15 July 2022
EMA/775191/2021
Stakeholders and Communication Division

Industry Standing Group meeting

21 June 2022

Chair: Marie-Helene Pinheiro (EMA), via WebEx

1. Welcome and introduction

1. Opening remarks

The meeting was chaired by Marie-Hélène Pinheiro (EMA) who opened the meeting and Melanie Carr (EMA) welcomed all participants and gave introductory remarks and explained the focus and objective of this new forum.

2. Industry Standing Group (ISG): mandate, objectives, composition

Juan Garcia Burgos (EMA) presented the Industry Standing Group (ISG) mandate, objectives, and composition. He highlighted that ISG isa forum intended to streamline interactions with industry in accordance with EMA's industry stakeholders' framework of interaction to further foster regular dialogue on topics of common interest of strategic nature, facilitate exchanges of e views and feedback from industry stakeholders. In its pilot stage, ISG scope will be dedicated to facilitating industry stakeholders' interactions in the context of EMA's extended mandate further to coming into force of Regulation (EC) 2022/123), and further extended, where and as appropriate in the future. It will complement existing fora for interaction, such as industry platform meetings, bilateral meetings, topic or project related meetings. Composition and next dates were also highlighted (See presentation).

3. EMA Mandate extension implementation activities - high level status updates

Marco Cavaleri (EMA), Monica Dias (EMA) and Silvy Da Rocha (EMA) provided respectively updates on the three key areas of the EMA extended mandate Regulation (EU) 2022/123:

a. Emergency task force
b. Medicines shortages and Medical Devices
c. Medical Devices experts panel

See presentations

4. Emergency Task Force (ETF)

4.1 Overview of ETF tasks and responsibilities

Manuela Mura (EMA) provided an overview of ETF tasks and responsibilities. The ETF is responsible

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mainly for 3 procedures: 1) scientific advice; 2) Scientific reviews and 3) scientific recommendations.

It was also explained how the ETF facilitates large multinational clinical trials by providing scientific support to sponsors on establishing joint clinical trials and sponsor agreements.

In the context of the extended mandate, the ETF can liaise with the Medicines Shortage Steering Group (e.g. to review list of critical medicines) and with the Expert Panels on medical devices for scientific support on selected devices, where and if appropriate.

ETF is also responsible for preparedness activities, including monitoring of potential emergencies and examples of activities conducted by the ETF in the ongoing monkeypox were given.

Other tasks of the ETF include international or interinstitutional collaboration, and contribution to EMA's activities related to post-authorisation monitoring of the use, safety and effectiveness of medicines addressing a public health emergency. Increased transparency of all activities during a declared emergency is also a crucial element of ETF.

Changes in the applicant portal for submission of initial and follow-up Scientific Advice were also explained. (See presentation)

ETF dedicated webpage

Follow-up and next steps

- It was agreed that questions raised during the meeting not addressed will be clarified post-meeting and shared with Industry stakeholders in due time.

5. Medicines shortages and Medical Devices

5.1 Medicines shortages activities

Monica Dias (EMA) and Nektaria Varela (EMA) provided an update on activities related to medicine shortages:

- Industry Single points of contact (i-SPOCs) for Marketing Authorisation Holders (MAHs) for each medicinal products authorised in the Union are to be identified so that EMA can engage efficiently should the MAH have medicinal products included in the lists of critical medicines according Regulation (EU) 2022/123. It is highlighted that to fulfil these requirements, MAHs will be requested to enter specific information into the IRIS online platform and that the **registration start date** for this will be **28th June 2022**. It was also noted that i-SPOC system deployed in April 2020 (scope: 31 INNs, hospital ICU medicines) was discontinued on 8 June 2022. EMA has already notified the relevant i-SPOCs.

To support industry a User guide and video DEMO will be available on EMA's corporate website and IRIS platform. A news item is planned for publication on 28 June 2022.

A List of critical medicines for COVID-19 containing medicines authorised for COVID-19 has been published with the objective to closely monitor their supply and demand to identify and manage potential or actual shortages. It will be updated on an ongoing basis to reflect changes in the epidemiological situation. MAHs reporting obligations for critical medicines for COVID-19 were also explained together with the timelines and process for submission.

In addition, a draft list of "main therapeutic groups" (MTGs) of medicinal products that are necessary for emergency care, surgeries and intensive care is being prepared. The MTGs will be published before 2 August 2022.

Nektaria Varela (EMA) gave an update on the development plan for the European Shortages Monitoring Platform (ESMP). She highlighted that its date of implementation is 2 February 2025. Its development will include relevant involvement and consultation with industry stakeholders.

The objective of this new IT platform is to facilitate collection of information on **shortages**, **supply** and **demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry's and Member States' SPOCs.

ESMP delivery will start formally under the SAFe Agile way of working in Q3 2022.

Aspects of the feasibility study and development requirements were presented, and industry stakeholders were reassured of their continuous involvement throughout the development process.

(See presentation).

Follow-up and next steps

- IMPORTANT DATE: 28th Jun 2022: start date to register I-SPOC for human medicinal products included in the list of critical medicines.
- Set up ISG "reporting operational group" to facilitate discussion on reporting requirements including optimisation of guidance/template for Industry.
- Confirmation of receipt of Industry ESMP Subject Matter Experts (SME). Internal review process on-going at EMA.
- Further explore industry stakeholders open/early dialogue on the potential expansion of the ESMP after 2025.

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

Klaus Kruttwig (EMA) explained that within the provisions of Regulation (EU) 2022/123, EMA has a central role in monitoring and mitigating shortages of critical medical devices in the context of a public health emergency (PHE). Implementation date for this provision is 2 February 2023.

The Executive Steering Group on Shortages of Medical Devices (MDSSG) and medical device shortages SPOC Working Party will be set up. A critical list of medical devices will be adopted and Industry single points of contact (i-SPOCs) for the devices in the list, will be identified. These i-SPOCs will be responsible for submitting information, as defined in the Regulation. MSs will also be responsible for providing information for the devices in the critical list, including demand data.

(See presentation)

Follow up and next steps

- Establishment of the ad hoc drafting group on medical device shortages, which will support the preparatory work for the establishment of the MDSSG and supporting Working Party.
- Establishment of necessary interactions with relevant stakeholders in the field of medical devices.

6. Medicinal Devices expert panels

Silvy da Rocha Dias (EMA) presented the Medical Devices (MD) expert panels.
Together with Miguel Antunes (EMA), Alexey Shiryaev (Team-NB) and Sabina Hoekstra (Team-NB), they explained Notified Body (NB) conformity assessment including the Clinical Evaluation Consultation Procedure (CECP) and the Performance Evaluation Consultation Procedure (PECP), that are managed

by the EMA Secretariat.

An update on the MD Expert panels advisory role on technical, scientific and clinical matters was provided, including the role of the EMA Secretariat in ensuring the integrity of the procedure under the legal timeframe.

The role of the expert panels in providing to manufacturers, at their request, scientific advice (SA) on their clinical development strategies for class III and IIb active medical devices for the administration or removal of medical products was highlighted and discussed.

(See presentation)

Follow up and next steps

- Industry will be invited to provide input for the development of the scientific advice procedure to device manufacturers.

Wrap up / end of meeting

Marie-Hélène Pinheiro thanked everyone for the interactive meeting and announces the next ISG meeting: 26 September 2022

The meeting triggered a series of questions which could not be raised during the meeting and it was agreed that they would be clarified post-meeting and shared with Industry stakeholders in due time.

Final a call to members for them to suggest issues and topics for discussion will be send in advance of the next meeting.