EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A common understanding for a list of critical medicines and medical devices

Panel I: Availability of medicines and medical devices

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Background

- Shortages of medicines: **global** problem and on the rise in Europe
- **Causes** are **varied**: manufacturing or quality related (GMP), economical (marketing / reimbursement decisions)
- Significant impact on **patients** and **healthcare systems** due to:
  - medicines rationing
  - delay of critical treatments
  - use of alternatives that may be less efficacious or increase risk of medication errors and adverse events

How does the EU manage shortages?

- Improving the **availability** of medicines authorised in the EU is a key **priority** for the European Medicines Regulatory Agencies.
  - In the EU, medicine shortages are mainly dealt with at national level by the National Competent Authorities.

- Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur.
- In December 2016, a **joint HMA/EMA Task Force** on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM) was established to provide **strategic support** and advice to tackle disruptions in supply of human and vet medicines and ensure their continued availability.

EU response to shortages during 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 medicine shortages and it initiated a number of activities, as follows:

- EMA set up the **EU Executive Steering Group (ESG) on shortages** of medicines caused by major events
  - EMA, in cooperation with EC, HMA and CMDh established a list of **critical medicines** for use in COVID-19 patients
  - EMA, the EC and the Member States developed **regulatory flexibilities** (e.g. ECMP, GMP/GDP provisions, labelling/ packaging requirements for pharmaceutical companies to prevent/mitigate shortages, adopted by the EU Exe SG;
  - EMA launched the **i-SPOC** (Single Point of Contact) **system** in April 2020, in relation to COVID-19 medicines (ICU setting)
  - EMA together with the Member States developed a common framework for **forecasting demand data** in the EU/EEA (**ad hoc Working group** on forecasting demand data)
- 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

List of critical medicines developed by the ESG in the context of the COVID-19 pandemic (April 2020)

- EMA **consulted the MSs** and collected information on medicines used in the management of COVID-19 patients (symptomatic or anti-viral) as well as medicines needed for primary care/hospital functioning for COVID-19 patients.
- The WHO list of priority medicines - developed in the context of the COVID-19 outbreak - was used as a starting point for collection of information from MSs.
- Based on the information received from MSs, a **list of critical medicines** at risk of shortage due to increase in demand for COVID-19 patients was established by the ESG.
- The list was used to select a subset of high-impact COVID-19 medicines (31 active substances) for shortage monitoring under the i-SPOC system (see next slide).

i-SPOC system (between industry and EU regulatory authorities)

- Aims at looking for remedial actions that can be taken at EU level to address root causes of shortages (e.g. proposals for regulatory flexibilities or actions at EC/MS level on logistics, or export restrictions).
- The role of the i-SPOC system is also proposed to be formalised as part of EMA's extended mandate.

EU oversight of shortages for high-impact COVID-19 medicines (31 INNs).

Monitoring of patterns by EMA. Anticipation of EU supply issues.

Non-mandatory reporting, but **positive engagement** from MAHs

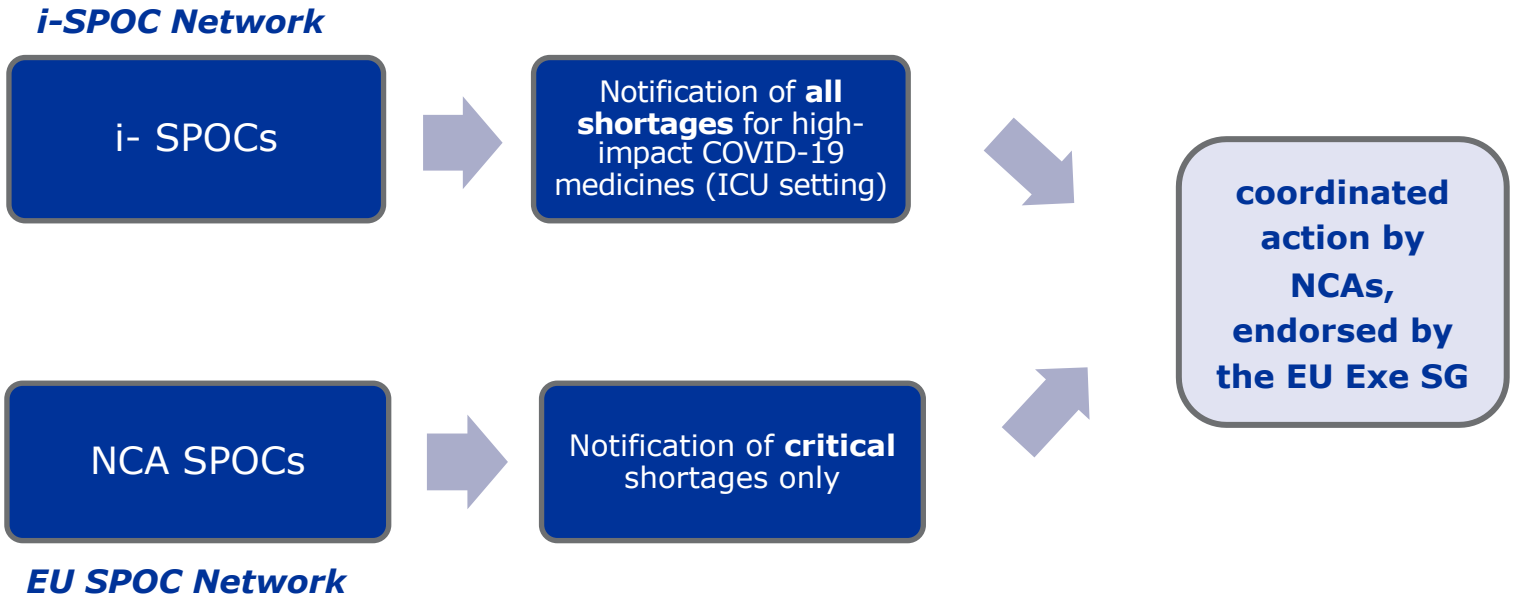
Each MAH appoints an i-SPOC

i-SPOC reports to EMA (and NCAs) all current or anticipated shortages

EMA compiles the information received from MAHs

Report shared with ESG for decision on EU-level measures

Process flow for COVID-19 shortages - i-SPOC and EU SPOC Network



Ad hoc Working Group on forecasting demand data: common framework for **forecasting demand data** in the EU/EEA

- **Aim:** To develop methods for the collection and sharing of data on demand for medicines across the EU/EEA.
- **Output:** Reflection Paper to improve the forecasting of demand for medicines in EU/EEA MSs.
- **Pilot phase (scope/objectives):** To obtain more experience with the common principles laid down in the draft RP on forecast of demand data, taking into account the tools available at national level or the tool developed by the ad hoc WG.
    - **Pilot Conclusions**: lessons learnt from the pilot have been taken into account in the finalisation of the Reflection Paper.

COVID-19 Health Response Package: Proposal for a reinforced EMA role

- The proposal for a reinforced EMA role includes a strengthening of the current role of EMA in **shortages of medicines** and crisis management, as well as a completely new role in the management of **medical devices shortages**.
- The legislative proposal for a reinforced role for EMA in shortages management:
  - Builds on achievements during the COVID-19 pandemic (e.g. EU Executive Steering Group and the i-SPOC system);
  - Requires EMA to get acquainted in a short timeframe with the field of medical devices where it so far had very little exposure (in particular as regards medical devices operators);
  - Establishes the ***Medicines*** *Steering Group* (MSG) and the ***Medical Devices*** *Steering Group* (MDSG) which amongst others will develop lists of **critical** medicines and medical devices.

Conclusions

- Since 2016 the EMA/HMA TF AAM have looked at availability issues, including supply chain disruptions, to improve **continuity of supply** of human and veterinary medicines across Europe.
- EMA has in the context of the **current pandemic** taken a greater role in the handling of shortages (as requested by the EC and the Member States) despite the absence of a clear legal mandate.
- The legislative proposal for a **reinforced EMA role** in the shortages management reflects much of the processes that EMA had put in place already for the COVID-19 pandemic (and even before) but formalises these system making them more robust.
- The new legislative proposal puts clear obligations to companies and MSs for reporting on shortages, supply capacity and demand data to the Agency, which will facilitate setting **recommendations** and **coordination of measures** to prevent or mitigate potential or actual shortages.

Any questions?

Further information

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