

## CZECH REPUBLIC

### Recent and planned developments in pharmaceutical policies 2022/2023

#### CHANGES IN PRICING

##### Ministerial price decree: 1. 1. 2023, MoH

- general rules of price regulation, mark – ups levels
- minor definitional changes (persons subject to regulation in the supply chain, some terms which were not defined yet (maximum price for the final consumer)

##### Act on Public Health Insurance – amendment to the law since 1. 1. 2022

- Germany has been added to the reference basket (replacement for UK)
- price revisions (for the whole cluster) every 3 years (admin. proceeding with special term – 50 days for the decision).

#### CHANGES IN REIMBURSEMENT

##### Act on Public Health Insurance – amendment to the law since 1. 1. 2022

##### 1) Highly innovative drugs

- new definition
- new period for temporary reimbursement (from 3 to 5 years (3+2) – no need to prove cost effectiveness, but expected to be cost-effective after temporary reimbursement)
- new compensation methods (MAHs: costs exceeding the submitted BIA + treatment for up to 24 months period if the medicine does not obtain permanent reimbursement)

##### 2) Orphan drugs

- new type of administrative proceeding (inclusion of professional societies, patient organisations in the process)
- definition based on EU regulation
- reimbursement is set permanently
- important role of the advisory body of the Minister of Health (issues binding opinion for SÚKL)
- compensation methods (MAHs: costs exceeding the submitted BIA)
- SPINRAZA, ONIVYDE PEGYLATED LIPOSOMAL

##### 3) Complex reassessment of reimbursed groups

- only if necessary (previously every 5 years)

#### OTHER CHANGES

##### Ministerial exceptional measures (to ensure the availability of medicines of public health importance)

- MoH can set the maximum price or set or change the reimbursement conditions
- the medicine is fully reimbursed (no co-payment) at the maximum price level (ex-factory price is based on the agreement between MAH and HIF, with VAT and mark-up)
- measure is valid for 12 months (can be prolonged)

#### SPECIAL TOPIC:

### Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

##### Medicine shortages

##### 1) Ministerial register of medicines (first step)

- distribution to foreign countries has to be declared to SÚKL
- SÚKL collects information on volumes from MAHs, distributors, pharmacies
- SÚKL evaluates that the current supply of the medicine no longer sufficiently covers the current needs of patients

##### 2) Ministerial ban of export (second step)

- not interchangeable (irreplaceable) medicine
- condition: shortage of the medicinal product for human use in the following three-month period (information from SÚKL)
- latest examples: LONQUEX, TOBREX, DALACIN C

##### Price increases:

##### 1) Ad hoc increase (administrative proceedings)

- MAH has to apply for the change of maximum price
- has to submit approval from all health insurance funds
- basically no limit (limit is only based on negotiations between MAH and HIFs)
- 75 days for the administrative proceedings (based on the law)

##### 2) Ministerial decree (price decision)

- MoH can deregulate certain ATC group (not regulated by the maximum price)
- not very flexible measure (issued usually once in 3 years)
- no limit for price increase afterwards (but can be removed from the list - once again regulated)