CZECH REPUBLIC

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Ministerial price decree: 1. 1. 2024, MoH

- General rules of price regulation, mark – ups levels
- Minor changes:
  - HIFs can apply for the maximum price, if the medicine is under the exceptional reimbursement (not set by SUKL)
  - Mark-up levels remain the same, but its distribution has been determined in maximum proportions between distributors and pharmacies.

Ministerial decision: 1. 1. 2024, MoH

- Deregulated ATC groups
- Deregulated ATC groups, if HIF signs a price contract with MAH

CHANGES IN REIMBURSEMENT

Measures to increased regulatory flexibility of entry of non-authorized medicines to the market and into the reimbursement system

- SUKL can temporarily set or change the maximum price and reimbursement conditions for essential medicinal products that are unavailable or at risk of becoming unavailable to ensure their availability for insured persons.
- The government can declare the reimbursement of a medicinal product as being in the public interest for public health protection.
- SUKL can take measures if it is in the public interest and certain conditions are met.
- For non-reimbursed medicinal products that are therapeutically interchangeable with unavailable reimbursed products, SUKL will set the maximum manufacturer price and reimbursement level. For already reimbursed medicines, SUKL will adjust the maximum manufacturer price and reimbursement level for up to one year.
- **The main principle is to maintain the same co-payment.**
- SUKL can issue measures ex officio or upon request from authorized persons.
- SUKL can terminate the validity of its measures earlier if the unavailability of reimbursed services no longer exists. SUKL informs the Ministry of Health about issued measures or decisions.

OTHER CHANGES

Mandatory ensuring of medicines supplies with set maximum price or reimbursement

- MAH are obligated to keep supplying medicine for 1-2 months after a notification of disruption of supply

Stock monitoring of medicines with „Limited availability" (in shortage and/or expected shortage)

- Physicians and patients have information about stock levels in individual pharmacies
- Pharmacist will have information about stock levels at distributor level
- **Timely limited export bans** for medicines with limited availability (in shortage and/or expected shortage)
- **Shortage management plan introduction by** MAH for medicines with limited availability
- Limited **stockpiling at pharmacy level according to consumption** for medicines with limited availability

Safety stock at distributor level for critical medicines (1 month)

- Intention to list first medicine groups (J01CE01, J01AB02, J01AB04)

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

HTA Process in the Czech Republic

The Health Technology Assessment (HTA) of medicines in the Czech Republic is managed by **the State Institute for Drug Control (SUKL)** and HTA plays a crucial role in pricing and reimbursement decisions:

1. **Assessment**: Manufacturers submit a dossier including clinical and economic evidence (cost-effectiveness, budget impact).
2. **Evaluation by SUKL**: SUKL assesses the added therapeutic value, cost-effectiveness and budget impact.
3. **Final Decision & Implementation**: If a technology is reimbursed, it is listed in the reimbursement list.

EU-HTA Regulation

The Joint Clinical Assessment (JCA) will be as fully as possible taken into account in the national HTA process. **The timing of reimbursement applications** in the Czech Republic will be a crucial factor. Delays in submitting national reimbursement applications may lead to outdated data (e.g. new comparators or recent clinical studies).

It is essential to have **sufficient professional and personnel capacities** for both the JCA and the national HTA agenda. it is generally challenging to recruit high-quality experts in the field of HTA. This difficulty stems from both the overall lack of such experts in the labor market and the need to compete with industry and other stakeholders for these limited resources.

Confidentiality, data protection and conflict of interest are also important topics, especially in relation to external stakeholders - clinical experts and patients. SUKL had signed the contract with medical society, where confidentiality and conflict of interest are the key points. Currently the similar contract with patient organizations is being developed.