EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines shortages: Giving up? Finding solutions!

Panel 2: Solutions from the EU and the Member States: Which solutions from regulatory perspective exists? - Which are additionally needed?

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Background: How does the EU manage shortages?

- Improving the availability of medicines authorised in the EU is a key priority for the EMAN. In the EU, medicine shortages are mainly dealt with at national level by the National Competent Authorities
- In December 2016, a joint HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use was established in order to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability.

Responding to the COVID-19 pandemic

In the context of the COVID-19 pandemic, EMA was requested by the EC and the Member States to increase its involvement in the handling of shortages and it initiated a number of activities, as follows:

- EMA set up the EU Executive Steering Group on shortages of medicines caused by major events
- EMA launched the i-SPOC (Single Point of Contact) system in April 2020, a fast-track monitoring system involving pharmaceutical companies, to help prevent and mitigate supply issues
- EMA continued to use the EU SPOC network for sharing information between Member States, EMA and the EC on critical medicine shortages in the context of COVID-19 (an initiative already undertaken in the context of the work programme of the aforementioned joint EMA/HMA Task Force)
- EMA together with the Member States developed a common framework for forecasting demand data in the EU/EEA
- EMA, the EC and the Member States developed regulatory flexibilities for pharmaceutical companies to prevent/mitigate shortages

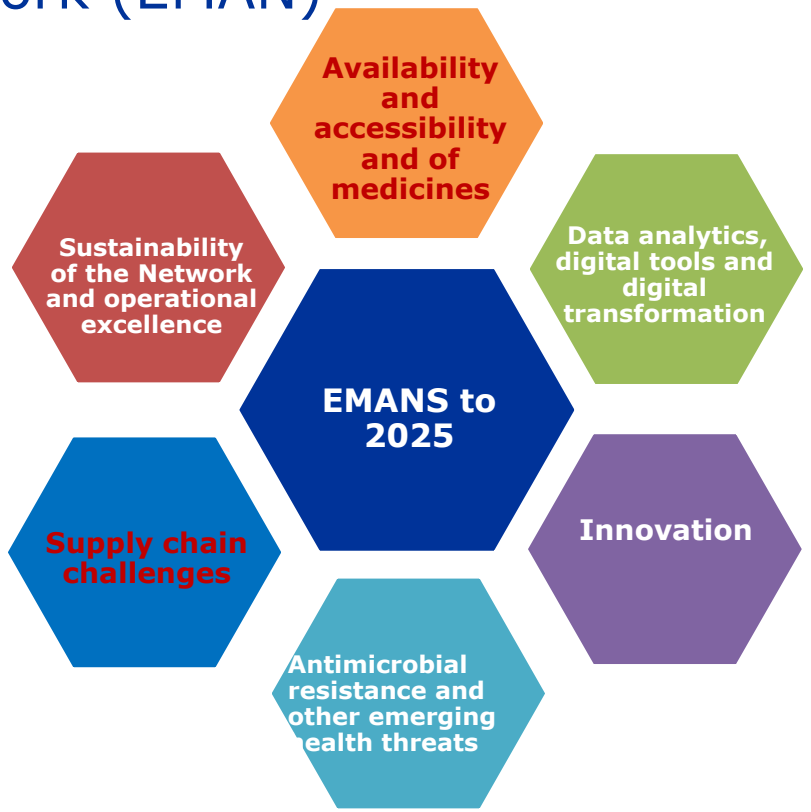
Facilitating the forecasting of demand data in the EU/EEA

- Taking into account lessons learned from the first wave of the pandemic and in order to prepare for a second wave, hereby striving to ensure the supply of medicines for patients, the EU Exe Steering Group agreed to improve the forecasting of demand of medicines used in ICUs for COVID-19 patients, and how to better match the estimated demand with the available supply
- As a result, it was agreed to establish an *ad hoc* working group (co-chaired by EMA and a Member State representative) that was tasked with the development of a Reflection Paper that sets out a common framework for forecasting demand data in the EU/EEA
- The *ad hoc* group on forecasting demand data has also determined which medicines should be included in this exercise
- A pilot phase is currently ongoing to allow the Member States to obtain more experience with the common principles on forecast of demand data laid down in the Reflection Paper; any lessons learnt from the pilot will be taken into account before finalising the Reflection Paper

European Medicines Agencies Network (EMAN) Strategy to 2025

Strategic focus areas:

- **Availability and accessibility of medicines**
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- **Supply chain challenges**
- Sustainability of the Network and operational excellence



Strategic focus areas – availability and accessibility of medicines and supply chain challenges

Theme 1 : Availability and accessibility of medicines

Goal 1: *Strengthen the availability of medicines to protect the health of European citizens and animals*

Objective 1: Identify the specific root causes of shortages (including specific causes for shortages of generics/off-patent products versus products still under patent protection) and develop strategies to improve prevention and management of shortages. Identify and suggest areas where changes to EU or national legislation could improve supply.

Objective 2: Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners

Objective 3: EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply.

Theme 5 : Supply chain challenges

Goal 1: *Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) and excipients*

Objective 1: Improve and inter-link information in current/existing databases to provide supply chain compliance overview.

Goal 4: *Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medicinal products.*

Objective 1: Enhance the reliability of evidence available to regulators for informing the decision making process on the supply chain and promote supply chain resilience and reliability of supply of APIs and medicinal products.