committee determines maximum price for prescription medicines and all veterinary medicines both at the wholesale and the retail level.

**Types of price decisions:**

1. Original products.
2. Parallel imported. (PI).
3. Generics.
4. Hospital product and Specialty care high-cost medicines.
5. Changes in prices.

There is no wholesale mark-up in Iceland but wholesale prices on prescription drugs are determined by an external price reference to the Nordic countries.
All pharmaceuticals are categorized into hospital products, original products, parallel imported products and generics, as the pricing varies for these categories.

**Original products:** price is compared to the average price on the corresponding original product in the reference countries (Nordic countries).

**Generics:** price is compared to the average price of the corresponding generics in the reference countries (Nordic countries).

**Parallel imported products:** Price should be lower than price on the corresponding original or generic product in Iceland.

**Hospital product and Specialty care high-cost medicines:** price may not exceed the lowest price of the four Nordic countries.

The external reference countries are the four Nordic countries: Denmark, Finland, Norway and Sweden.

Timeframe for price decisions and price increase request is: 90 days.
Price reductions can be done electronically in the price list or by application and they have to be submitted before the 10th. of each month to be in pricelist for the following month.

**See application form in English for prescription drugs for out-patients and application form in English for hospital drugs ( S-merkt lyf)**

**Reimbursement application and decisions:**

Main considerations when granting general reimbursements are:

- Safety of the drug.
- Clear indication and place in therapy.
- Pharmacoeconomical issues, e.g. price in relation to efficacy, price and efficacy of comparator.
- Budget impact e.g. rate and incidence of the decrease in Iceland and cost of comparator therapy.

Following are the criteria evaluated for general reimbursement of a new medicinal product.

1. If the medicine is safe and has significant clinical effect on clearly on well defined indications.
2. If the price of the medicine is relative to efficacy
3. Anticipated sales volume to estimate budget impact

General reimbursement for a medicine is not approved if the drug has a broad spectrum of indications and if a part of those is not entitled to reimbursement according to the law.

Furthermore, a drug is not entitled to general reimbursement if:

1. There is an obvious risk for that it can be used for other purposes than the approved indications.
2. The drug is used, only or mainly, for purposes which are not entitled to general reimbursement .
3. The effect of the drug has not been clinically confirmed.
4. It is not clear if or when the drug is a first choice in therapy.
5. The drug is mainly used at hospitals.

There is no English application form for reimbursement but a reimbursement application should at least contain:

- The drugs SPC.
- Information on reimbursement status in the other Nordic countries.
- Information on budget impact in Icelandic settings e.g. number of patient estimated and comparator(s).
- Sales forecast for the next three years based on the above.

The committee can request further information from the applicant.
Preferred is a covering letter with the application clarifying the use of the drug in Icelandic settings.

Timeframe for reimbursement decision is: 90 days.
Timeframe for joint application for reimbursement and Price are 180 days.

**All Generics and Parallel imported products receive the same reimbursement status as same Original product.**

Applications forms of the committee have been reviewed and an electronic application system constructed.
Price and reimbursement can be applied for separately or joint.
Approved price is based on external price reference.
Reimbursement is based on clinical and economical value of the drug to its comparator together with the forecasted budget impact.

**Retail pharmacy mark-up:**

Maximum retail mark-up for pharmacies is set by the Icelandic Medicine Pricing and Reimbursement Committee in two steps:

1. Products with wholesale price <11.999 kr, (€ 78)[1], retail mark-up is 9% plus 868 kr. (€ 5,56 )
2. Products with wholesale price above 12.000 kr. (€ 78 ), mark-up is 2.255 kr. (€ 14,45 ). VAT of 25, 5% is then added.

[1] May 2104 exchange rate € 1 = 156,045 kr.

The retail mark-up for medicines with wholesale price up to € 78[2] is 9% mark-up plus a € 5,56 handling fee. All other medicine have a handling fee of € 14,63 .

For hospital products ( s-merkt lyf) the retail pharmacy mark-up is as follow:

1. For products with wholesale price 0-10.000 kr. (€ 64 ), the retail mark-up is 15%.
2. For products with wholesale price above 10.000 kr. there is 1.500 kr. (€ 9,6 ), dispensing fee. VAT of 25, 5% is then added.

The mark-up for hospital medicines with wholesale price up to € 64 have a 15% mark-up. All other hospital medicine have a handling fee of € 9,6 .

**Current co-payment system:**

A new co-payment system was implemented on the 4th May 2013.
Now the co-payment is a proportion of 12 month usage and not based on the category of the pharmaceutical used (ATC-code) as previously. This means that there will be a step-wise increase in co-payment by the Icelandic Health Insurance up-to a full reimbursement. Maximum annual payment for adults is € 445 and for elderly, for children, disabled and adults over 67, the annual cap is € 296 .

See regulations regarding copayments by the Icelandic Health Insurance

Act on Patient Insurance, No. 111/2000

Rg. 353/2013 um greiðsluþátttöku sjúkratrygginga við kaup á lyfjum

Reglugerð um gerð lyfseðla, áritun og afhendingu lyfja nr. 91/2001

Rg. 091/2001 Reglugerð um afgreiðslu lyfseðla, áritun og afhendingu lyfja

[2] May 2104 exchange rate € 1 = 156,045 kr.