EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2022
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Stakeholders and Communication Division

# Industry Standing Group meeting

26 September 2022

Chair: Juan Garcia Burgos (EMA), via WebEx

## 1. Welcome and introduction

The meeting was chaired by Juan Garcia Burgos (EMA) who opened the meeting and welcomed all participants.

## 2. Adoption of agenda and highlights from previous meeting

The agenda for the ISG meeting of 26 September 2022 and the highlights from the ISG meeting of 21 June 2022 were adopted.

## 3. Medicine and medical device shortages

### 3.1 Update on medicine shortages activities

Joao Ferreira (EMA) gave a short update on the medicines shortages activities, starting with the status of industry single points of contact (i-SPOC) registrations. All marketing authorisation holders (MAH) in the EU were required to register an i-SPOC for supply and availability issues before 2 September 2022. To further increase compliance, EMA will be launching a dedicated communication campaign to remind industry of the requirement and highlight available guidance and technical support.

The ISG operational group has now been set up, as a focus group for exchanges between EMA and Industry around MAHs' reporting obligations as defined in Regulation (EU) 2022/123 for mMedicine shortages. The main objective of this group will be to collect and review feedback from MAHs so that EMA can further facilitate Industry's submission journey using the established (interim) tools and processes. An update was given on the proposed ISG operational group including its composition and scope of activities. The ISG operational group will report to the ISG. Industry were invited to submit nominations to attend the first ISG operational group on 14 October.

An overview was given of the number of MAHs on the lists of critical medicines under Regulation (EU) 2022/123 for COVID-19 and monkeypox Public Health Emergencies (PHEs). These MAHs must adhere to the assigned reporting timelines using the appropriate template and EMA's interim submission tool. Further guidance is available to relevant MAHs.

Pedro Ferreira (EMA) presented the Agile governance model for the European Shortages Monitoring Platform (ESMP). A workshop with IT directors and the SPOC working party will be held in October 2022.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

During the Q&A session, EMA welcomed efforts by trade associations to raise awareness about the requirement to register i-SPOCs. It was further clarified that a single i-SPOC can be registered at company headquarter level to oversee activities across all company affiliates.

The differences between collecting and submitting data on shortages for NAPs (e.g., dexamethasone in the context of COVID-19) versus CAPs was raised by Medicines for Europe. A rapid lessons learnt exercise was proposed to help make the process smoother going forwards.

Further clarification of the roles of the ISG and the ISG operational group was provided, in the context of related activities such as those from HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use (TFAAM) and the Medicines Shortages Steering Group (MSSG).

**Follow-up and next steps**

- EMA to issue further communication on requirement for MAHs to register i-SPOC.
- Industry is invited to submit nominations to attend first ISG operational group (one nomination per trade association).
- Industry stakeholders are invited to gather input on experiences on submission of data in the context of shortages for discussion at an upcoming ISG operational group meeting, with feedback at the subsequent ISG plenary meeting.
- Industry is invited to submit suggestions for further topics for the multistakeholder workshop on shortages.

See presentation.

### 3.2 Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency

Monica Dias (EMA) gave an overview of recent activities relating to EMA's mandate to monitor and mitigate shortages of critical medical devices, which will be implemented in February 2023. A feasibility study has been carried out to identify a suitable IT system for reporting and monitoring of shortages of critical medical devices during a public health emergency.

EMA is setting up the Executive Steering Group on Shortages of Medical Devices (MDSSG). The MDSSG will adopt a list of categories of critical medical devices, monitor the supply and demand for medical devices and make recommendations on measures to prevent or mitigate shortages.

Work is also underway to set up the Medical Devices Shortages SPOC working party. This will be an operational group, with NCA representatives, that will report on volumes of demand and forecasts of demand for devices on the critical medical devices list. In terms of the single point of contact for medical devices on the critical list, reporting requirements during a public health emergency are similar to those for medicines on the list of critical medicines.

Other actions are underway to facilitate the implementation of EMA's extended mandate in the are of medical device shortages. These include the establishment of an *ad hoc* drafting group on shortages of critical medical devices, which will support the establishment of the MDSSG and supporting working party. Interactions with industry associations are foreseen in November 2022.

During the discussion it was confirmed that the reporting tool will be available at the time reporting becomes mandatory, which is after a list of critical medical devices has been adopted by the MDSSG.

**Follow-up and next steps**

- Ad hoc drafting group on shortages of critical medical devices to support the preparatory for the implementation of the mandate in February 2022, including interactions with industry associations

in the medical devices sector and with Notified Bodies.

- Implementation of the IT framework for medical device shortages.

See presentation.

## 4. Emergency Task Force (ETF)

### 4.1 Overview of ETF tasks and responsibilities

Manuela Mura (EMA) presented an update of ETF activities, including an overview of ETF's tasks and responsibilities and the dedicated ETF webpage. Guidance to industry for scientific advice and support to academia for clinical trial conduct is being updated and IT tools are being further refined. In particular, the IRIS interface for the scientific advice procedure will go live on 11 October 2022.

A summary was provided of ETF's activities in the context of monkeypox, which has been declared a public health emergency. This includes extension of all legal provisions for COVID-19 to monkeypox.

ETF is also undertaking activities to ensure preparedness for future public health emergencies, such as facilitating large multinational and platform trials of therapeutics or vaccines and providing scientific advice to applicants in the area of certain key pathogens.

During the discussion it was clarified that ETF support is intended for clinical trial sponsors. The discussion also focussed on pathogens that pose a potential threat, confirming that these include both viral and bacterial pathogens and further definition would be done in coordination with DG HERA and be aligned with other public health authorities, such as FDA and WHO.

See presentation.

## 5. Update on medical devices expert panels implementation

The last session started with a presentation by Sheila Walsh (NBCG-MED), who gave an overview of the Notified Bodies' (NB) initial experience with the medical device expert panel consultation process. It was noted that the timelines for each step can be variable, as the process involves preparatory work. In addition, in some cases before the opinion is issued, the NBs would welcome the opportunity to have an open dialogue to discuss the expert panel conclusions. Finally, a number of administrative points were raised, as well as a request for more information about the annual overview of notifications to be drawn up by the European Commission.

Silvy da Rocha Dias (EMA) followed with an update on the medical devices expert panels implementation, acknowledging the importance of maintaining an open dialogue and confirming EMA's commitment to ensuring predictability and the integrity of the process. The presentation included clarification of the timelines, explaining that the administrative steps needed after the submission of the application by the NB are done prior to the start of the 60-days timeline. A clarification was also made stating that the only change that was done to the previous process was the introduction of a communication to the NB on the expected timeline for each procedure to ensure predictability. An update was given of the number of CECP and PECP applications submitted, highlighting that all decisions, opinions and views were delivered within the deadlines.

The administrative points raised by NBCG-MED/Team NB were also addressed and it was noted that questions regarding the annual overview should be addressed to the European Commission as author of the report. Finally, suggestions for improvements and simplification were welcomed and it was emphasised that the Experts Panel Secretariat is open to further dialogue with the NBs.

During the Q&A session, Silvy da Rocha Dias clarified that all thematic panels for the CECP are fully functional since April 2021. However, it was acknowledged that in certain periods, e.g. Summer

months, identifying available experts can be more challenging in certain areas, so the Secretariat is thinking of ways for improvement.

A question was raised as to whether expert panels can be approached for scientific advice. This will take into account the outcome of a recent stakeholder survey, and some pilot projects for scientific advice provided by the Expert Panels are being considered for next year.

**Follow-up and next steps**

- Further discussion on some of these topics in the following meetings.

See Team-NB presentation

See EMA presentation

## 6. Summary of actions and next steps

Juan Garcia-Burgos thanked all the participants for their valuable contribution. The next ISG meeting will take place on 22 November 2022. This meeting will be a face-to-face/hybrid meeting and its scope may be broadened to include other relevant topics beyond EMA's extended mandate. Further details about timelines and scope of issues to be discussed at the next meeting will be shared in advance. Industry stakeholders were also invited to submit in writing any urgent outstanding questions that were not addressed in the meeting.