EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Securing availability of medicines across the EU

EMA 25 years

Presented by Monica Dias, PhD
Policy and Crisis Coordinating Officer, Office of the Deputy Executive Director

Background: How does the EU manage shortages?

- Improving the availability of medicines authorised in the EU is a key priority for the European medicines regulatory network. In the EU, most medicine shortages are dealt with at national level by 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.
- In April 2019, the task force established a **single point of contact (SPOC) network** to improve information sharing between MS, EMA and the European Commission on shortages of critical human and veterinary medicines. This includes information sharing on alternative medicines available in other Member States.

Main root causes of shortages in the context of the pandemic

- Temporary lockdowns of manufacturing sites;
- Travel restrictions impacting exports;
- Export bans;
- Increased demand for medicines used to treat COVID-19 patients;
- Stockpiling by hospitals, by individual citizens or at Member State level.

Products currently in shortage or at risk of shortage

- Medicines used off label for the treatment of COVID-19 (e.g. chloroquine, hydroxychloroquine, monoclonal antibodies)
- Medicines used in intensive care units:
  - Anaesthetics
  - Antibiotics
  - Analgesics
  - Sedatives

Responding to the COVID-19 pandemic

In the context of the COVID-19 pandemic, EMA is going beyond its legal remit and has initiated a number of activities, as follows:

- EMA set up the EU Exe Steering Group on shortages of medicines caused by major events which meets every week, also with industry associations;
- EMA launched a survey to all MAHs in March 2020 on the impact of the COVID-19 pandemic on the availability of CAPs;
- EMA launched the i-SPOC system in April 2020, a fast-track monitoring system, to help prevent and mitigate supply issues.

EU Executive Steering Group on shortages caused by major events (EC, EMA, HoAs)

- Provides strategic leadership for urgent and coordinated action to prevent and mitigate supply disruptions within the EU during the pandemic.
- Composed of representatives from EMA, European Commission, HMA, Coordination groups for Mutual-recognition and Decentralised Procedures for human and veterinary medicines (CMDh and CMDv) and risk communication specialists.
- Chaired by the European Commission.
- Meets with industry associations on a weekly basis.

EU Single point of contact (SPOC) network

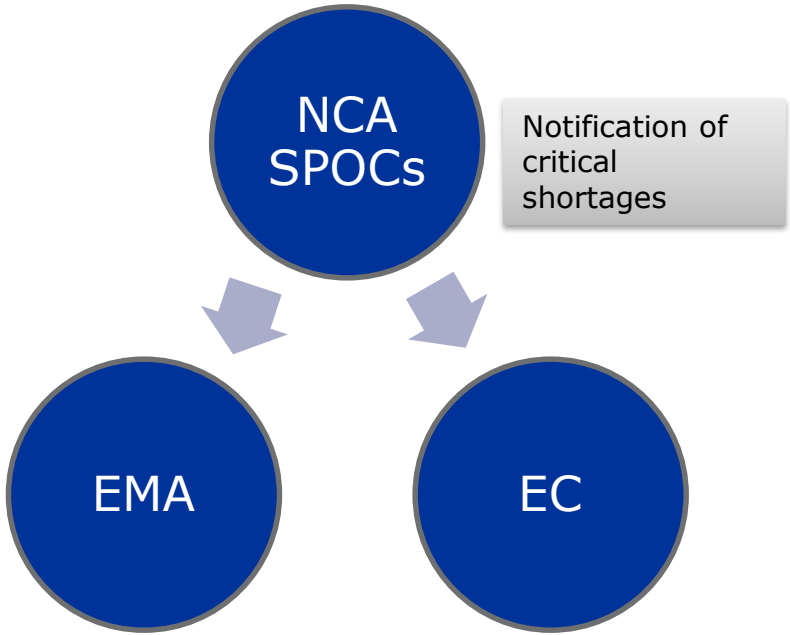
In the context of COVID-19, the EU SPOC Network:

- Continues **sharing information** between Member States, EMA and the European Commission on **critical medicine shortages** in the context of COVID-19
- Gathered information on **medicines used for COVID-19 patients (ICU setting) currently on shortages or at risk of shortage**. This info has been used by the Health Commissioner to make a plea for industry to increase production of these medicines.
- In addition, due to export restrictions imposed by the Indian Government, EMA collected **demand data from MSs** (through the NCA SPOCs) for **14 APIs under export restrictions**. This data was used by the Health Commissioner in direct negotiations with the Indian Government.

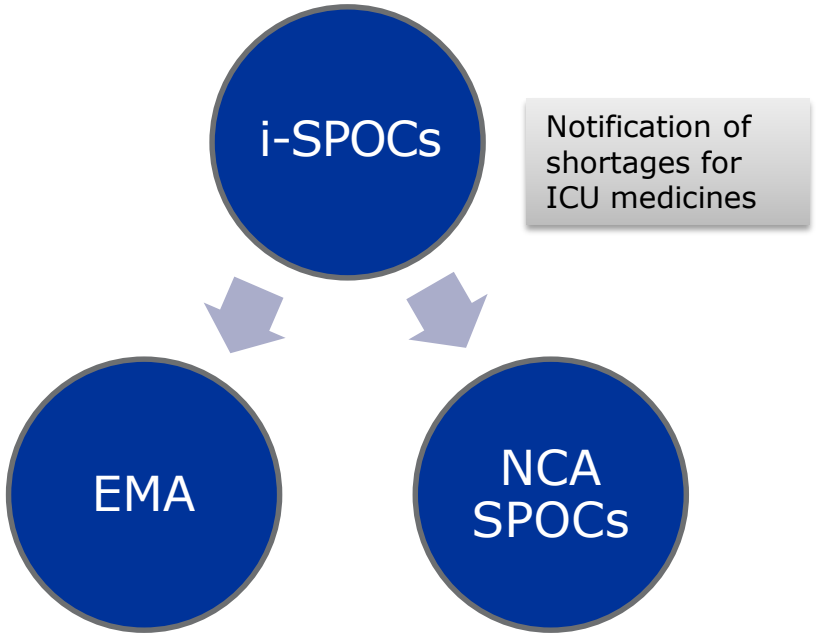
i-SPOC reporting system between industry and EU regulatory authorities

- Requested by pharmaceutical industry for reporting shortages of COVID-19 medicines only, and agreed by the EU Exe SG and launched in April 2020
- Scope is to allow direct reporting to EMA by MAHs of supply shortages for crucial CAPs and NAPs used in the context of COVID-19, in parallel to reporting to the NCAs concerned
- Designed to collect information on current or anticipated supply disruptions and their causes in relation to COVID-19 medicines (primarily used in ICU setting).
- Aims at **preventing shortages** from occurring, by initiating action through the EU Exe SG to address root causes or enable mitigating actions (e.g. regulatory flexibility or actions at EC/MS level on matters affecting supply of medicines or related materials, on logistics, export restrictions).

EU SPOC network



Industry-SPOC network



Regulatory flexibility to prevent/mitigate shortages

Guidance is available for **companies** on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic

- First version was published 10 April 2020
- To be considered when deciding on mitigation measures for shortages
- It is regularly updated to address new questions


EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

HMA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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NOTICE TO STAKEHOLDERS

QUESTIONS AND ANSWERS ON REGULATORY EXPECTATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE DURING THE COVID-19 PANDEMIC

Guidance for medicine developers and companies for COVID-19: Guidance on regulatory expectations and flexibility (human medicines)
Guidance for medicine developers and companies for COVID-19: Guidance on regulatory expectations and flexibility (veterinary medicines)

Any questions?

Further information

Monica.Dias@ema.Europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

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