

# Czechia

## Recent and planned developments in pharmaceutical policies 2026

### CHANGES IN PRICING

#### Medicinal Products Deemed Significant for the Provision of Healthcare designated by the MoH in a special decree (Act 289/2025 Sb., §39 (3) eff. 01/01/2026, Price Decree 2/2026/OLZP)

SÚKL sets the maximum manufacturer's price for **medicinal products at risk of shortages** using the following cascading hierarchy (each step applies only if the previous is not feasible):

1. Average of up to **7 (not 3) lowest** EU prices from the 18-country reference basket — requires presence in  $\geq 2$  basket countries
2. Average of prices across **EU Member States**
3. Price of the **closest therapeutically comparable product in CZ**
4. Average of **closest therapeutically comparable products** across the reference basket

Where multiple comparators exist, the lowest price for the same substance/form/strength applies, matched by closest package size.

#### Price Decrees Restructured (1/2026/OLZP, 24 Oct 2025)

Price regulation now issued as a general measure (OOP) → subject to judicial review for first time. Trade mark-up schedule unchanged but mandatory distributor-pharmacy split no longer applies to hospital-only products (Article V (3)).

### CHANGES IN REIMBURSEMENT

#### Comprehensive P&R Reform of Act No. 48/1997 Coll., on Public Health Insurance (Act 289/2025 Sb., eff. 01/01/2026).

Largest P&R overhaul since 2008. Amends Act 48/1997 Coll. across nearly all reimbursement provisions (§§39a–39n). Main changes:

- **Separation of P&R procedure for medicinal products (Part VI) from P&R procedure from Foods for Special Medical Purposes (Part VIII).**
- New P&R procedure for **medicinal products for immunization (§39db).**
- P&R procedure of **pharmaceutical products in combination with other pharmaceutical product** amended.
- **Implementation of the JCA Reports into national P&R procedures** (the EU HTA Regulation 2021/2282, as applied from 12/01/2025).
- **Stricter Cost Control for Orphans (§39da).** Administrative procedure to change reimbursement can be initiated by the payers in case of substantial price changes even before 3 years period.
- **Application (P&R).** Newly, whenever a pharmacoeconomic model has been used, the applicant must submit it as an annex to the application in a form that allows full visualization and fine-tuning of all parameters, assumptions and formulas necessary for the proper functioning of the model.

### OTHER CHANGES

#### Centralised Hospital Procurement (§40d, Act 289/2025 Sb.)

New statutory basis for nationwide tenders for hospital-only medicines by health insurance companies. Implementation commenced 2026.

#### EU Pharma Legislation: Political agreement

Technical amendment (corrections) of the Public Health Insurance Act expected ~2026-7. Substantial changes and directive transposition expected ~2028-9. Will affect data exclusivity, supply obligations, orphan incentives.

### SPECIAL TOPIC:

#### Regulation, pricing and reimbursement of pharmaceutical combination products

**Definition:** SÚKL uses term fixed dose combination (FDC)

**Regulation:** EMA Guideline CHMP/EWP/240/95 Rev. 2 applies. Standard EU MA routes. There are **no Czech-specific regulatory or clinical requirements** applicable solely because a medicinal product is a combination product

**Pricing:** Standard EPR (avg. of 3 lowest EU prices) applied to the combination as a whole – not decomposed into component prices. Availability-preserving variant (7-country avg.) available for essential medicines.

**Reimbursement:** Two categories based on whether components are separately reimbursed (supportive/supplementary substances disregarded).

- Category A — all components reimbursed: default = sum of component reimbursements per ODTD (§39c(7)) or EU manufacturer price for identically-composed FDC if lower
- Category B —  $\geq 1$  component not reimbursed: default = EU manufacturer price for identically-composed FDC.