

ESTONIA

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Prescription fee

Increase of prescription fee: 3.50 Euro (01.01.2025)

VAT changes

Medicines still 9%, everything else 22% and from July 2025 24%

Extemporaneous Medicines

We are proposing an amendment to the regulation on "Maximum Wholesale and Retail Mark-Ups for Medicines" to increase the limits for extemporaneous preparations.

Currently:

- Max **proportional mark-up**: 50% of ingredient and packaging costs
- Max **fixed mark-up**: €0.96 per sales package

The new approach would consider preparation time, pharmacists' average salary, facility costs, and set differentiated rates based on dosage form and quantity.

CHANGES IN REIMBURSEMENT

Expansion of Supplementary Reimbursement to Include Medical Devices (effective from 1 January 2025)

The existing supplementary reimbursement system will be expanded to cover the costs of discounted medical devices. The aim is to offer more comprehensive financial support to insured individuals who face higher healthcare costs throughout the year.

Discounting in pharmacoeconomics analysis (01.01.2025)

As of 2025, the discount rate has been reduced to 3.5% (previously 5%)

New Estonian Health Technology Assessment Guideline (01.01.2025)

- Innovative medicines with high added value
OS hazard ratio at least 0,6; EQ-5D improvement 30%; QALY gain 3 → If one of these criteria is met → accepting higher ICER
- „Me-too” medicine -10% if no added value compared to the existing alternative

Hospital medicines (01.01.2025)

No need for national clinical assessment if a reimbursement report from another country is available and applicable.

HTA reports (look below)

OTHER CHANGES

1. **The Digital Medication Plan will be introduced in early 2025**, consolidating the entire management of a patient's medications into the Health Specialist Portal. This includes the creation, modification, and cancellation of digital prescriptions, which will eventually be issued exclusively through the Medication Plan after a transition period. The system, implemented in two phases, will enhance safety, collaboration, and efficiency in healthcare by integrating both prescription and over-the-counter medications.
2. **Reimbursement for Extemporaneous Medicines in Estonia Planned for 2026**: In Estonia, extemporaneous medicines are not eligible for reimbursement. This issue particularly affects children and patients with swallowing difficulties, as these medicines can be expensive due to high raw material costs. Since suitable industrially manufactured medicines are not always available, pharmacy-prepared drugs may be their only option. To address this, regulatory changes are planned, including fairer compensation for pharmacists, with implementation set for 2026.

SPECIAL TOPIC:

Current advances in HTA

(for EU Member States: Implications from EU-HTA Regulation)

For EU Member States:

On 11 January 2022 the EU-Regulation 2021/2282 on health technology assessment (HTAR) was published and applies since 12 January 2025. It promotes a streamlined HTA process through Joint Clinical Assessments in the EU and stipulates the use of common assessment methodologies along the HTA pathway.

If an HTA report is submitted together with the reimbursement application (i.e. up to date), a separate clinical expert opinion will no longer be required — assessment will be based on the report. To simplify and speed up the process, applications and annexes can now be submitted in Estonian **or** English.

National assessment processes will be aligned with Regulation (EU) 2021/2282. Clinical joint assessment reports and other data submitted during the EU-level HTA process (available via the European Commission's IT platform) will be considered during reimbursement application review. This ensures applicants won't need to resubmit data already provided at the EU level.

Faster access – Efficient assessment – Evidence-based funding

The Ministry of Social Affairs allocated €4.2 million (2024–2027) to support treatment for rare diseases beginning in childhood. A new state program (from 2024) covers additional costs for: medicines, special nutrition and medical & supportive services.

In 2024, €4.26M was distributed via the State Shared Service Centre:

-  Tartu University Hospital Children's Foundation – €3,564,407
-  Tallinn Children's Hospital Support Fund – €546,632
-  Estonian Phenylketonuria Association – €152,654