



Council of the
European Union

Brussels, 9 March 2023
(OR. en)

6672/1/23
REV 1

SAN 117
PHARM 35

NOTE

From: General Secretariat of the Council
To: Council

Subject: Shortages of medicines in the EU market
- Information from the Czech delegation, supported by the Austrian, Cyprus, Greek, Hungarian, Italian, Lithuanian, Maltese, Netherlands, Portuguese, and Slovenian delegations.

Delegations will find in Annex an information note from the Czech delegation, supported by the Austrian, Cyprus, Greek, Hungarian, Italian, Lithuanian, Maltese, Netherlands, Portuguese, and Slovenian delegations on the above mentioned subject to be raised under “Any other business” at the meeting of the EPSCO Council (Health) on 14 March 2023.

Background Note from the Czech delegation supported by Greece, Italy, Austria, Lithuania, Cyprus, Slovenia, Malta, Portugal, Netherlands and Hungary:

Shortages of medicines in the EU market

The Czech Republic has been experiencing serious shortages of number of essential medicines, especially antibiotics, and noted that several other Member States reported at various technical meetings to be in a similar situation.

Due to significantly higher number of patients with respiratory diseases compared to previous years, to the related increase in demand, to the manufacturing reasons, such as lack of Active Pharmaceutical Ingredients (APIs) or packaging materials and limited capacity of final production at the EU located facility, and to the disruption of global supply chains – which we have been experiencing since the COVID-19 pandemic, several Member States have recently indicated problems with safeguarding sufficient amounts of several types of medicines. While reasons of shortages may vary, the EU’s current legislative framework fails to secure sufficient supplies of a number of medicines, making it, in our point of view, of an utmost importance to prevent this situation to happen again in the autumn and to work on easing the access to the EU market, on sufficient incentives as well as on investments that will attract manufactures, laboratories and other stakeholders to the EU market. The planned revision of the pharmaceutical framework is expected to bring promising changes, but it will take several years before it is applicable.

During the COVID-19 pandemic, we have decided to strengthen the preparedness framework, including key agencies, i.e., European Medicines Agency (EMA) with its newly established Executive Steering Group on Shortages; and European Centre for Disease Prevention and Control (ECDC). DG HERA with its unique competences in times of crises and preparedness has been established. And while these bodies and platforms provide useful information, it is necessary to use the empowered potential of this structure to secure supplies of essential medicines for the EU.

Monitoring the situation, as well as the initiatives made under the Structured Dialogue Initiative, DG GROW, DG HERA and EMA are very important. In our view, supporting further dialogue not only with the marketing authorisation holders and industry, but also with third countries is needed,

since the problem the EU faces is of a global nature, and it cannot be addressed solely by monitoring availability of essential medicines within the EU market.

The Czech Republic is working hard on stabilizing the current situation. Thanks to bilateral negotiations with marketing authorisation holders, manufactures and distributors, it has been possible to secure extraordinary deliveries and accelerate planned deliveries of needed medicines in recent weeks.

We find it crucial to ensure that we do not find ourselves in a similar situation in the autumn again. We are aware of the situation's complexity, various global influences and positions of producers. We should focus on finding solutions with long-term impacts that will ensure accessibility and availability of medicines in the EU to avoid repeating of the same mistake in safeguarding supplies of medicines to the EU market in the future. We see as a matter of importance to be prepared for a potential market failure of global nature that the EU might not be able to solve by actions aimed only at the EU market. The current situation shows that even a local shortage of medicines often leads to its reselling, reexport and other steps that further disrupts the market.

Should the EU face global lack of essential medicines, it shall be able to negotiate with producers, marketing authorization holders and other stakeholders. Since joint procurement represents very complex and lengthy procedure, we should focus on joint negotiations with the goal of ensuring availability of medicines at the EU market. To support such negotiations, we need to be able to gather data, e.g. on origin of API used in the EU, production capacities in the EU, and other crucial information, to be able to clearly define what can be done at the EU level when it comes to joint negotiations with global players.

We consider as useful to raise the attention about this topic at the level of ministers of health at the EPSCO Council meeting within AOB point and to call for further discussions on relevant platforms as we need to safeguard medicines for the patients in the EU.