

Reimbursement decisions

When reimbursements decisions are taken the following is evaluated:

- Safety of the drug.
- Clear indication and place in therapy.
- Price in relation to efficacy and in comparisons to already reimbursed drugs.
- Budget impact – how many patients, for how long.
- Reimbursement in Denmark, Norway, Sweden and Finland.

All generics/biosimilar and parallel imported products receive the same reimbursement status as the same original product.

The law criteria for Specialty care high-cost medicines are.

- Costly.
- Challenging to administer.
- Only to be used according to clinical guidelines.

Clinical and economical evaluation for Specialty care high-cost medicines are done in co-operation with the University hospital and Icelandic Health Insurance

Application forms can be found on our website www.verd.lyfjastofnun.is

Pricing decisions.

IMA determines maximum price for prescription medicines and all veterinary medicines both at the wholesale and the retail level. Discounts can be given from retail price but not from wholesale price.

The law requires cost containment measures. Prices of prescription medicines are compared to prices in Denmark, Finland, Norway and Sweden. Prices for over the counter drugs are not regulated.

All pharmaceuticals are categorized into hospital products, original products, parallel imported products and generics/biosimilar, 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).

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

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

Specialty care high-cost medicines: Price is compared to the lowest price in the reference countries (Nordic countries).

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.

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 the medicinal products act no. 100/2020.

Price reductions can be done online 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.

Application form in English for pricing of prescription drugs and for pricing specialty care high cost medicine. <https://verd.lyfjastofnun.is/?pageid=5>

Timeframe for price decisions and price increase request is: 90 days.

Timeframe for reimbursement decision is, 90 days.

Timeframe for joint application for reimbursement and price are 180 days.

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 pricing and reimbursement:

Medicinal products act no. 100/2020. <https://www.althingi.is/lagas/nuna/2020100.html>

Regulation no. 1414/2020 <https://www.reglugerd.is/reglugerdir/eftir-raduneytum/hrn/nr/1414-2020>

Retail pharmacy mark-up:

Maximum retail mark up on prescription drugs is set in three steps:

1. Products with wholesale price 0-19.999 kr. the retail markup is 11% + 1.208 kr.
2. Products with wholesale price 20.000 - 99.999 kr. the markup is 2% + 2.640 kr.
3. Products with wholesale price above 99.999 kr. the markup is 0,3% + 5.251 kr.

Co-payment system:

The co-payment is a proportion of the annual usage There is a stepwise increase in co-payment by the Icelandic Health Insurance up to a full reimbursement.

<https://www.sjukra.is/english/social-insurance-in-iceland/medicine/>