21 November 2024
EMA/9662/2025
European Medicines Agency

Highlights - 11th Industry Standing Group (ISG) meeting

21 November 2024 – Chaired by Marie-Hélène Pinheiro, EMA Industry Corporate Liaison

1. Welcome and introduction

The chair welcomed all participants to the last ISG meeting of 2024 and thanked all members for their participation and collaboration throughout the year.

The overview of follow up actions arising from the 10th ISG meeting was provided encouraging Industry stakeholders to contribute to the currently open public consultations (i.e. European Platform for Regulatory Science Research concept paper consultation; EMANS to 2028 consultation) and upcoming activities.

2. Shortages prevention management activities

2.1. Update on release of Union list of critical medicines Version 2 (H)

The EMA provided an update on the revision of the Union list of critical medicines (ULCM) published in December 2023, version1. ULCM version 2 and the related Questions and answers on the Union list of critical medicines are expected to be published in mid-December 2024 and will take into account EMA's list of main therapeutic groups, HERA medical countermeasures and the input received from stakeholders. The ULCM version 2 will include 28 additional active substance groups and combinations and will enhance transparency by including details on the route of administration. It was emphasised that the union list will be updated regularly as needed.

Industry stakeholders (Medicines for Europe, EFPIA) recognised the efforts made and expressed the need to keep the focus of ULCM on critical substances in order to guide regulatory policies and to manage situations of crisis. The point made was acknowledged by EMA who highlighted that in this ULCM update (version 2), additional restrictive criteria (e.g. seriousness of disease, availability of alternatives; incidents criticality) across member states when selecting the substances were included complemented also by national lists. It was clarified that the ULCM will be used to develop regulatory actions (such as inventory management, supply and stock monitoring) and other relevant activities that will arise from the Critical Medicines Alliance and the new pharma legislation.

Link to presentation.

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2.2. Update on Shortage Mitigation Plan (SMP)/ Shortage Prevention Plan (SPP) (H)

The ISG members were updated on the upcoming pilot phase implementing the templates for Shortage Mitigation Plans (SMP; to be used to address potential or actual shortages and includes proposals to mitigate the impact of the shortage on patients) and Shortage Prevention Plans (SPP; to be used to identify possible vulnerabilities in the supply chain and includes proposals to manage those risks) which were adopted and published in June 2024 following consultation with stakeholders.

The 6 months pilot phase is expected to be launched in December 2024 and will focus only on certain active substances for human use and therefore relevant Marketing Authorisation Holders (MAHs) will be directly invited to contribute. Nevertheless, all interested industry stakeholders were recommended to familiarise themselves with the templates whose use will be enforced in case of a crisis for medicines included in the list of critical medicines for a public health emergency (PHE) or major event (ME).

Industry stakeholders (PPTA) flagged the need to take into account specific active substance and medicine cases (e.g. plasma derived medicines, radiopharmaceutical medicines) and they were invited to use the templates and report any comment/suggestion for improvement. EMA informed that SPPs or SMPs of other products not included in the pilot are welcomed to streamline the process.

Link to presentation.

Post meeting note:

Pilot launched in December 2024: Medicine shortages and availability issues: guidance for companies | European Medicines Agency (EMA).

Action arising:

- The EMA to communicate on the SPP, SMP pilot phase.
- ISG members to familiarise themselves with the templates and participate to the pilot phase as needed.

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

ISG members were thanked for their support to the development of the European Shortages Monitoring Platform (ESMP). The launch of the MAH routine shortage reporting for product authorised via the centralised procedure (CAPs) is confirmed for the 28th November 2024. Industry was reminded of the recent European Shortages Monitoring Platform (ESMP) training session on routine shortage reporting for marketing authorisation holders of CAPs) and was invited to consult the available published material in preparation for the go live.

It was clarified that, after the launch, national reporting requirements will still be applicable for products authorised via National Procedures (NAPs) while for CAPs a transition period will last until February 2025. Additional guidance and training initiative will be made available on the ESMP webpage accordingly.

The ISG was also reminded about the current PMS mapping and the requirement for industry to continue to submit pack size information of medicines included in the Union list in XEVMPD/Art.57 by

February 2025 to enable progression of mapping activities and to submit manufacturers and structured pack size by December 2025.

Upcoming events were outlined and participation encouraged.

Clarifications were asked on the XEVMPD/Art.57 data required for the additional substances expected to be added in the ULCM (Medicines for Europe) and it was confirmed that for these, new timelines will be given in due course. The current scope of PMS data entry requirements apply to the current critical list (version 1).

Link to presentation.

Actions arising:

- Industry stakeholders to review CAPs and non-CAPs data via PMS API and PLM PUI systems; to submit pack sizes for non-CAPs for Union list of critical meds to XEVMPD by Feb 2025; enrichment of structured manufacturers data and pack sizes for non-CAPs (ULCM) in PUI by December 2025; optional submission of data carrier identifier in PUI from January 2025.
- Industry stakeholders to take part to relevant events and activities (as outlined on slides 13 and 14).

3. Implementation of HTA Regulation

3.1. Regulatory/HTA interface under the HTA regulation (H+MD)

An overview was provided on the status of the implementation activities carried out by the EC and the Member States, which has resulted in the adoption of 3 implementing acts (Joint Clinical Assessment (JCA) procedures for medicinal products; Procedures for cooperation with the EMA, Procedures for the management of conflicts of interest) and in the ongoing finalisation of 3 additional acts (Joint Scientific Consultation (JSC) procedures for medicinal products; Procedures for JSC for medical devices and in-vitro diagnostics; JCA for medical devices and IVDs).

Focusing on the regulatory/HTA interface under the Regulation, details were given in relation to the operational aspects of the parallel notification process and on the framework for sharing information between the EMA and the Heath technology Assessment (HTA) secretariat.

The importance of submitting the letter of intention to both the EMA and the HTA secretariat in parallel to ensure compliance was highlighted. Industry stakeholders were reminded of the importance of preparedness activities.

Industry stakeholders (EFPIA) recognised the importance of the new notification form and its impact on the assessment of medicines and requested clarification on confidentiality safeguards and the use of confidential information by HTAs. The ISG was assured by the EC that confidential information will be appropriately identified and securely shared with the HTA Coordination group and its subgroups via the HTA IT platform. Published material will not contain confidential information. The need to increase submission predictability was acknowledged by the ISG members who discussed the importance of the letter of intent single form in facilitating predictability.

Link to presentation.

Actions arising

- Industry stakeholders (human, medical devices) to undertake preparedness activities for the implementation of the HTA regulation provisions.

4. Other topics of strategic interest

4.1. EMAN strategy to 2028 updates

The Agency provided further insights on the process that led to the revision of the European Medicines Agencies Network Strategy (EMANS) to 2025 into the EMANS to 2028 which is currently open for public consultation until the 30th of November 2024. More clarifications were provided on the 6 strategic areas (1.Accessibility; 2. Leveraging data, digitalisation and Artificial Intelligence;3. Regulatory science, innovation and competitiveness; 4. Antimicrobial resistance and other health threats; 5. Availability and supply; 6. Sustainability of the network). For more details, stakeholders were referred to the reflection paper published in October 2024. Stakeholders were invited to contribute to the public consultation and to participate to the virtual multi-stakeholder workshop planned for the 13th of February 2025 where the feedback received and the final strategy will be discussed in advance of its final adoption at the March 2025 EMA Management Board meeting.

Link to presentation.

Actions arising:

- ISG members to contribute to the public consultation by 30th of November 2024.
- EMA to provide details on the multi-stakeholder (virtual) meeting planned for the 13th of February 2025.

4.2. Information on Cross EU Agencies One Health Task Force (H+V+MD)

The EMA provided an overview of the activities taken at EU level in the context of the One health Task Force which is recognising the interconnection between human, animal, plant and environment health. An overview of the Scientific Advice Mechanism (SAM) and of the One health task force joint framework, formed by European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA), and the European Medicines Agency (EMA) ECDC, ECHA, EEA, EFSA and EMA was given. The task force aims at contributing to the implementation of one health approach in European Agencies with the ultimate goal of strengthening the ability of the EU and its Member States to respond to health crisis. Key objectives (strategic coordination, research coordination, capacity building, communication and stakeholder engagement, partnerships and joint activities) were presented flagging stakeholder engagement mapping as a fundamental objective for the progression of the work.

Link to presentation.

4.3. Industry stakeholder presentation om cumulative impact assessment of the Green-related files (EFPIA (H))

EFPIA provided their assessment of the potential cumulative impact represented by several policies linked to the green deal files highlighting the significant interactions between pharmaceutical and non-

pharmaceutical legislations. The need of ensuring a coherent policy development that can take into account possible implications for research and development and medicines availability was highlighted. The need for stakeholder engagement forum was flagged.

The EMA acknowledged the points made and encouraged industry stakeholders to also raise the reported concerns with relevant authorities including the European Commission.

4.4. ACT EU and CTIS activities updates (H)

The EMA provided an update on the activities undertaken to revise the Accelerating Clinical Trials in the EU (ACT EU) workplan in order to incorporate stakeholders' feedback (received through the Clinical Trial Regulation (CTR) survey, the Multi-stakeholder platform advisory group (MSP AG) and CTR collaborate). The workplan will be updated in terms of programme structure and content with focus on short/medium term deliverables. Among others, the CTR procedural and technical aspects, the dedicated support to non-commercial sponsors, the ICH E6 change management and training activities and the continuation of the consolidated advice pilot initiative were highlighted as main priorities.

The ISG was also updated on the discussions held at the CTIS forum highlighting system improvements make following its stabilisation and flagging area for further improvement. In terms of transparency, the EMA confirmed that CTIS will continue, until further notice, to not publish dose strength information for all study categories. With respect to category 1 trials, it was also confirmed that sponsors will be allowed to use 'dummy data' (e.g. 00 digits) when the 30-month deferral of publication is not sufficient to protect commercially confidential information.

Link to presentation.

4.5. EMA update on IT Portfolio Agile governance key 2025 dates and Subject Matter Experts (SMEs) status

ISG members were reminded of the upcoming Quarterly system demo (12/12/2024) and were informed about 2025 tentative meeting dates for the Quarterly Strategic Portfolio Review, Quarterly System Demo and Regulatory Optimisation Group.

An update on the recent extension of some industry Subject Matter Experts (SMEs) and new calls made was also highlighted.

Link to presentation.

4.6. EMA international activities: Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative

ISG members were reminded of the Opening procedures at EMA to non-EU authorities (OPEN) initiative and its scope extended after the COVID-19 pandemic (Antimicrobial Resistance (AMR) response treatments and novel antimicrobials; priority medicines designated under the PRIME scheme; products which address a high unmet need; vaccines and medicines that respond to health threats or public health emergencies). Further to industry comments, the MAAs' "Letter of Intent" has been updated for applicants, as part of their regulatory strategy to express their interest to participate to the OPEN initiative. However, since the changes was implemented, no applications were submitted.
EMA is interested to gather feedback from industry stakeholders and asked relevant EU industry (trade) organisations to their members to be in the position to discuss the output at the next ISG meeting scheduled for the 28th March 2025.
Industry stakeholders acknowledged the request and flagged the need to share more insights on the tangible benefits of the initiative.

Link to presentation.

Action arising:

- A small industry working group will be set up early 2025 to discuss the scope of the survey between EMA and Industry.
- Relevant Industry EU (trades) organisations to survey members on challenges preventing OPEN applications and report back at the next ISG meeting in March 2025.

5. Close of the meeting and next steps

The ISG members were informed about the planned dates for 2025 meetings (28/03/2025 (hybrid); 30/06/2025 (virtual); 30/09/2025 (hybrid); 11/12/2025 (virtual) and were encouraged to provide their feedback by the 20th of December 2024 on their experience with one or more meeting attended in 2024.

Action arising:

- ISG members to participate to the feedback survey by EOB 20th December 2024.