Classification in reference price categories

Guidelines

The Icelandic Medicines Agency (IMA) classifies generic medicines, biosimilars and medicinal products with equivalent efficacy in treatment into reference price categories for determining health insurance co-payments. Additionally, medicines without payment contributions. The reference price categories are equivalence Medicine exchange catalogue.

Rules and criteria for interchangeability

Prerequisite for a medicine to be classified in a reference category is that the medicine holds a valid market authorization and is already marketed.

The exceptions are:

- Medicines that have an H-label in the Icelandic medicine price catalogue (IMPC) (medicines that are used in healthcare institutions).
- Medicines classified as Specialty Care High-Cost Medicines (SCHCM).
- Over-the-counter medicinal products (unless they have health insurance co-payments)
- Veterinary Medicines
- Exemption medicine

Procedure

Application for classification in reference price categories

- Application forms can be found here.
- Once an applicant applies for a price for a generic and or biosimilar medicine, application form "*Application for wholesale price*". the applicant must then specify which generic and or biosimilar medicine the medicine is interchangeable with. IMA can request for justification if necessary.
- If specifying a similar medicine in the price application fails, it is possible to request after the classification of medicine in reference category when applying for publication in the Icelandic Medicine Price Catalogue, application form *"Request for publication in the Price Catalogue and the Product Catalogue*". This is done by selecting in the form "*Request for the product to appear on the substitution list, substitutable product:*". If IMA

believes that there is a doubt as to whether the concerned medicine is interchangeability it may not be possible to comply with a request for classification in a reference price category at the time of publication.

- An agent or marketing authorization holder (MAH), Drug Therapeutic Committee (DTC) at the National University Hospital (NUH) and Icelandic Health Insurance (IHI) can request for a medicine that is already listed in the Icelandic medicine price catalogue to be classified in a reference price category. Such a request must include a justification and other necessary documents, the request should be sent to the following email address: verd@lyfjastofnun.is
- IMA has the authorization to arrange the medicines in referenced price although the applicant had not requested it.

Assessment of interchangeability

Every medicine is evaluated separately. The medicines are usually classified together in reference price categories if medicines have same active ingredient, the same strength, with same dosage form and if the medicine are bioequivalent. Although if these conditions are fulfilled, other factors such as narrow therapeutic index can cause medicine not to classified together.

When assessing interchangeability, IMA considers the decisions that have been made in the reference countries that is, Denmark, Sweden, Norway, and Finland. The relevant information can be found on the websites for each country which are accessible at IMA website, https://www.lyfjastofnun.is/verd-og-greidsluthatttaka/upplysingar-nordurlondum/.

For IMA to consider a medicine interchangeable with another medicine, it is sufficient that it is interchangeable to the same medicine in one reference country yet interchangeability in one country does not mean that it will be interchangeable in Iceland. If there is a discrepancy between the decisions of pharmaceutical institutes in the Nordic countries or if doubts arise, a more specific evaluation of interchangeability is carried out.

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IMA categories medicines together into reference price groups in the following way:

1. Tablets/capsules – are grouped by quantity per package:
   - 1 – 30 pcs.
   - 31 – 249 pcs.
   - 250 pcs. or more.

   This classification generally applies to tablets and capsules, but there may be exceptions to this, e.g., when medicines have different indications, dosages, and treatment duration, such as certain antibiotics, antivirals, and antifungals.

2. Other pharmaceutical forms and devices, such as lotions, skin ointments, eye drops, nasal sprays, transdermal patches, and inhalants, those are only grouped together in a reference price group with the same strengths and package sizes. The pharmaceutical forms must be the same and the devices comparable.

3. Packages that are solely intended for dosage dispensing are arranged separately in reference price categories and are only arranged with other comparable packages which are intended for medicinal dispensing.

4. There are special rules for classification in reference price categories apply to addiction medicine due to dispensing restrictions.

If IMA is to deviate from the general rule cf. above, this will be announced on IMA´s website together with justification and information regarding when the decision will take effect.

If an application to classify a medicine in a reference price category (application not linked nor attached to a price application) is approved, IMA then sends a confirmation letter to the agent responsible for the medicine in question inclusive of information as to when the decision will take effect.

If IMA considers rejecting an application for a medicine to be classified in reference price category/group, IMA then sends a letter regarding the possible rejection to the agent responsible for the medicine. The agent can send his objections to the possible rejection within two weeks of receiving the letter.

If IMA decides to reject an application for classification of a medicine in a reference price group, the decision must be justified and the agent responsible of the medicine must be informed of his authority to bring the decision of IMA before the courts.

IMA is authorized to review its decisions regarding the classification of a medicine in a reference price category.

Shortage of a medicine in the reference price category

Once a supply shortage is foreseeable of a medicine in the reference price category, the agent or MAH responsible for the medicine in question must notify IMA as soon as possible.

Once the shortage comes into effect, the Icelandic Health Insurance Institution (IHII) will automatically receive the update from the distributor´s supply systems and will accordingly co-pay in the next cheapest medicine in the same reference price category according to the applicable Icelandic Medicine Price catalogue.

If the shortage exceeds 90 days, the medicine in question will then be removed from the Medicine price catalogue at the end of the month. Please see further information in the guidelines of the procedure for removal of medicines from the Medicine Price catalogue due to lack of stock.

Medicine removed from reference price category

If medicine (one product number) remains in the relevant reference price category (e.g., due to the deregistration of another medicine), it is removed from the reference price category.

Payment to pharmacies for dispensing the cheapest medicines in reference price categories

Pharmacies get specially payments for dispensing the cheapest medicines in reference price categories if the cheapest medicine is chosen or with price less than 5% from the cheapest price. In the Medicine Price Catalogue it is stated which medicine is involved, the payments are made by Icelandic Health Insurance Institution.

Definition/Legal basis

The Medicinal Products Act no. 100/2020:

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).

When dispensing a prescription in a pharmacy, a pharmacist is permitted to change the doctor's prescription to another medicine in a similar quantity to the prescription, but only if the medicine is on the Medicines Agency's exchange list. The Medicine Agency shall maintain and publish on its website an exchange register were generic medicine, biosimilars and drugs that have similar therapeutic effects are grouped together (Article 52, paragraphs 1 and 4).

The Medicines Agency's exchange list appears in the drug price list as reference price categories.