

Meeting of EU-Directors for Pharmaceutical Policy

29 October 2020

Fit for Future – Shaping the EU pharmaceutical landscape

Summary

On 29 October 2020, EU Directors for Pharmaceutical Policy exchanged virtually on the topic of “Fit for Future – Shaping the EU pharmaceutical landscape” at the Meeting of EU-Directors for Pharmaceutical Policy.

What has become clear from the meetings’ discussion is that all Member States agreed with shaping the EU Pharmaceutical Strategy around the seven areas the Commission outlined in their non-paper and that the strategy should tackle challenges from availability to sustainability to make the pharmaceutical landscape fit for future.

There was broad consent between Member States that while the EU Pharmaceutical Strategy provides a global framework, its action plan with concrete measures will be crucial for success, creating quick wins where possible. For this purpose, Member States ask for prioritisation of key actions. The Commission together with the Member States should push for those after publication of the EU Pharmaceutical Strategy on 24 November 2020. Many Member States contributed with ideas for prioritisation such as seen by the initiative of the Netherlands and the Visegrad Group.

Member States underlined the importance of “Ensuring the supply of medicinal products in the EU” while taking into account stockpiling at various levels. In addition, many Member States emphasized that for them defining clear criteria for “unmet medical needs” especially with regard to the orphan drug legislation and redesign the framework for ATMPs is a major concern in moving the strategy

forward. The Commission and Member States should prioritise further discussions around concrete actions in this area within the EU Pharmaceutical Strategy's action plan.

Within the area of “Ensuring the supply of medicinal products in the EU” as one of our guiding themes of the EU Council Presidency in the area of health, Member States continued discussions around the following cornerstones: 1) Increasing transparency and information exchange at EU level; 2) improving the quality of API; 3) diversifying supply chains and 4) creating financial incentives for the maintenance and relocation of API manufacturing sites to the EU in two break-out sessions.

It became clear once again that the EMA contributed significantly to improving transparency during the COVID-19-pandemic. The EMA implemented the

- a) Single Point of Contact (SPOC) and Industry Single Point of Contact (i-SPOC) systems (SPOC- and i-SPOC-System),
- b) fostered alignment between EU and Member State's actions

It may be beneficial for the future to establish more formally the mechanisms put in place during the COVID-19 crisis to monitor and respond to challenges and address issues relating to availability of critical medicinal products.

In the discussion of session 3.1., Member States also concluded that there is a need to collect information on the whole supply chain – including manufacturing sites for API to provide more transparency, even for procurement decisions. Germany put in place a legal regulation, which provides for the publication of API-manufactures. Together with information about the volume of productions, this could be a first step increasing transparency and knowledge of the supply chain, especially regarding important, vital medicinal products on EU-level.

In addition, Member States agreed that the security of supply of medicinal products is directly linked on the API-quality and can be ensured by improving GMP-Inspections. Anyway, more inspections need resources, which could be obtained by effective international cooperation.

It was highlighted that due to nitrosamine impurities in medicinal products containing sartans, a review of the CEP-procedure should be pursued further. Marketing authorisation holder must be aware of their suppliers and the quality of

the intermediates and active substances they use to be able to take the responsibility for the medicinal products.

In the discussion of session 3.2., Member States emphasized that there is no plan to revert globalisation of supply chain, but aim for better resilience by diversified supply chain. Therefore, efforts should focus on critical medicinal products such as antimicrobials. Member States should collaborate with the EMA and jointly work on a list of those critical medicinal products.

It was highlighted that Member States may develop comprehensive purchasing policies and strategies to diversify supply chains. Those policies and strategies should take into account considerations regarding resilience, risk management and security of supply when procuring pharmaceuticals, especially critical medicinal products such as antibiotics. They shouldn't neglect the sustainability of their health systems. Many Member States also emphasized to invite the Commission to consider adapting the "Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak".

The discussions at the Meeting of EU-Directors for Pharmaceutical Policy underlined the importance that the EU Commission and Member States work closely together in the development of the EU Pharmaceutical Strategy. In this regard, it would be a strong signal for the development of an action plan, if Member States agree on concrete measures around "Ensuring the supply of medicinal products in the EU" in council conclusions. It is supposed to adopt those council conclusions by EPSCO Council on 2 December 2020 in the course of Germany's Presidency of the Council of the European Union.

Finally, all Member States look forward to the Commission's communication on the EU Pharmaceutical Strategy on November 24 2020. All Member States appear to be eager to continue discussions especially for immediate actions in prioritized areas. The Meeting of EU-Directors for Pharmaceutical Policy appears to be a very suitable forum for further discussion.