26 September 2024
EMA/449820/2024
European Medicines Agency

Highlights- 10th Industry Standing Group (ISG) meeting

26 September 2024 – Chaired by Marie-Hélène Pinheiro, EMA Industry Corporate Liaison

1. Welcome and introduction

The chair welcomed all representatives from the human and veterinary pharmaceutical and medical device industry sectors as well as the EU Member States, European Commission and Notified Bodies members.

An update on the implementation of the actions arising from the 9th ISG meeting was provided noting in particular the high level of pharma and medical device industry participation to respectively the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) and to the Information session on the pilot for expert panels' advice for orphan medical devices. Upcoming events and initiatives were highlighted.

2. Medicines and medical device shortages (H+MD)

2.1. New process for Medicine Shortage Communications (H)

The ISG was informed on the new process for Medicine Shortage Communications (MSC) recently endorsed by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) aiming at optimising communication to healthcare professionals for critical shortages caused by commercial or supply capacity reasons (and unrelated to quality/safety and efficacy reasons). The proposed MSC approach is similar to the already established Direct Healthcare Professional Communications (DHPCs), which will still be used for communicating on medicines shortages linked to quality, safety or efficacy issues and involving CHMP.

The ISG noted the upcoming pilot phase of both template and process (October 2024- March 2025). Relevant details will be published in due course.

Actions arising:

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- Industry, within scope, to participate in the pilot phase of the Medicine Short Communications (CMS) from October 2024 to March 2025 and provide comments on both the template and process. This means that for any critical shortage caused by commercial or supply capacity reasons (and unrelated to quality/safety and efficacy reasons) the new template should be used.

Link to presentation.

2.2. Update on the development of the European Shortages Monitoring Platform (ESMP) (H)

The EMA updated on the ESMP development confirming that most of the features linked to crisis and MSSG-led preparedness for CAPS and NAPs have been completed or are being further refined based on the feedback received from Industry stakeholders for the February 2025 implementation deadline.

In addition, the go live of the Marketing Authorisation Holder (MAH) preparedness and crisis reporting for CAPs feature was also confirmed for November 2024. It was highlighted that this reporting functionality is not replacing additional national reporting requirements. In preparation to November 2024 deadline, a User Acceptance Testing and webinar are planned and relevant Industry stakeholders were invited to participate.

Interoperability discussion is currently progressing with NCAs and Industry Subject Matter Experts (SMEs) to facilitate MSSG-led crisis preparedness. In this regard, the technical specification for machine-to-machine solution have been released to MSSG-ESMP WG and SMEs in September 2024 and a consultation on NCAs technical specification will start in Q4. Further work with SMEs on MAHs data set is planned between December 2024 and March 2025.

It was also confirmed that, as the ESMP platform retrieves CAP and non-CAPs data from the Product Management Service (PMS). Data stored in PMS are in turn loaded from both the XVMPD and SIAMED EMA IT data storage systems. It was communicated that all authorised products data has been successfully migrated from these systems as appropriate.

Authorised product data available in PMS can therefore be accessed by registered users through two types of applications:

- the Product User Interface (PUI) hosted in the Product Lifecycle Management (PLM) portal
- Application Programming Interface (API) also known as system-to-system connection.

Industry stakeholders were reminded to:

- Review their own data submitted for CAPs and Non-CAPs data via PMS API and PLM PUI systems.
- Submit pack sizes for non-CAPs for Union list of critical medicines to XEVMPD by February 2025.
- Enrich structured manufacturers and pack sizes data for non-CAPs (ULCM) in PUI as of January 2025 (optional submission of data carrier identifier in PUI).

Upcoming events providing further support and clarifications were also outlined:

- Public training webinar on PMS PUI: 16 October 2024 (10:00 – 11:00 CEST) (registration)
- Q&A Clinics on PMS API & PUI: 22 October 2024 (10:00 – 10:30 CEST) (registration); **29 October 2024** (10:00 – 10:30 CEST) (registration)

Link to presentation.

Actions arising:

- CAPs and NAPs MAHs to support ESMP February 2025 go live reviewing and/or continuing reporting their medicinal products pack sizes by the previously mentioned deadlines and participate to relevant training to clarify the reporting requirements, process and deadlines.

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

An update was provided on the activities of the Health Emergency Preparedness and Response (HERA) Joint Industrial Cooperation Forum (JICF) subgroup on Medical Devices. An overview on the methodology for establishment of the "public health emergency critical medical device list" and on the procedures for data collection of medical devices in a recognised public health emergency at Union level.

In addition, HERA provided a short overview of the process for medical device and in vitro diagnostics data collection during public health crisis and of the medical countermeasure (MCM) in-depth analysis.

An update was also provided on the implementation of improvements of the Critical Medical Devices (CMDS) IT System, enabling, enabling country specific data collection from relevant Economic Operators.

EMA will continue the discussion in the EMA-HERA JICF working group with a focus on data analysis while HERA will continue to collect feedback from the members to improve the procedures and tools for MCM data collection and in-depth analysis.

Clarifications were asked on the access to EUDAMED database and scope of the data requests (e.g. clinical trials) (MPP).

The complexities in reporting requirements and possible interlinks between different reporting obligations were highlighted by industry stakeholders (EUCOPE). The need for further clarifications was noted.

Actions arising

- EMA will inform industry associations on further steps regarding communication strategies on CMDS
- HERA to continue the development of the MCM Catalogue and Questionnaire for the in-depth analysis.

3. Medical devices expert panels (MD)

An update was provided on the expert panels' pilot on advice to device manufacturers of class III or IIb active devices destined to administer or remove a medicinal product on the clinical development strategy and/or proposals for clinical investigations. The pilot is running into its final phase and the procedure will become available again in early 2025 with the adaptations taken from the learnings of the pilot. It was clarified that some "combination products", i.e., only medical devices with an ancillary medicinal substance are in scope of this procedure.

More details were provided on the new pilot on advice on orphan devices development. This pilot will run until the end of 2025, but after the end of October 2024, 4 submissions will be selected as the first

projects to test the advice on orphan device status and/or the sufficiency of clinical data/clinical strategy. The pilot will test the role described for the expert panels in the MDCG guidance on the clinical evaluation of orphan medical devices. A summary of the Information session on the pilot for expert panels' advice for orphan medical devices was given noting the high interest showed by the participants. It was also informed that orphan in vitro diagnostics will be considered at a later stage under a new MDCG guidance.

Link to presentation.

4. Implementation of Regulation (EU) 2024/1689 on artificial intelligence impacting EMA's activities – Cross industry stakeholders impact analysis and preparedness (H+V+MD)

Representatives from the pharmaceutical industry, medical device industry and the European Association of Medical Device Notified Bodies (Team NB) provided their perspectives on the implementation of Regulation (EU) 2024/1689 on Artificial Intelligence (AI) (AI Act).

- Cross-pharmaceutical industry stakeholders (EFPIA, Europharm SMC, AESGP, EUCROF, Medicines for Europe, MedTech and Pharma Platform (MPP), EuropaBio, EALTH, AVC) recognised that regulation (EU) 2024/1689 is not the first attempt to regulate AI and welcomed the introduction of a definition in line with OECD. Understanding if and how "R&D exemptions" outlined in article 2(6) apply is considered to be key in order to have full understanding on the implications of this regulation for the pharmaceutical sector. Currently this sector understand that they fall within the exemption as foreseen in the Regulation but recognised that this was not confirmed by the European Commission.
- Cross-medical device industry stakeholders (MedTech Europe, COCIR) flagged the need to ensure coordination between all stakeholders involved to facilitate alignment between the AI act and the medical device and in vitro diagnostic regulations. Ensuring access to data and involvement of relevant stakeholders into the AI act implementation process were also emphasised.
- TeamNB also recognised the availability of other legislation regulating AI and flagged the differences in risk classification of AI use cases and medical devices classification. It was confirmed that notified bodies across the EU are preparing for the AI act implementation and that smooth implementation will be determined by the interplay of all actors concerned including those impacted by the medical device regulation and in vitro diagnostic regulation and by the successful development of standards.

The EMA welcomed the discussions with stakeholders on this important topic and confirmed close cooperation with the European Commission to ensure clarity of requirements and impact especially for the development and the monitoring of medicinal products.

ISG members flagged the need to have an open dialogue with relevant bodies to ensure clarity of requirements given the challenges of ensuring interlinks with national legislation and other relevant regulations.

EMA thanked all participants for sharing their implementation preparedness status and for highlighting their respective challenges. The ISG was invited to follow the discussions at the upcoming HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) - enabling the safe and responsible use of AI

where the EMA AI workplan will be discussed and any aspects of the below affecting EMA activities highlighted as relevant.

Actions arising

- Industry Stakeholders to participate to HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) - enabling the safe and responsible use of AI to strengthen EMA and its stakeholders understanding of its operational and environmental sector direct impact.

5. Regulatory/HTA interface under the HTA Regulation (H+MD)

The ISG was updated on the activities linked to the implementation of the Health Technology Assessment (HTA) regulation focusing on the interface between regulators and HTA bodies (i.e., Joint Scientific Consultation (JSC), Joint Clinical Assessment (JCA) and identification of emerging technologies and workplan contribution).

Concerning the information to be provided from the regulatory assessment in the centralised procedure, the new requirements as per Article 3 of the Implementing Regulation on JCA for medicinal products were outlined. The ISG was reminded on the need to submit parallel notifications for an upcoming submission of a marketing authorisation application that is also in scope of JCA assessment ("Letter of intent"). Industry EU trade organisations were invited to flag this information within their affiliated members.

It was also flagged that the Guidance on Parallel EMA/HTA body (HTAb) Scientific Advice for the Interim Period is ending at the end of 2024 and that a new procedure of parallel JSC under the HTA regulation is being developed. Also it was noted that a dedicated Implementing Regulation on cooperation by exchange of information with EMA has been drafted, which provides additional clarity on confidentiality safeguards.

Industry stakeholders (EFPIA) expressed concerns on the provision of information regarding the target filing date and indication for upcoming applications. More clarity on how such data is processed by the HTA secretariat would be appreciated. In response it was noted that such notification is necessary for the planning of processes outlined in the HTA regulation.

Actions arising:

- Industry stakeholders to remind members on the requirement of parallel notification for products in scope of JCA assessment via the "Letter of intent" template.

Link to presentation.

6. Update on ISG focus group on Regulatory Science Research Translation (H)

An interim update from the ISG focus group established during the 6th ISG meeting (September 2023) on advancing regulatory science research with the objective to develop recommendations, priorities and approached for enhancing the translation of regulatory science research outputs into practical applications.

The ISG was informed on an upcoming public consultations on the updated regulatory science research needs and on the concept paper for setting up the European forum for regulatory science research.

It was clarified that the regulatory science research needs are stemming from the European Medicines Network Strategy (EMANS) to 2025. The importance to also participate to EMANS to 2028 public consultation in order to ensure reflection of regulatory science research needs into the strategy was flagged.

Action arising

- ISG to participate to upcoming public consultation on the updated regulatory science research needs and on the concept paper for setting up the European forum for regulatory science research.
- ISG to participate to upcoming public consultation of the EMANS to 2028.

Link to presentation.

7. Close of the meeting and next steps

The interest and participation of ISG members into the discussions were welcomed.