21 March 2023
EMA/44728/2023

Highlights of 4th Industry Standing Group (ISG) meeting

21st March 2023 – chaired by Marie-Helene Pinheiro

A. EMA Mandate extension

1. Welcome/Introduction

The meeting was chaired by Marie-Helene Pinheiro (EMA) who welcomed all participants and encouraged them to have an open dialogue and interaction.

2. Medicine shortages and Medical Devices

2.1. Medicines shortages activities

- Joao Ferreira (EMA) provided an update on iSPOC registration, companies reporting rate and ISG operational group on medicines shortages activities. It was highlighted that Marketing Authorisation Holders (MAHs) reporting compliance rate in relation to supply and demand data linked to COVID-19 and Monkeypox (MPX) lists of critical medicines is still relatively low. The related measures taken in order to promote reporting and provide support to those MAHs experiencing challenges in submitting data were presented.
- In terms of iSPOC[1] registration through IRIS platform, a 30% increase was reported compared to the data presented in November 2022 ISG meeting, potentially linked with more guidance being made available and direct contact with MAHs.
- Since its creation, the ISG operational group on medicines shortages has been having technical discussions targeting the reporting template and reporting obligations. Stakeholders feedback on the tools established is appreciated. Operational group Members are currently being consulted on the reporting template to be used during Public Health Emergency (PHE) and Major Events (MEs) and the European Shortages Monitoring Platform (ESMP) industry webforms.

[1] Industry-Single Point Of Contact (iSPOC)

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- During the Q&A session it was clarified that, for those medicines included in the critical lists, reporting obligations apply to all companies identified in the list and are applicable regardless of any actual or potential shortages.

Link to presentation.

- Pedro Pina Ferreira and Sofia Zastavnik (EMA) provided an update on ESMP vision, roadmap and development progress status. It was highlighted that for 2023-Q1 to 2025 the focus is on delivering the Minimum Viable Product (MVP) which will not encompass the full functionalities of the platform. These will be further developed after Q1 2025. A solution for data submission is expected to be available to Industry stakeholders by end of 2023.
- It was highlighted how regular update/consultation/feedback with/of the Industry Subject Matters Experts (SME) is critical to the development of the MVP of the ESMP.
- It was acknowledged that the vision and the roadmap put the development of the ESMP on the right track.
- During the Q&A session it was acknowledged how collection of certain demand/supply data (i.e. hospital consumption) at Member State level is challenging given the different national requirements and levels of maturity of national reporting systems. This challenge will be further addressed in 2024 when discussing data collection from Member States with the SMEs.
- It was also clarified that the ESMP (and the intermediate solution) focuses on crisis events and related medicines on the critical medicines lists.

Link to presentation.

Follow up and next steps:

- MAHs to increase reporting compliance and IRIS registration.

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

- Siofradh Mc Mahon and Klaus Kruttwig (EMA) provided an update on the set up of the Medical Device Shortages Steering Group (MDSSG) as per provision of Regulation (EU) 2022/123.
- MDSSG responsibilities during PHE were outlined including the close collaboration with other stakeholders groups (e.g. DG HERA[2], ECDC[3], MDCG[4], and the support provided by the future Medical Device Shortages SPOC working party. This working party will eventually replace the current ad hoc drafting group on critical Medical Devices shortages. During public health emergencies EO-SPOCs and NB-SPOCS will provide relevant information, In addition, some details were provided on the HERA-EMA JICF[5] working group on data collection recently established in order to gather stakeholders feedback on technical implications amongst others.
- In terms of the IT system to allow data collection on critical medical devices from relevant economic operators, notified bodies and national competent authorities, the Critical Medical Devices Shortages (CMDS) system is being gradually implemented and expected to be finalised in July 2023. The system consists of different functionalities, including user registration, data

[2] Health Emergency Preparedness and Response (HERA)
[3] European Centre for Disease Prevention and Control (ECDC)
[4] Medical Device Coordination Group (MDCG)
[5] Joint Industrial Cooperation Forum (JICF)

collection, data warehousing and analytics. Medical Device representatives were encouraged to attend the Quarterly System Demo scheduled for the 22 March 2023 where the Economic Operator functionality of CMDS is expected to be demonstrated. Economic Operators were also encouraged to take part to the system usability test planned for April 2023. Nominations will be sent out by industry organisations.

- The need to strengthen the interactions with industry associations in the medical device sector and with notified bodies was flagged.
- During the Q&A session, it was clarified that the collection of Medical Devices data is only required during a declared public health emergency, and data is only collected on devices that are included in the list of critical medical devices adopted by the MDSSG for that public health emergency. Need for further engagement with Medical Devices Industry on how to facilitate data collection was acknowledged.
- Clarifications were provided on the interlinks of ESMP and CMDS for combination or co-packaged products as well as the expected cooperation between the MSSG and MDSSG when establishing a list of critical medicines/critical medical devices, and between EMA and HERA. More in-depth discussions with Medical Device industry is needed on how to best use data to avoid duplications in terms of reporting responsibilities.

Link to presentation.

Follow up and next steps:

- Medical Device Industry encouraged to participate to the next Quarterly System Demo planned for 22 March and April usability test.
- EMA to further engage with Medical Devices Industry in order to understand how to facilitate data collection, how to use joint data and reporting responsibilities.

3. HERA-EMA JICF joint working group on data collection update

- Olivier Girard (HERA) and Monica Dias (EMA) provided an overview of the activities under the JICF working group on data collection. Through this working group, HERA and EMA are working together with Industry stakeholders in order to ensure good coordination in relation to data collection. Priority topics were outlined. It was also clarified that there are interlinks with DG Growth and DG Sante.
- A reference was also made to the recent agreement signed between HERA and EMA in order to strengthen the cooperation and to coordinate their work in support of health emergency preparedness and response in the area of medical countermeasures.
- The importance of relevant Industry Stakeholders participation and input to this newly established joint forum was highlighted. DG-HERA is soon going to send information about the next meeting.

Link to presentation.

Follow up and next steps:

- Add the date of next Joint HERA-EMA meeting.

4. Medical devices expert panels

- Silvy da Rocha Dias (EMA) provided an update on Expert panels' activities and related overview of applications submitted since November 2022. It was noted that although there the number of CECP[6] submissions remain low, especially if we compare it with the numbers excepted by the notified bodies for the period. This situation could be linked to the extension of the MDR transitional period according to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023.
- The overview given on the Expert panels consultation procedures also highlighted ongoing activities related to process improvement and workload management. It was also stressed that there needs to be a balance between the mandatory consultation procedures and the submission for advice to manufacturers, currently being object of a pilot. In case of overload, priority needs to be given to the former.
- Miguel Antunes (EMA) provided some insights on the medical device manufactures advice pilot launched in February 2023 to review manufacturers' clinical development strategy and/or proposals for clinical investigations for any class III device or active class IIb devices destined to administer or remove a medicinal product. Due to the needed balance mentioned before, a limit of 10 applications for the pilot phase was established and a prioritization criteria was established in case that number is exceeded. Nevertheless, industry was invited to submit additional applications in order maximize the coverage of therapeutic areas.
- During the Q&A session the definition of "orphan devices" was discussed and it was highlighted that the Orphan devices Task Force set up by the European Commission is currently discussing a working definition. How to establish a structured dialogue between manufacturers and notified bodies for clinical investigation advice to increase advice outcome predictability was also discussed.
- Shayesteh Fürst-Ladani (MPP) provided an overview of pipeline submissions on behalf of the Pharmaceutical Industry members of MPP flagging that the products currently in the pipeline are not in the scope of the pilot and that there are gaps in this context of getting feedback from authorities on combined products and other classes of devices, especially other class IIb.

Link to presentation.

Follow up and next steps:

- EMA to follow up with industry to better understand the pipeline of planned submissions.
- EMA to establish a structured dialogue with notified bodies to increase consultation requests' predictability.

5. Emergency Task Force (ETF): ETF implementation update including preparedness activities

- Manuela Mura (EMA) provided an update on the ETF main activities aiming to monitor and reach preparedness for dealing with future health threats. The scientific advice procedure during

[6] Clinical Evaluation Consultation Procedure (CECP)

preparedness was presented, highlighting ETF's role in the assessment not only during health emergency situations but also in pre-emergency situation for preparedness purposes.

During the Q&A session Industry stakeholders discussed how ETF role and scientific advice structures and timelines were considered adequate and that cooperation and coordination between the different parties involved should be further reinforced. Clarifications were provided on working parties involvement and expectation on formal documentations submission. The involvement of ETF on the EU preparedness for future emergencies was overall considered positive especially the availability of flexible and quicker regulatory procedures.

Link to presentation.

6. CTR implementation and ACT EU update

- Peter Arlett (EMA), provided an update on the activities occurred in 2022 and those planned for 2023 to support the CTR[7] implementation and CTIS[8] use and the response to the Targeted consultation on the implementation of the Clinical Trials Regulation (EU) No 536/2014. Additional guidance on transparency and addition stakeholders engagement was also noted.
- An update was also provided on the ACT EU[9] initiative where the focus for 2023 remains on CTR/CTIS implementation, support to academic sponsors and setting up the multi-stakeholders platform which is having its first kick off meeting on the 22nd and 23rd of June 2023.
- During the Q&A session discrepancies between Member States on part II requirements of the application dossier were reported by Industry. It was also noted that ACT EU Q&A on transparency has been published as a temporary measure until the finalisation of the guidance document on protection of personal data and commercially confidential information while using CTIS is finalised (expected Q2 2023). It was also mentioned that a revision of the current CTIS disclosure rules is expected to be initiated as agreed in December 2022 by the EMA Management Board.

Link to presentation.

7. EMA COVID-19 Lessons Learned activities

- Melanie Carr and Zigmars Sebris (EMA) provided an overview on the outcome of EMA COVID-19 lessons learned noting that, despite the challenges represented by the pandemic, the regulatory network was able to establish regulatory tools enabling rapid approval of medicines and ensuring adequate and timely medicine support, safety monitoring, enhanced the cooperation not only within the EU authorities and organisations but also at international level.
- The unprecedented visibility that the EMA acquired with the pandemic, trigged the need to better refine the communication strategy targeting mis-information and to reinforce capacity and tools to ensure preparedness for any future health threat.

Link to presentation.

8. Agile transformation update

- Zaide Frias (EMA) provided a status update on the EMA Agile transformation initiative highlighting the channels available to Industry stakeholders to engage on all the Agile related activities either at strategic, operational or tactical level.

[7] Clinical Trials Regulation (CTR)
[8] Clinical Trials Information System (CTIS)
[9] Accelerating Clinical Trials in the EU (ACT EU)

- During the Q&A session it was once again highlighted the importance of ensuring that the Industry Subject Matter Experts are enabled to provide a meaningful contribution (two-ways feedback process) from the Industry Community, cross sector and beyond individual company representativeness

Link to presentation.

9. Outcome from 2022 ISG Survey and Key Industry stakeholder 2023 meeting

- Maria Filancia (EMA) provided a brief overview of the feedback received form the 2022 ISG survey noting that generally the meetings and topic proposed were appreciated by attendees and acknowledging the need to ensure adequate level of interaction and participation and avoid duplication of discussions with other fora.

Link to presentation.