

## Q&A on the maximum co-payment for medicines

### Introduction

From 1 January 2026, co-payments for certain medicinal products will be based on the maximum recommended dose according to the marketing authorisation of a medicinal product in Iceland. Where appropriate, approved clinical guidelines will also be used. If use exceeds the maximum recommended dose, no co-payment will be granted for the excess dose. The aim of the amendment is to promote a more responsible, safer and more efficient environment for the use of medicines, both for individuals and the healthcare system as a whole. First, such rules create incentives for users and those who prescribe prescriptions to adhere to the recommended maximum dose of medications. Second, the restrictions are important to reduce possible misuse, especially in the case of drugs that can cause habit or are prone to misuse. Finally, the rules promote better use of public funds and are intended to prevent the accumulation of medicine stocks beyond necessity as this can lead to waste and, in the worst cases, shortages of medicines.

### Questions and answers

#### 1. Why was it decided to set a limit on co-payment of medicines?

To ensure that co-payments are targeted at the doses that research and clinical guidelines have shown to be both safe and effective. The amendment aims to strengthen drug safety, prevent incorrect patterns of use, overuse and risks to the user's health. This contributes to a more responsible, safer, and cost-effective medication use environment.

#### 2. Where does the authorization for the maximum co-payment come from?

Provisions for this authorisation have been in place in the Regulation on Iceland Health Co-payment of Pharmaceutical Costs since 1 December 2013, cf. Regulation No. 313/2013. In February 2025, the Consultation Portal discussed sharpening this provision in the current Regulation No. 1143/2019 on Iceland Health co-payment of pharmaceutical costs. Subsequently, a regulation amendment was made that took effect on September 1, 2025.

#### 3. When does the change take effect?

The project will take effect on 1 January 2026. Drug use, which is the basis for assessing whether the maximum dose has been reached, is calculated from that time.

#### 4. Does the maximum co-payment apply to all medicines?

In the first phase, rules will be established on the maximum criteria for certain drug classes that have been selected according to the results of the risk assessment. The goal is to implement the maximum co-payment in stages. In the first phase, restrictions apply to medicines that Iceland Health analyses have shown to be used in excess of the recommended maximum dose, medicines where withdrawals in the medicine database are not in accordance with doctors' instructions for use, as well as medicines that experience shows are sold without a prescription in an illegal manner. In the first phase, special attention will be paid to the categories of drugs where waste or misuse has been assessed the most. Subsequently, further analyses will be carried out and drugs will be added in stages.

#### **5. Can medicines be dispensed in a pharmacy if the use exceeds the limit?**

The dispensing of medicinal products shall continue to be in accordance with Regulation No. 740/2020 on prescriptions and dispensing of medicinal products. The maximum co-payment only prevents medicines that are dispensed in large quantities from being subsidised by Iceland Health. Individuals can dispense medication at their own expense.

#### **6. How is co-payment calculated?**

When medicines are dispensed, the co-payment is calculated based on the individual's status in the co-payment system for medicines and on previous invoices that have been sent to the Iceland Health when dispensing medicines from the pharmacy.

At each dispensing, invoices (medicine withdrawals) are viewed three months back in time. When the total use during the period exceeds the maximum dose, the co-payment is cancelled and the individual pays for the excess dose. Drug use, which is the basis for assessing whether the maximum dose has been reached during the period, starts to be calculated from 1 January 2026.

#### **7. What dose is targeted?**

In general, this is based on the maximum recommended dose according to the marketing authorisation of medicinal products. If higher dose criteria are accepted based on evidence-based evidence, such as clinical trials or accepted clinical guidelines, these criteria are used.

#### **8. Could a person or pharmacy receive a back bill for a dispensed medicine?**

Co-payments are calculated in real time at the checkout. Therefore, there should be no back bill for medicines.

#### **9. Do pharmacies need to make changes to their systems?**

No, the function is automatic.

**10. Is it possible to pick up a larger amount of medicine when individuals go abroad?**

No, the maximum co-payment cannot be exceeded. In most cases, it is possible to have medicines dispensed abroad if needed. Iceland Health participates in the subsidy of medicines that have been purchased abroad if certain conditions are met. Participation in the payment of medicines abroad is as if it were a co-payment for medicines in Iceland, provided that the medicines are equivalent to the medicines covered by Iceland Health. If a medicine certificate is available, Iceland Health takes this into account when calculating co-payment. An application for reimbursement of foreign medical expenses must be sent to the International Affairs of Iceland Health, and the reimbursement is in accordance with the co-payment of medicines domestically.

**11. Is it possible to get an exemption from the maximum co-payment?**

In special cases, when urgent medical reasons require higher doses than the recommended criteria allow, the treating physician may apply for a drug certificate for higher doses. Evaluative considerations are not taken into account, but specific clinical cases that do not fit with the usual use of medicines. The treating physician must explain the reasons why there are urgent medical reasons for higher doses. The application must be submitted from a specialist in the relevant field. Laboratory results must confirm that the individual in question has a disease or that there is a condition that affects pharmacokinetics or other comparable physiological abnormalities that justify doses in excess of controls. The diagnosis should be confirmed by the appropriate laboratory data. It is also a requirement that the treating physician substantiates that the treatment is based on evidence-based medical knowledge. The application must refer to relevant studies or peer-reviewed sources that demonstrate that the treatment has been studied and is effective for the clinical problem in question.