18 December 2023
EMA/513682/2023

Highlights - 7th Industry Standing Group (ISG) meeting

23rd November 2023 – chaired by Marie-Hélène Pinheiro

A. EMA extended mandate topics

1. Welcome/ Introduction

The chair welcomed all participants and highlighted how the participation of representatives from the European Commission, notified bodies, pharmaceutical and medical device industry has been fundamental in bringing valuable perspectives into the discussions on challenges and opportunities to implement EMA extended mandate and topics of cross industry strategic mutual interest

2. Medicines shortages and medical devices

2.1 Medicines shortages communications update

Clarifications on European Commission (EC) communication COM(2023) 672 on Addressing medicine shortages in the EU

The EC provided an overview on the EC communication addressing medicines shortages In the EU issued in October 2023 presenting cross-commission views.

Acknowledging that shortages are a complex challenge with multifactorial root causes, the communication is a call for the EC, National Competent Authorities (NCAs) and relevant stakeholders groups to further work on a coordinated and collaborative approach in order to strengthen security of supply. The experience gained with the established systems stemming from the adoption of the Pharmaceutical strategy of Europe 2020, the structured dialogue initiative, the legislative formalization with the EMA extended mandate and the establishment of Health Emergency Preparedness and Response Agency (HERA) and the future Reform of EU Pharmaceutical Legislation are considered building blocks from where future approaches can be built. Within the overall vision to ensure a strong, risk-proof, resilient European Health Union, three key goals are recognised:

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1. manage and mitigate critical shortages in a coordinated manner (e.g., EMA coordination and information sharing; voluntary solidarity mechanism, joint procurement, regulatory flexibilities);
2. strengthen security of supply of critical medicines with activities anticipating elements of the reformed pharma legislation (i.e. establishment of a Union list of critical medicines, identification of vulnerabilities and supply chain preventive measures, establishment of a critical medicine alliance);
3. support availability at global level (team Europe) through international dialogue and initiatives.

All Industry stakeholders welcomed the forward looking aspects of the communication and flagged the importance of clarity in the message given to the public in order to prevent any eventual over-reactions. The need to avoid over-reporting and to ensure a shortage-specific targeted approach were also flagged.

Status of development of the Union list of critical medicines

The EMA provided an update on the progress made on the drafting of Union list of critical medicines (version 1), which is expected to be published in December 2023. The background and methodology used to draft the list were reiterated emphasising that the phase 1 goal has been to leverage already available national lists and criteria (i.e. medicines categorisation in "critical", "at risk", "other" based on therapeutic indication and availability of alternatives) in order to compile a document that can be used in particular by those member states where no list is available. For phase 2, starting in 2024, the focus will be given to promotion of convergence and prioritisation of therapeutic groups of major interest.

It was clarified that the soon to be published list will report the list of substances as per WHO Anatomical Therapeutic Chemical classification codes and will be expected to be updated on a yearly basis. It was also clarified that unless shortages will be identified from public health perspective, Industry was not expected to take any specific action at this stage.

Link to EMA presentation.

MSSG toolkit on recommendations on tackling shortages of medicinal products

Clarifications were provided on the recommendations included in the MSSG toolkit (Medicines Shortages Steering Group) which are focused on prevention and mitigation of actual or potential shortages. The toolkit is to be considered a living document gathering the experience gained from COVID-19 and other critical shortages, and includes a non-exhaustive compilation of recommendations (targeting monitoring of supply and demand, European cooperation, increase of supply and fair distribution, regulatory flexibility (common and exceptional), communication and engagement and international cooperation) that the MSSG can consider to manage critical shortage.

The ISG was pleased to have a compilation of all the recommendations and regulatory flexibility options. It was clarified that exceptional flexibilities should only be applied based on a recommendation from MSSG (i.e. their application cannot be proposed by the manufacturers and marketing authorisation holders, but rather initiated only by regulatory authorities), and only in cases where other measures are not sufficient. In addition it was noted that, as per usual process, the company experiencing the shortage will be part of the relevant discussions on possible stock reallocation and any potential to increase manufacturing capacity.

Link to presentation.

2.2 Update on ESMP development progress status

EMA provided an update on the progress of the European Shortages Monitoring Platform (ESMP) development, noting that the main focus of the current scope is activities related to submissions in the preparedness phase and the development of the internal system for case management to optimize business processes. EMA also informed about the intention for to pilot preparedness features for MAH submissions in the first half of 2024.

Ensuring systems interoperability is currently an important aspect under discussion with Industry stakeholders and National Competent Authorities (NCAs). The needs of all concerned parties (i.e. Industry, NCAs, HERA) will shape the roadmap for 2025.

All acknowledged the importance of interoperability of all relevant IT systems, data sources, and standards, where and as appropriate to optimise the functionalities of the ESMP once operational.

Link to EMA presentation.

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

EMA updated the ISG on the follow up activities done with NCAs and economic operators to improve the Critical Medical Devices Shortages (CMDS) since its launch in July 2023. Updates made to the webforms are expected to be showcased during the next quarterly system demo in December 2023. The importance of continuous dialogue was emphasised in order to ensure any necessary refinements are made to the system even in the absence of a public health emergency.

Link to EMA presentation.

B. Other cross-stakeholders strategic topics

3. Update on international activities

Update on EMA collaboration with AMA

The EMA provided a short overview on the activities being done in collaboration with EU National Competent Authorities in order to set up the African Medicines Agency (AMA). Although the future African agency is being modelled on the EU system, the need to ensure an African continental network is also considered key to its future success. In this context, Industry stakeholders were invited to share from their perspective the key pharmaceutical priority needs for successful establishment of such Agency. Medicine evaluation processes and standards and Good Manufacturing Practices (GMP) inspections were considered key.

When and as appropriate, further information will be made available to facilitate and foster relevant industry stakeholders engagement.

Update on reliance and other collaborative pathways including EMA assessment reliance and "OPEN" pathway global submission alignment

The ISG was given an overview of all the established reliance and collaborative pathways amongst regulators that enable to synergise globally for the benefits of patients worldwide.

- Certificate of pharmaceutical products (CPP): this is a key reliance tool which confirms marketing authorisation status and GMP compliance.
- European Public Assessment Reports (EPAR): these reports increase transparency on committees scientific discussion and can be used by several countries. Industry stakeholders were invited to share such reports.
- EMA-World Health Organisation (WHO) cooperation through EU-M4all initiative, WHO collaborative registration procedure and facilitated product introduction is facilitating registration and capacity building in low and middle income Countries.
- Last but not least, the Open procedures at EMA for non-EU authorities (OPEN) initiative covering amongst other antimicrobial resistance and PRIME medicines. It was highlighted that Brazil was also now part of such process in addition to Canada, Switzerland, Australia, Japan and WHO.
  In that context, EMA stressed the importance for Industry stakeholders to align as much as possible Marketing Authorisation Application submissions and engage early in order enable identification of OPEN partners, as listed above
  Industry stakeholders highlighted the importance to consider their marketed intentions/choices, when considering partners participation.

Link to EMA presentation.

EMA-FDA international collaboration in the context of Oncology medicinal products global development

The EMA and the US Food and Drug Administration (FDA) collaboration over 20 years was presented to ISG members. More specifically, the oncology cluster not only includes FDA but also participation of other partners such as Health Canada, PMDA, TGA, Swissmedic. It was emphasised how the cluster is a key tool to foster global discussion on the entire product lifecycle and strengthen collaboration on early cancer drug development worldwide. Last but not least, the cooperation promotes identification of topics where guidance to stakeholders is needed.

Link to EMA presentation.

Update on the ICMRA future vision of PQKMS developments including an update on the 2 pilots (PAC and CHIP)

An overview of work done in the context of the International Coalition of Medicines Regulatory Authorities (ICMRA), was presented. Under this framework and following the experience gained during COVID-19 pandemic, the Pharmaceutical Quality Knowledge Management System (PQKMS) group was formed in September 2021 with the aim to enhance availability of quality medicines through regulatory reliance and agility. As part of PQKMS activities, including the adoption of dossiers unique identifiers and collaboration with International Council on Harmonisation (ICH), International Pharmaceutical Regulators Programmes (IPRP) and Pharmaceutical Inspection Co-operation Scheme (PIC/s), for two

pilot phases (collaborative assessment on chemistry, manufacturing, and control (CMC) post-approval changes and hybrid inspections) were presented. Industry stakeholders were invited to participate to these activitis and align global application submissions. Overall there was a high interest and support from Industry stakeholders' on all these pilots and initiatives at ICMRA level.

Link to EMA presentation.

4. Innovation in manufacturing at global level – QIG 2023 achievements and related international collaboration initiative

EMA provided an overview of the activities of the Quality Innovation Group (QIG) to support innovation in medicines manufacture in EU for the benefit of patients, since its launch in 2023. QIG priority topics for 2023 have been continuous manufacturing, decentralized manufacturing and digitalization/automation. QIG activities centred in the organization of two listen and learn focus group (LLFG) meetings with stakeholders (industry and academia) to discuss their challenges with the development and implementation of these technologies and their proposed solutions to address them, and publication of the meeting reports. This has been complemented with follow-up 1:1 meetings with stakeholders, contribution to ITF meetings, provision of product support via scientific advice, and preparation of guidance documents to share knowledge (e.g. a published Q&A on the use of X-ray sterilisation process for single use systems, and a Q&A on process models under preparation). QIG also met FDA colleagues from CDER and CBER to exchange experience and explore avenues for closer collaboration in this area and support international collaboration. QIG will continue to provide support to stakeholders.

Industry stakeholders were encouraged to continue involvement pro-actively and approach the QIG group with specific innovative technologies/products where support is needed.

Actions arising:

- Industry stakeholders to participate to QIG group activities with specific case studies/products (QIG@ema.europa.eu with copy to EMAIndustryLIaison@ema.europa.eu) in line with QiG priorities.

Link to EMA presentation.

5. ISG 2023 topics review

The ISG was invited to submit topic proposals for 2024 by **EOB 15th December 2023** using slido QR code (see presentation).

Link to EMA presentation.

6. Close of the meeting and next step

The open dialogue achieved throughout 2023 was a key factor for the success of the Industry Stakeholder Group (ISG) meetings as a fora enabling Industry stakeholders to exchange views not only on the implementation of the EMA extended mandate but also on other cross industry strategic topic of interest. Support to this continued dialogue was expressed be pursued in 2024.

The chair and all Industry Stakeholder team wished all ISG Members a merry Christmas and happy new year 2024!

Next meeting dates:

- 22 March 2024 – virtual
- 28 June 2024 – hybrid
- 26 September 2024 – virtual
- 21 November 2024 – hybrid