7 August 2024
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European Medicines Agency

Highlights - 9th Industry Standing Group (ISG) meeting

28th June 2024 – Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The chair welcomed the ISG members, highlighting the broad representation from the pharmaceutical industry (human and veterinary) and the med-tech industry as well as from the European regulatory network including representatives from the European Commission, member states and Notified Bodies.

An update on the implementation of the actions arising from the 8th ISG meeting was provided, noting the contribution of Industry stakeholders to several pubic consultations and participation in events organised. Upcoming events were also highlighted.

2. Update ISG mandate (H+V)

ISG members noted the recent expansion of ISG membership to include representatives of the veterinary pharmaceutical industry and related regulatory bodies (CVMP, CMDv). Relevant amendments to the ISG mandate were presented, highlighting how this will ensure the participation of relevant stakeholders in discussions on strategic and cross-sectorial topics of common interest. Consequently, each agenda item will also reflect the sectors of interest.

Link to presentation.

Actions arising:

- EMA to publish updated mandate.

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3. Medicine shortages (H)

3.1. Launch of the Critical Medicines Alliance (CMA) and vulnerability assessment

DG HERA provided an overview of the Critical Medicines Alliance (CMA)'s composition and activities. As a consultative mechanism bringing together relevant stakeholders from EU Member States, industry, civil society, and the scientific community, the CMA complements the work of the already established Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and Medicine Shortages Single Point of Contact (SPOC) Working Party (SPOC WP). CMA focuses on the holistic identification of vulnerabilities affecting human medicines and on the identification of relevant measures to strengthen the supply chain. The activities of the two related working groups (WG) (WG1: Strengthening manufacturing capacities in the EU; WG2: Diversifying supply chains, international partnerships and cooperation) and the results of the pilot exercise on the identification of supply chain vulnerability assessment for a subset of critical medicines were presented.

Industry stakeholders were encouraged to participate in the work of the CMA.

Industry stakeholders welcomed the initiative and asked for the CMA to ensure that synergies are identified with other established groups, including those at EMA as appropriate, and initiatives in order to avoid duplication (EFPIA). The need to take actions to address the vulnerabilities already identified was also highlighted (Medicines for Europe). In addition, the CMA was asked to ensure that all stakeholders, especially manufacturers, are involved into the discussions (EUCOPE) and that the challenges faced by small-, medium-sized enterprises in relation to pricing, incentives and reimbursing mechanism are taken into account (Europharm SMC).

Actions arising:

- Regulators to continue to ensure alignment and synergies, where appropriate.

Industry stakeholders to ensure participation in relevant activities.

3.2. Update on "MSSG recommendations to strengthen supply chains of critical medicinal products"

EMA presented MSSG recommendations to strengthen supply chains of critical medicinal products clarifying that these recommendations are to be considered as product specific regulatory measures (i.e., short-medium term recommendations). On the contrary, the CMA recommendations should be considered as more holistic industrial policy measures with a long term applicability.

Industry stakeholders noted the possible overlaps with the recommendations outlined in the MSSG Toolkit on recommendations tackling shortages of medicinal products (EFPIA), however it was clarified that the MSSG toolkit objective is to address critical shortages of medicinal products and is applicable to all critical shortages while the MSSG recommendations are preventive measures to strengthen supply chains of critical medicines included in the Union list of critical medicines. Additionally stakeholders invited EMA to consider the actual implementation timing of certain recommendations especially when it comes to new technologies (such as addition of suppliers and manufacturers) (EFPIA). Proposals on other types of recommendations (e.g., tackling demand, export bans, ePI, pack size) were discussed (EFPIA, EUCOPE, Affordable Medicines, EuropeBio, Medicines for Europe).

Actions arising:

- ISG to provide comments/proposals on the MSSG recommendations to strengthen supply chains of critical medicinal products directly to MSSGSecretariat@ema.europa.eu.

EMA provided also an update on the Shortage prevention and mitigation plans (SPMP) templates recently published following a stakeholders consultation. It was clarified that the templates are applicable to medicines for human use and would need to be used mandatory during a crisis concerning any substance included in the Union list of critical medicines for that crisis. Additionally, in line with the Good practices for industry for the prevention of human medicinal product shortages, the use of the SPMP templates is recommended for all human medicinal products marketed in the EU. An implementing guidance is being developed and is expected to be adopted in Q4 and piloted in 2025.

Industry stakeholders flagged the need to ensure that the pilot phase is planned and announced in due time to ensure Industry preparedness (EuropaBio).

Action arising:

- EMA to update industry stakeholders with guidance and pilot details.
- Industry to contribute the pilot phase, once launched. Further details will be sent closer to the date to all relevant EU Trade Associations.

Link to presentation.

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

EMA confirmed that the development of ESMP is on track including finalisation of the functionalities "marketing status" and "manufacturing details and production plan for Centrally Authorised Medicines (CAPs)". As published on the ESMP webpage, the next milestone is planned for November 2024 with the release of Marketing Authorisation Holder preparedness and crisis reporting. This will be followed by the release of the National Competent Authorities MSSG-led preparedness and crisis reporting in February 2025. Industry stakeholder participation and engagement was noted in the context of the webinar European Shortages Monitoring Platform Essentials and Industry Reporting Requirements. Following a user acceptance testing exercise performed with Industry Subject Matter Expert, additional system improvements are planned. Relevant communication and implementation strategy activities are being planned in order to ensure preparedness for the ESMP launch.

The data workflow from XEVMPD, Product Management Service (PMS) and ESMP was outlined clarifying that pack size information already submitted in XEVMPD will be consumed by PMS and therefore will be automatically available in ESMP. Therefore, in order to facilitate future crisis management, it was stressed how MAHs are required to ensure that authorised pack size for products included in the Union list of critical medicines are submitted to XEVMPD before February 2025. ISG members were encouraged to attend the Public webinar on pack size submissions: from XEVMPD to product management service (PMS) planned for the 11th of July which is expected to provide more clarity on the requirements.

It was clarified that for routine shortage reporting only CAPs are required, therefore no action on the part of the industry is required. The Union list of critical medicines has been established as a starting point that helps avoid late submissions by applicants for crisis reporting and MSSG-led preparedness.

Industry stakeholders flagged challenges for MAHs in providing the required information given the need to update internal systems (EFPIA). The need of further discussion was acknowledged and expected to be addressed as part of the 11th July webinar.

The point on ensuring alignment amongst value streams and need to discuss all digital products being developed by EMA and National Competent Authorities (AESGP) was addressed in agenda point 9.

Link to presentation.

Action arising:

- Industry stakeholders to participate to the Public webinar on pack size submissions: from XEVMPD to product management service (PMS).

4. Medical Devices expert panels (H+MD)

EMA clarified the activities attributed to the medical device expert panels (i.e. mandatory clinical assessment as foreseen in the medical device Regulation; voluntary advice requested by manufacturers of certain devices; advice to commission or Medical Device Coordination Group (MDCG), identification of concerns and emerging issues; development and maintenance of guidance and common specifications). An update on consultation procedures done under the Clinical Evaluation Consultation Procedure (CECP), the Performance Evaluation Consultation Procedure (PECP) and the MDCG advice was provided highlighting the growing number of requests since April 2021, yet still below the expected announced numbers overall.

ISG members were reminded of the deadline to submit applications for pilot on advice to medical device manufacturers by the 30th of June 2024. Following closing of the pilot at the end of 2024, further reflection will be made on the design of a final process.

An overview of the recently published New guidance on the clinical evaluation of orphan medical devices was provided. The introduction of a definition for "Orphan device" was noted. The guidance is expected to be implemented with a dedicated pilot phase and a dedicated workshop event in September 2024 (dtc). Further details will be provided in due course.

Link to presentation

Action arising:

- EMA to provide further details on orphan guidance pilot phase and September 2024 webinar.

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

5.1. Overview of implementation activities

EMA provided an update on the implementation activities related to the Health Technology Assessment (HTA) regulation, which will apply from January 2025. ISG members were informed of the routine inclusion of this topic on the ISG agenda to allow discussions on implementation activities with the sole focus on the regulatory/HTA interface in the context of the Regulation.

It was highlighted how the Regulation builds on the experience from collaborative work between regulators and HTAs along the medicine lifecycle.

The areas of collaboration between regulators and HTAs foreseen in the legislation were outlined (i.e. Identification of emerging technologies/contribution to work plan; Joint Scientific Consultation, Joint Clinical Assessment). It was clarified that "joint" refers to collaborative HTA work; if conducted with regulators it is "parallel" work .

ISG members were encouraged to consult the Minutes of Concluding EMA – EUnetHTA bilateral meeting: "Celebrating joint achievements - progressing future collaboration" in order to gain additional insights on the activities and the Implementation rolling plan.

5.2. Operational aspects of the parallel processes for centralised procedure and joint clinical assessment

EMA provided further insights on the operational aspects of the parallel process for Centralised Procedure (CP) and Joint Clinical Assessment (JCA) for medicinal products, clarifying that the scope from January 2025 is targeting only certain human medicines (i.e. for treatment of cancer and ATMPs). It was stressed that separate remits need to be respected which includes the independence of the benefit/risk assessments.

To notify the HTA Coordination Group on new marketing authorisation for medicines in JCA scope, applicants are now required to declare in the Letter of Intent the applicability of the JCA assessment 7 months in advance of the submission. Relevant guidance was updated accoridingly.

Industry stakeholders were pleased to learn on the simplifications and automation of processes and asked for more details on arrangement foreseen for facilitating EMA-HTA secretariat exchange systems (EFPIA).

Link to presentation.

6. EMAN Strategy to 2028 update (H+V)

EMA confirmed that the European Medicines Agency Network Strategy (EMANS) to 2028 is expected to be adopted by the Management Board in October 2024 and the public consultation postponed to Q4 2024.

ISG members were pleased to see the progress and flagged the need to incorporate environmental sustainability amongst the strategic priorities (AESGP).

Link to presentation.

Action arising:

- EMA to inform ISG members of the public consultation.
- ISG members to contribute to the public consultation.

7. CTIS revised published portal launch (H)

EMA confirmed the recent launch of the CTIS public portal implementing the revised transparency rules highlighting that only key documents of interest will be now published without deferral and that redaction will now be used as the only method to protect Commercially Confidential Information (CCI). Following concerns raised by Industry stakeholders, the current platform temporary excludes publication of dose strength information which is considered CCI in certain cases.

ISG members were invited to consult the recording of Clinical Trials Information System (CTIS) Bitesize Talk: Revised transparency rules and the new CTIS public portal in order to obtain additional insights.

Industry stakeholders were pleased to learn about the simplifications brought by the revised transparency rules and asked whether there were plans to align the different rules and policies in terms of concept, definitions and application on CCI and Personal Data protection. It was confirmed that generally alignment is always sought and that any discrepancy that could impact innovation or public health should be flagged. Additional simplification measures are being also considered by a recently established CTIS simplification task force.

Link to presentation.

Action arising:

- Industry stakeholders to report any possible discrepancy between all the available transparency rules.

8. Artificial Intelligence activities across EMA (H+V)

EMA provided an overview of all activities addressing Artificial Intelligence (AI) being taken by the Agency and the EU network acknowledging that this is not a new topic for the manufacturing and pharmaceutical environment. An outline of the 2023 HMA/EMA workshop and of the AI workplan to 2028 was provided flagging the relevant initiatives included under 4 main areas: Guidance, policy and product support; Tools and technologies; Collaboration and change management and Experimentation.

The activities of the EU Agencies AI Virtual Community, chaired by EMA, were briefly described. C

Industry stakeholders welcomed regulators openness on the activities linked to AI and welcomed global collaboration and harmonisation to maximise the use of this tool. Clarifications on EMA position on the EU AI act were sought (EFPIA). It was confirmed that an AI guidance will be considered in the context of the Methodology Working Pary activities. An AI reflection paper is currently being drafted in consultation also with US FDA and is expected to be published by end of the year. Industry stakeholders noted the opportunity to join relevant discussions on this topic in a workshop foreseen in November.

Action arising:

- EMA to provide details on the workshop foreseen in November 2024. Further details to follow closed to the meeting.
- Industry stakeholders to participate to planned workshop.

Link to presentation

9. Update on EU Network Portfolio activities of strategic focus, including Regulatory Optimisation Group (ROG) (H+V)

EMA provided an update on the activities of the EU network Portfolio, confirming that the processes established at EMA are now all transitioned under the Agile governance. ISG members were encouraged to participate to the upcoming ceremonies and events.

The Regulatory Optimisation Group (ROG) is being re-activated with the aim of providing strategic input on relevant topics to the Network Portfolio Advisory Group (NPAG) and to the Veterinary Strategic Focus Group.
Four main areas are included in ROG scope: legislative, digital, human and veterinary. Under the umbrella of ROG, a wider Network business representative community is being considered to ensure harmonisation of national activities and ensure alignment across all value streams.

Industry stakeholders will have the opportunity to brainstorm on how best to interact with the ROG with a dedicated workshop planned for the 10th of October 2024. Further information to follow closer to the meeting.

ISG members noted the evolution of ROG composition. It was reiterated that the scope of the planned workshop is to further define the optimal mechanism to allow Industry stakeholders involvement in ROG activities, also taking into account the interactions ensured by the Agile governance.

Action arising:

- EMA to provide details on the workshop planned for the 10th of October 2024.

Link to presentation.

10. ICMRA collaboration pilots (H)

EMA provided update on the experience with ICMRA collaborative assessment (applications still accepted) and ICMRA Collaborative Inspection Pilot pilots exercises highlighting the international cooperation and the steps made to collaborative assessments (one submission=one global approval) and inspections (hybrid inspections with combined dossiers and a common secure IT platform).

ISG members noted also additional programme aiming at leveraging international collaboration to support medicines supply globally.

A dedicated workshop on the collaborative assessment pilot and a report on the pilot experience are expected by end of 2024.

Action arising:

- EMA to provide details on the workshop and report planned for end of 2024.
- Industry stakeholders to participate to planned workshop and consider applying to ICMRA collaborative assessment pilot phase.

Link to presentation.

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

Topic deferred to next ISG September 2024 meeting.

12. Close of the meeting and next steps

The chair thanked attendees for the open and fruitful discussion and reminded all members of the next virtual ISG meeting scheduled for the 26th of September 2024.