



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Follow up on discussion on certain national security of supply measures and survey results

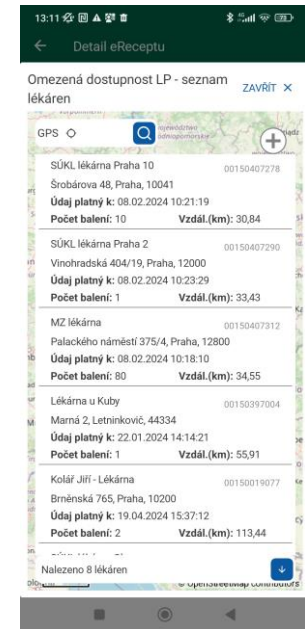
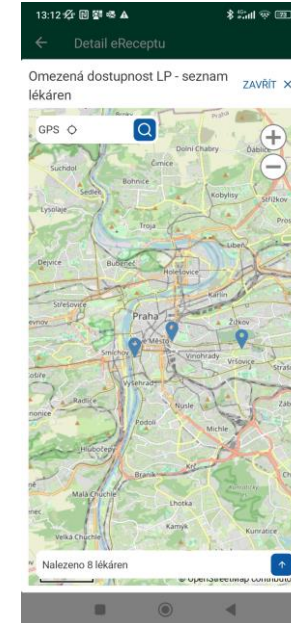
9th July 2024

Czech proposal from Pharmaceutical Committee 23th November 2023

- Following the Communication of Commission on „*Addressing medicine shortages in the EU*“ and pharmaceutical package preventing and mitigating shortages of medicines during autumn 2023 and winter 2023/2024
- Not to add additional administrative burden
- **Previous information sharing at the EU level focused only on the characteristics of national measures, but not on the impact on other Member States**
- Safeguarding medicines availability in the EU
- Reacting on domestic shortages of national medicines supplies for the patients via 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

New Czech national legislative medicines shortages measures in practice

- **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
 - Increased **regulatory flexibility** of entry of non-authorized medicines to the market and into the reimbursement system
- **Safety stock at distributor level for critical medicines (1 month)**
 - Intention to list first medicine groups (J01CE01, J01AB02, J01AB04)



*valid from 1.6.2024; this index is assigned by NCA decision based on analysis of shortages and the market, currently about 50 medicines listed

Survey conducted after Pharmaceutical Committee

- *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 (2023) or in the upcoming year (2024)?*
- *Do you expect that these national measures (legislative and non-legislative) could have an impact on the availability of medicines in other Member States?*
- *Has any strengthening of enforcement of supply obligations and reporting obligations been happening this year (2023), or will it be implemented next year (2024)?*
- 20 responses from 19 Member States
 - 1 response referred to working groups already focused on similar tasks (MSSG, SPOC WP, TF-AAM, JA CHESSMEN)
 - 1 Member State does not have legislative solution to address medicines shortages yet

Survey results

- **Only 4 Member States (out of 19) have no plans to adopt nor have already adopted national measures to solve and prevent current medicine shortages this year (2023) or in the upcoming year.**
 - **Re-export** – only 4 Member States mentioned using restrictive measure
 - **Stockpiling/stock reserve** – 6 reporting Member States have this measure in place, one Member State is planning such measure this year (2023). In most cases partial effectiveness is expected. All answers predict more than 150 medicines to be involved, usually proactive approach is foreseen. The scope of the stockpiling differs in individual Member States from 2 weeks to 6 months depending also on type of an owner, obstacles: storage facility demanding, availability issues, in addition, several medicines have shorter shelf life, lack of financial incentives
 - **Changes in price/reimbursement** – 10 Member States reported this measure having in place or in preparation. In most reported cases increase of price has been applied since last year (2022), usually it is applicable for certain kind of medicines, usually are involved more than 150 medicines. In most cases partial effectiveness is expected. In many Member States, there is change in legislation needed.
 - **Import of non-authorized medicines from other Member States** – in many Member States, there is some possibility of importing at least some kind of medicines (e.g., special dosage forms for children), that are needed. It is obvious that Member States have more flexibility. In some cases, such mechanism was in place even years ago. One Member State informed that such measure is in preparation. In some Member States, there was the need of legislative change to apply this kind of measure, others indicated no need of legislative change. In many answers, the impact on other Member State indicated as not quantifiable or unknown. In 4 cases impact indicated as a 10% increase on medicines supplies of Member State. One Member State expects no impact. Reactive approach in case of medicine shortage.
 - **Adoption of list of critical medicines** – in 5 Member States, they have developed their own list of critical medicines, in some cases their list of critical medicines is in preparation, or they are building on EU list of critical medicines. Few Member States specified number of medicines included on their list and if specified, it was more than 150 medicines.

Survey results

- **Measures potentially impacting medicines availability in other Member States***
 - Stockpiling initiatives
 - Re-export bans
 - Incentives, pricing/reimbursement increase
 - **Measures with limited effect to other Member States**
 - Fees for medicine shortage notifications
 - Strengthening of enforcement or proper reporting and supply
 - Enhanced reporting of medicine shortage obligation
 - Medicine substitution protocols
- ⇒ Some Member States confirm that their legislation changes may affect the availability of medicines in other Member States. Especially, smaller Member States point out the possible influence due to their small markets.
- ⇒ When creating its measures, the Czech Republic was aware of the risks of influencing other Member States, which is why our measures are decent compared to some others.

*some negative evaluation of impact was based on „small market“ or by time given for implementing



MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

**THANK YOU FOR YOUR
ATTENTION**