SLOVENIA

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

- no changes to the price determination system, still implementing regular semi-annual price reviews (ERP for all MPs financed from public funds – cca. 4.800) – ongoing,
- increasing number of applications for exceptional higher allowed price (EHAP) with the aim to have maximum allowed price not published (allowed according to legislation, but decreasing transparency),
- changes in the ERP model for biosimilars (100% of the lowest price of comparable biosimilar MP in any of the reference countries, 68% of the lowest price of the relevant reference biological MP if not on the market in any of RCs), leading to variable changes of biosimilar prices, but equalizing prices of comparable biosimilars (implemented from 3rd April 2021).

CHANGES IN REIMBURSEMENT

Positive list: 100 % covered by compulsory health insurance (3.350 MPs)

Intermediate list – cessation on 31. 12. 2023 due to changes in voluntary co-insurance.

Hospital/Ampullated drugs

List B (352 expensive MPs separately paid to hospitals for treatment for in-patients)

List A (205 MPs separately paid to all providers for out-patients including home treatment)

OTHER CHANGES

Legislation is being adopted regarding the national strategy for managing medicine shortages in the Republic of Slovenia. This legislation will regulate and unify protocols and measures concerning shortages. The adoption of the implementing act is expected in June 2025.

The measures currently being undertaken to address and/or mitigate medicines shortages include:

- identifying critical shortages in the supply of medicines and communicating with MAHs and other stakeholders to facilitate the import of medicines from other markets. Previously, communication was conducted through DHPC (Direct Healthcare Professional Communications). From April 2025, the communication channel MSC (Medicine Shortage Communications) will be implemented and used,
- implementing regulatory adjustments (such as foreign packaging and tax reliefs) and other adaptations (optimizing the OES approach and shortening deadlines in case of impurities),
- initiatives to other MAHs in other countries and calls for temporary medical authorizations,
- communicating with healthcare providers and at-risk groups regarding possible alternatives and other opinions.

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

In December 2024, a new Law on Quality in Healthcare entered into force and is in use since March 2025. With this law, a new Agency for Quality in Healthcare was established. The Agency is among others responsible for the HTA.

Currently, the Agency is not fully operational yet, so the established procedures in pricing and reimbursement have not changed accordingly. Elements of HTA are considered in pricing as well as in reimbursement procedures and decisions.

The main challenges in the adherence to the HTA regulation are currently the only recently established agency, the lack of expertise and human resources as well as the lack of established HTA procedures.