

Sweden

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Sales volume will have an increased impact on the price of new medicines

In December 2024, TLV published a report on strengthened access to medicines for rare health conditions. A key outcome is that TLV will gradually begin to apply a developed practice where the expected number of patients and sales value will be taken into account to a greater extent in decisions on price.

[Report on practical prerequisites for strengthened access to medicines for rare conditions \(in Swedish\), TLV \(2024\)](#)

Increased ceiling prices for off-patented medicines had effect

In 2023, a large share of pharmaceuticals with competition, including many antibiotics, received an increased price ceiling through TLV's criteria-based decisions. An evaluation shows that:

- The conditions for access and availability of antibiotics have improved
- Further increases should be based on profitability assessments
- A sustainable price ceiling system can strengthen the access

[Assessment of increased ceiling prices for antibiotics, TLV \(2024\)](#)

CHANGES IN REIMBURSEMENT

A revised co-payment scheme will be implemented in July

The government has changed the design of the high-cost protection scheme for reimbursed medicines. The maximum co-payment for patients will be increased by approximately 30 percent, from SEK 2 900 to 3 800 (€ 260 to 350) for a 12-month period from the first purchase. Patients will pay the full price for medicines up to SEK 2 000 (€ 180) with the revised scheme, compared to SEK 1 450 (€ 130) today. The new scheme will be implemented in July 2025.

[An update of the high-cost protection scheme for pharmaceuticals \(Prop 2024/25:144\) \(in Swedish\), Government of Sweden \(2025\)](#)

OTHER CHANGES

TLV has adopted a new strategy that will influence all aspects of our work and guide us with a focus on the year 2030.

The starting point is TLV's mission of achieving *The best possible health for the taxpayers' money*. The direction describes what within the authority's culture that strengthens the ability to carry out our mission: trust, courage and simplification. In order to succeed with the authority's mission and the goals towards 2030, certain conditions also need to be met. These are described in the strategy. The strategic direction then points out the areas where we need to strengthen and develop the operations, through ten goals until 2030.

[Annual report 2024 \(in Swedish\), TLV \(2025\)](#)

SPECIAL TOPIC:

Current advances in HTA

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

Description of the HTA system in Sweden

For out-patient products SE has an application-based national system, where TLV conducts the HTA, including health economic assessment and decides on price and reimbursement. For in-patient products TLV conducts HTA, including health economic assessment on request from the Swedish regions. The New Therapies (NT) Council has the regions' mandate to issue recommendations on the use of medicines that are subject to [National Joint Introduction](#).

Out-patient sector-products under the HTA Regulation

Conducting HTA	Deciding on reimbursement	Basis for decision
TLV and/or SBU*	The Pharmaceutical Benefits Board at TLV decides on price and reimbursement.	National HTA report, based on joint assessment of relative effect (JCA) and national health economic evaluation from TLV Health economics at TLV

In-patient sector-products under the HTA Regulation

Conducting HTA	Issuing recommendations for use	Basis for recommendation
TLV and/or SBU*	The NT Council issues recommendations on use to the Swedish regions.	National HTA report, based on JCA, health economic assessment from TLV and the Ethical platform for prioritization

Implications of the EU HTA Regulation

From SE, SBU and/or TLV can participate in European Joint Clinical Assessments (JCA). For products launched in SE, TLV will conduct the national health economic assessment based on the relative effect presented in the JCA-report, when this information is available. TLV may collaborate with colleagues in [Joint Nordic HTA-Bodies](#), JNHB, when conducting health economic assessments based on a JCA-report.

* Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)