

**Contextual information from the Czech delegation for the meeting
of the Pharmaceutical Committee on 23rd November 2023**

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

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

Last winter and over the whole year, the Czech Republic has been experiencing shortages of number of medicines, especially antibiotics, and noted that several other Member States reported at various technical meetings to be in a similar situation.

From the perspective of this autumn and the upcoming winter, the Czech Republic would like to focus on topic of shortages of essential medicines and related national measures at the meeting of Pharmaceutical Committee on 23rd November 2023. The aim is to have a discussion to gain better overview and more clarity about the measures in place and planned measures in Member States to prevent and mitigate existing and potential medicine shortages.

Already at the EPSCO Council meeting last March, the Czech delegation has presented a non-paper called “Shortages of medicines in the EU market” with the support from 10 Member States. The main message was to use the empowered structure at the EU level (EMA, ECDC, DG SANTÉ, DG HERA, DG GROW) to secure supplies of essential medicines for the EU via active negotiations with producers, marketing authorization holders and other stakeholders at the global level.

Later, in April, the Czech Republic joined the Belgian non-paper “Improving the security of medicines supply in Europe” together with other 17 Member States and in September the new EU solidarity mechanism which resulted from it.

In this context, we welcome provisions proposed in the pharmaceutical package that are to help Member States to address certain aspects of the supply chain with the producers in more active role. Joint Action Chessmen has been launched this year but the outcomes are expected at the earliest next year while we wish to react to the situation now.

Having in mind that many of the initiatives at the EU level have already been described in the Commission Communication “Addressing medicine shortages in the EU” published last October, we consider it important to take the steps which would be necessary to prevent and mitigate existing and potential shortages of medicines before the pharmaceutical package enters into force.

At the end of October, the European Council in its conclusions pointed out the necessity to overall address this topic. Therefore, a political discussion in the context of the aim to reach Open strategic autonomy of the EU will take place at EPSCO Council meeting on 30th November 2023.

Notwithstanding the currently accessible information, we are of the opinion that updates are desirable due to frequent changes of the situation. Previous information sharing carried out at the EU level focused on the characteristics of national measures, but not on the impact on other Member States. The Czech Republic is aware of many initiatives taking place in the Member States and at the EU level to prevent and mitigate shortages of medicines during this autumn and the upcoming winter. Our aim is not to add additional administrative burden but to gain more clarity about the intentions at national and EU level. This discussion could be

useful
in context of preventive policy of medicines shortages.

We would like to make clear that we see the value in the possibility of reacting on domestic shortages by national targeted legislation. We are also aware of the high political sensitivity of the topic for Member States. Yet, at the technical level, we would like to be aware of the existing or planned national measures preventing and mitigating medicines shortages as proper evidence which can feed the decision-making process at both, national and EU level.

The purpose of the discussion is to learn mutually about targeted national measures for essential medicines and discuss, multilaterally or bilaterally, whether these measures could potentially affect access to such medicine in other Member States. In general, this proposal could become a useful tool how to help safeguarding medicines for the patients in the EU in short term time, before the planned structural changes will be in place.

Member States are kindly invited to provide feedback. We prepared guiding questions for discussion and look forward to hearing the positions of Member States. The options are proposed to facilitate the 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