



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Discussion on certain national security of supply measures (discussion based on national examples)

Updates on actions related to the security of supply of medicines and
shortages

Pharmaceutical Committee

23rd November 2023

Current medicines shortage measures in the Czech Republic

- Monitoring of disruption of supplies of medicines since 2007
- Online electronic form
- Online register of shortages
- ePrescription system
- Voluntary stock increase of MAH
- Increase in production of local producers
- High-level meeting with MAH headquarters
- Special authorisation for non-authorized medicinal products
- Re-export bans
- Preparation of medicinal products in pharmacies
- Regulatory flexibility
- Price increases
- Forecasting
- Supply obligation enforcement of late notification
- MoH/NCA controlled distribution
- Systemic restriction of off-label prescription
- Enabling deliveries of foreign language batches
- Individual treatment and special licence for non-authorized medicinal products

Czech national legislative medicines shortages measures in winter 2023/2024

- **New security of supply measures expected to be in practice in winter 2023/2024:**
 - **Mandatory ensuring of supplies of medicines 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 will have online information about stock levels in individual pharmacies**
 - **Pharmacist will have online 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
 - **Safety stock at distributor level for critical medicines** (1 month)
 - **Limited stockpiling at pharmacy level according to consumption** for medicines with limited availability
 - **Increased regulatory flexibility** of entry of non-authorized medicines to the market and into the reimbursement system
- => Implementation of Commission Communication on *“Addressing medicine shortages in the EU”*

Czech proposal on gathering information about medicines shortages measures in Member States for winter 2023/2024

- Following the Communication of Commission on *Addressing medicine shortages in the EU* and pharmaceutical package preventing and mitigating shortages of medicines during this autumn and the upcoming winter
- Not to add additional administrative burden
- **Previous information sharing at the EU level focused on the characteristics of national measures, but not on the impact on other Member States**
- Safeguard medicines for the patients in the EU
- Reacting on domestic shortages by national targeted legislation
 - ⇒ **Added value in sharing information at technical level on the existing or planned national measures preventing and mitigating medicines shortages as proper evidence for decision-making process at national and EU level**
 - ⇒ **Learning mutually about national measures for essential medicines and discuss whether such measures could potentially affect access to that medicine in other Member States**
 - MSSG or SPOC Working Party as preferable platforms for sharing of this type of information?
 - Proposed guiding questions for discussion

Guiding questions for discussion

1. Are you planning to adopt, or have you already adopted *national measures* to solve and prevent current medicine shortages in your Member State this year or in the upcoming year?
 - i. Please specify the concrete measures which have been taken or are planned:
 - ii. Please specify the phase of preparation and the timeline for these measures:
2. If YES, please identify whether these measures are aimed to be legislative changes at the national level:
 - i. Please specify the concrete legislative changes which have been taken or are planned, if not stated in question 1:
 - ii. Please specify the phase of preparation and the timeline for these changes, if not stated in question 1:
3. Do you expect that these national measures (legislative and non-legislative) could have an impact on the availability of medicines in other Member States:
 - i. Please specify the concrete situation



MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

**THANK YOU FOR YOUR
ATTENTION**