19 December 2023
EMA/423751/2023

Highlights - 6th Industry Standing Group (ISG) meeting

21st September 2023 – chaired by Marie-Hélène Pinheiro

A. EMA extended mandate topics

1. Welcome/ Introduction

The chair welcomed all participants encouraging active interaction and contribution to the discussions.

2. Emergency Task Force (ETF)

2.1. ETF implementation update including preparedness activities

EMA updated the ISG on the ETF activities noting that the current work is focusing on preparedness to future threats given the end of both Covid-19 and Monkey Pox Public Health Emergencies status.

According to the Report of the EMA/ETF workshop on Lessons Learned on Clinical Trials in Public Health Emergencies, stakeholders have confirmed the need to have bigger, faster and well-coordinated clinical trials in the EU and globally during Public Health Emergency (PHE) situations. Amongst the solutions/follow up actions proposed, the importance of having an EU level cooperation mechanism between ethics committees and Member States; the benefits of pre-submission assessments and expert consultations and the need to use a one stop shop model inclusive of all relevant regulators during ETF revision of clinical trial protocols were mentioned. In addition, the role of a coordinating committee was deemed useful for the improvement of coordination of clinical trials prioritisation not only during PHE but also during inter pandemic periods. The ISG member were also informed that PHE was added as a Priority Action of the Accelerating Clinical trial in the EU (ACT EU) initiative. The areas where the ETF and the Health Emergency Preparedness and Response Authority (HERA) are collaborating were also outlined. During the Q&A session it was clarified that Industry stakeholders will be involved in the discussions at a later stage.

Link to presentation.

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3. Medicine shortages and Medical Devices

3.1. Status of development of the Union list of critical medicines

EMA provided an overview on the methodology being used to draft the EU (Union) list of critical medicines which is part of the activities of the EMA-HMA Task Force on availability of authorised medicines (TF-AAM). The work is a continuation of the European Commission (EU) structured dialogue initiative initiated in 2021 with multiple stakeholders, including Industry.

In advance of the adoption of the proposed pharmaceutical legislation, Member States, EMA, and the Commission have already started actions that go in the direction of this reform, including the earlier adoption of the Union list of critical medicines. The Union list aims to ensure the availability of specific critical medicines for healthcare systems at all times. Additional coordinated Union-level measures and industrial/capacity support to address supply chain vulnerabilities are foreseen in this context.

It was clarified that the Union list of critical medicines would be used to enable supply security policy measures (in normal times) and should not be confused with other lists used during crisis preparedness (i.e. HERA's Catalogue of Critical Medical Countermeasures, MSSG's List of main therapeutic groups of medicines) as well as crisis response (i.e. HERA's List of Critical Medical Countermeasures in Public Health Emergencies, MSSG's List of Critical Medicines for a Major Event, MSSG's List of Critical Medicines for a Public Health Emergency).

Notwithstanding the differences in the lists currently available at a national level, it was confirmed that there is an ongoing effort to enable the EU broad categorisation of medicines regardless of national considerations and licensing. In particular, the central methodology used to create the Union list of critical medicines is considering the therapeutic indication and the availability of alternative medicines and categorising medicines based on risk levels according to a specific matrix.

The first version of the Union list of critical medicines is expected to be released in Q4 2023 and will be based on several published national lists of critical medicines or lists currently under development, which followed the central methodology agreed by the HMA/EAM TF-AAM in June 2023; subsequently, new versions prioritising review of therapeutic groups of major interest will be released in 2024. In this case, industry stakeholders will be consulted.

EMA clarified that, with the publication of the first version of the EU (Union) list of critical medicines, no immediate consequences are foreseen for companies. Nevertheless, Industry stakeholders flagged the need to consider the potential investment required for companies, especially small and medium-sized enterprises (SMEs).

Link to presentation.

3.2. Update on ESMP development progress status

EMA provided a progress update on the activities done in developing the European Shortages Monitoring Platform (ESMP) in collaboration with Industry Subject Matter Experts (SMEs) who provide continuous input in the business requirements as the functionalities are being developed. A related system demo of the functionalities developed in the latest quarters was also organised and industry stakeholders were invited to take part in such events as these are considered an important opportunity to receive updates and discuss technical aspects. It was also pointed out that the EMA is supporting the Medicines Shortages Steering Group (MSSG) in retrieving details on antibiotics manufacturers in the context of preparedness activities and communication ahead of 2023/2024 winter season. The team will also be focusing on enabling the collection on data on the Marketing Status of Nationally Authorised Products (NAPs) through the ESMP during Crises or Major Events. Ensuring the

interoperability of the ESMP with other systems is also a key aspect of the legislative requirement as it enables data exchange between different systems in support to crisis and preparedness activities. In order to develop the Minimum Viable Product (MVP), several workshops are being scheduled with Industry SMEs between 2023 and 2024. The first workshop is confirmed to take the 8th November 2023. Further information will be sent to/through relevant EU Industry (Trade) organisations.

Actions arising:

- Industry EU trades to promote participation to system demos to gather operational and technical input on the IT products developments.
- Industry SME to participate and coordinate Industry stakeholders feedback to the upcoming interoperability Workshop.

Link to presentation.

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

EMA provided an update on the development of the Critical Medica Devices Shortages (CMDS) reporting system whose MVP development was finalised in July 2023 with the important and valuable contribution of Industry and Notified Bodies. Additional user testing is planned to identify opportunities for improvement with National Competent Authorities in September 2023 and with Notified Bodies in Q4 2023.

Stakeholders were also informed of the publication of Methodology for the establishment of the "public health emergency critical medical devices list which provides details on the methodology used by the Medical Device Shortages Steering Group (MDSSG) to establish the public health emergency critical devices list in case of a PHE.

Link to presentation.

4. Medical devices expert panels

4.1. Update on the mandatory activities

EMA updated the ISG on the current activities linked to expert panels advice noting the receipt of 89 submissions for the clinical evaluation consultation procedures (CECPs) with 10 opinions published and the receipt of 18 performance evaluation consultation procedures (PECP) with 16 published. It was clarified that also any advice requested by either the Medica Device Coordination Group (MDCG) or the EC is made public on the EC website. In this context, EMA technical and scientific support was requested by the European Commission on establishing a definition for "Orphan Devices" and explore ways in support of evidence generation and assessment of such devices.

Link to presentation.

4.2. State of play of the ongoing pilot on advice to medical device manufacturers

EMA provided also the preliminary results from the pilot on advice to medical devices' manufacturers initiated in February 2023 nothing the high interest received and highlighting that the majority of letters received so far are linked to devices used in circulatory system and orthopaedics and the

majority of requests originated from small and medium-sized enterprises SMEs (see further details in the presentation).

Link to presentation.

B. Other cross-stakeholders strategic topics

5. Agile transformation update

EMA provided insights on EMA Agile transformation in LACE (Lean Agile Centre of Expertise)'s vision and mission highlighting the progress made and the benefits of Industry stakeholders involvement and collaboration through the nominated industry Subject Matters Experts (SMEs), strategic portfolio review meetings and quarterly system demos.

EMA provided an overview of the retrospective workshop done in July 2023 highlighting how generally industry stakeholders SMEs were satisfied with the community and interaction reached although further improvement was asked in some areas especially for what relates the application of confidentiality agreements and its harmonised implementation across IT products development and value streams. This being foreseen by industry to prevent sharing of non-confidential information and hence potentially representing an obstacle to cooperation. How to best ensure cross product visibility between all industry SMEs was also a point raised. EMA confirmed that all identified improvement actions are being considered and remedial actions are being investigated for feasibility and prioritised for action. the aim is to have selected actions committed by Q1 2024.

EMA informed ISG members on the transparency improvements made on the EMA corporate website with the publication of all IT Products industry SMEs contact details, all upcoming industry SMEs calls for Expression of Interests (see webpage).
It was clarified that industry SME calls for nominations are launched through relevant EU industry (trade) organisations.
Industry stakeholders were also informed of the extension of certain industry SMEs mandate duration beyond December 2023 and the expected continuation of these industry SMEs involvement, provided the scope of the activities remain within the initial scope of the specific IT product call.Any extensions to SME mandate duration will be coordinated via the relevant EU industry (trade) organisation in the coming months.

Actions arising:

- EMA to present proposed Industry SMEs WS remedial action plan including those related to the application of the confidentiality agreement at the March 2024 ISG meeting (Q1, 2024).
- Industry stakeholders to provide additional comments on industry SMEs IT products involvement experience (Att. EMAINdustryLiaison@ema.europa.eu) by 15th December 2023.

Link to presentation.

6. Update on ACT EU and CTIS (incl. revision of transparency rules)

EMA provided an update on the Accelerating Clinical Trials in the EU (ACT EU) activities, the Clinical Trials Information Systems (CTIS) and the revision of the transparency rules.

For what relates to the ACT EU initiative, an overview of the priorities to be included in the revised 2023-2024 workplan was given. Amongst other activities, the work linked to the implementation of the Clinical Trial Regulation (CTR) (including the CTR Collaborate initiative and launch of a second CTR survey), the support to non-commercial sponsors, the set-up of the multi-stakeholder platform (including the upcoming call for nominations for the establishment of the related advisory group and the EC/Member State project addressing interplay between IVDR/MDR and CTR), the pilot for convergence of scientific advice currently being developed and creation of the Public Health Emergency priority action were flagged. Industry stakeholders were also invited to monitor the recently launched ACT EU website for additional information on other ACT EU initiatives and scheduling of upcoming workshops.

An update on activities related to CTIS was provided. In that respect, the CTIS transition to SAFe Agile and the upcoming call for Industry SMEs in October was flagged during the presentation.

In addition, an overview of the work done for revising the currently implemented CTIS transparency rules (i.e., Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014") was given.

The proposal for the revised CTIS transparency rules takes into consideration the feedback received from stakeholders and members of the public (i.e. CTIS users; 2022 sponsors targeted survey; June 2023 public consultation on CTIS transparency rules). The revision aims at enabling a less complex, more efficient and user-friendly system by ensuring at the same time early public access to key clinical trial information. As such, the changes made are expected to bring significant benefit to sponsors, in terms of process simplification, as well as patients and healthcare professionals given the possibility to have early access of key relevant information and documentation.
EMA also informed Industry stakeholders that these revised CTIS transparency policy are expected to be adopted by EMA Management board on the 5th October 2023 and published thereafter.
In terms of next steps, it was also announced that the new specifications and implementing changes to CTIS will be done Q4 2023 - Q2 2024 and the launch of a "revamped" CTIS public portal and application of revised transparency rules would be in 2024.

Industry stakeholders were pleased by the simplification presented and asked to have some time to carefully review and pose questions related to the proposal. EMA agreed to the receipt of any additional need for clarifications by Friday 29th September 2023.

Actions arising:

- ISG members to provide questions on the revision of transparency rules for CTIS by E.O.B. 29th September 2023 (att. EMAIndustryLiaison@ema.europa.eu).

Link to presentation.

7. EMA Regulatory Science and use of public private partnerships' results to address Regulatory Science Needs

EMA provided an overview of the work being done by EMA on identifying the progress and updating the Regulatory science research needs (RSRN), which were published end 2021 and are linked to the Strategic goal 5 in the EMA Regulatory Science Strategy to 2025. The RSRN includes a lifecycle

approach where the goal is to close regulatory gaps through translation of results, for example by updating the regulatory standards and guidelines, informing scientific advice to developers and improving medicines development and assessment, and additional ways to translate to achieve visible impact that should be explored and established. A public consultation is considered for the draft updated RSRN.

EFPIA presented a summary of their mapping analysis of EMA's published RSRN against completed or ongoing projects under the IMI/IHI Partnerships, highlighting areas of potential high public health impact and the need for accelerating getting to regulatory acceptance. Industry proposed to set up a focus group aiming to reflect on mechanisms for efficiently translating results coming from such public-private undertakings, on optimising how to establish regulatory acceptance, and on creating impact through use in research and regulatory practice.

Actions arising:

- EMA to further reflect on the proposal to set up a focus group to continue the dialogue with relevant Industry stakeholders.

Link to EMA presentation.

8. A.O.B.

ISG members were provided the outline of the meeting dates for 2023 and 2024 (see presentation). In addition the updated email address to contacting EMA industry liaison for any correspondence of EU Trade Associations across EMA organisation was highlighted i.e. EMAINdustryLiaison@ema.europa.eu. Finally Industry stakeholders were informed of the updated EMA corporate webpage for Pharmaceutical Industry which now allows to easily retrieve all the information and supporting materials available for ISG, platforms and bilateral meetings.

Link to presentation.