31 May 2024
EMA/130028/2024

Highlights- 8th Industry Standing Group (ISG) meeting

25th March 2024– chaired by Marie-Hélène Pinheiro

1. Welcome/Introduction

The chair welcomed all participants to the first ISG meeting of 2024 and introduced the agenda noting the participation of veterinary industry representatives in addition to Human pharma and medical device industry representatives, Notified Bodies, Member states and European Commission delegates for some of the topics.

An update on the implementation of the actions arising from the 7th ISG meeting and the overview of industry stakeholder topic proposals for 2024 were presented.

2. Medicine shortages and Medical Devices

2.1 Medicines shortages communications update

EMA provided an update on the phase 2 delivery of the Union list of critical medicines - version 1 published in December 2023. Whilst in 2023 phase 1 focussed on operational work, which led to the finalisation of the methodology by the European medicines regulatory network and the release of version 1, phase 2 is now focusing on the prioritisation of therapeutics of major interest from existing reference lists (e.g., EMA list of Main Therapeutic Groups, DG HERA MCM catalogue) and will include a targeted multi-stakeholder consultation, including Industry, to identify active substance(s) that need to be reviewed by Member States and critical medicine(s) that should be included in the next update.

The consultation was launched on 25th March 2024 for a period of 2.5 months until 31st May 2024.

ISG members were pleased to learn about the planned stakeholders consultation.

Actions arising:

Industry stakeholders to contribute to the public consultation by 31st May 2024.

Link to presentation.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

EMA provided a progress update on ESMP development activities planned for Q2 2024 confirming that the key features of the platform for Marketing Authorisation Holders (MAHs) are almost completed and that the work is currently focussing on MAHs crisis submission features, interoperability and on building the platform for National Competent Authorities (NCAs). It was highlighted that in Q4 2024 the MAHs' shortages reporting portal for preparedness and crisis is expected to Go-Live. This will be followed in Q1 2025 by the launch of the NCAs MSSG-Led preparedness submissions, critical national shortage and crisis reporting, as well as an ESMP public platform, ensuring therefore that the 2nd February 2025 legal ESMP implementation deadline is met.

The ESMP MAHs' portal was also showcased during the ISG meeting and Industry stakeholders were invited to join the quarterly system demo planned for the 26th of March 2024 where further IT ESMP technical details on the development would be presented.

In terms of dependencies with the Product Management Service (PMS), Industry stakeholders were informed on the need for MAHs to include data on pack size for Nationally Authorised Products (NAPs) in xEVMPD/Art.57 as soon as possible but not later than February 2025 for all products included in the Union list of critical medicines, and within 2 weeks for products belonging to a specific list of critical medicines in scope of a particular crisis, if one is declared. The timeline of 2 weeks for submission of data on pack sizes on NAPs also applies in case the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) declares a preparedness activity for the close monitoring of a particular group of medicines.

In addition, it was highlighted that data regarding NAP manufacturing sites will also be required to be submitted *via* the PMS Product User Interface (PUI) from January 2025 to December 2025.

Industry stakeholders were encouraged to join the PMS Info day scheduled for the 16th of April 2024 where PMS dependencies and stakeholders required actions for ESMP and PMS/XEVMPD will be presented to stakeholders.

In terms of interoperability, Industry stakeholders were informed on the options available for data submission:

- submission of data spreadsheet *via* the user interface (as of Q4 2024).
- submission of data *via* machine to machine (phased approach as of Q1 2025).

In order to ensure suitable data submission and alignment with the business and technical specifications of datasets in scope of the reporting requirements, Industry stakeholders were urged to plan and perform any needed IT change in due time.

EMA will provide detailed technical guidance from Q2 2024, including a dedicated ESMP webpage for updates on ESMP development and training opportunities.

Industry stakeholders (AESGP) made comments on the PMS agile governance in terms of industry stakeholders SME policy changes and it was clarified that further details will be made available.

Actions arising:

- ESMP MAHs' CAPs' shortages portal preparedness and crisis reporting is schedule to Go-Live in Q4, 2024, followed by NCA's medicines shortages portal reporting by 2nd February 2025.
- Industry stakeholders to participate to planned engagement activities i.e. ESMP System Demo on 26th March 2024 and PMS info day on 16h April 2024;
  Post-meeting note:
- 26th March 2024 System Demo video recording.
- Industry stakeholders to follow up on NAPs data enrichment (data on pack size for Nationally Authorised Products (NAPs) in xEVMPD/Art.57 as soon as possible but not later than February 2025; NAP manufacturing sites is also requited *via* the PMS Product User Interface (PUI) from February 2025 to December 2025).
- Industry stakeholders to plan and perform any needed IT change in due time.
- EMA to provide detailed guidance on SME nominations and replacement in Q2 2024.

Link to presentation

3. Expert panels activities update

EMA provided an update on the medical device expert panel activities:

- ***Update on expert panels opinions*:** since the beginning of the expert panel activities in 2021, a total of 103 applications for Clinical Evaluation Consultation Procedure (CECP) were submitted with 11 opinions issued.
  For Performance Evaluation Consultation Procedure (PECP) a total of 20 applications were submitted resulting in 19 opinions delivered to date.
  The number of the applications received, and opinions issued are below the expected numbers, leaving the possibility for expert panels to further engage in the advice pilot processes.
- ***Learnings from expert panels advice pilot and next steps*:** following the 1st and 2nd expert panels' advice pilot launches in February and October 2023 respectively, EMA announced that this will be extended with a further 3rd advice pilot phase from the 2nd April until 30th June 2024. It was reminded that theclinical development advice is for high risk active medical devices class III or IIb use to administer or remove medicines. As before, such advice is free of charge and the same selection/pilot entry criteria apply i.e. prioritisation of devices intended to benefit small group of patients, unmet medical needs and novel devices with major critical health impact, orphan devices etc.. However it was highlighted that in this pilot, Health Technology Assessment (HTA) bodies, involved in pricing and re-imbursement at Member State level, may participate as observers upon device manufacturers' request, which device manufactures need to clearly state when applying for the advice.
- Learnings gained from the 1st and 2nd medical device advice pilots in terms of metrics, therapeutic area etc. were shared together with recommendations on the application

process i.e. the need for early engagement and dialogue to set mutual expectations and improve the submission quality and maturity of the device manufacturers' briefing packages.

The ISG was also informed of upcoming procedural and scientific guidance on orphan devices being drafted in collaboration with the European Commission Orphan device task force.

Finally, EMA informed the group that a workshop with notified bodies was scheduled to be organised on 22nd of April 2024 to promote alignment on clinical assessment,

Further to a question (AESGP) on EMA involvement in any future changes to the Medical Device and In Vitro Diagnostic Regulations proposal, it was clarified that EMA shares all current specific medical device experiences and learning within its remit with the European Commission and that EMA would provide any specific additional scientific and/or technical input when and if requested.

Actions arising:

- Medical Device manufacturers to apply for CECP and PECPs to aligned predictive submissions statistics information shared with concrete submissions and / or inform EMA of any specific issues;
- Medical device Manufactures (Class II or IIb) to consider applying for scientific advice pilot phase 3 open from 2nd April to 30th June 2024 and highlight the need for HTA observers participation;
- EMA to share the European Commission Orphan Device Taskforce guidance once available.

Link to presentation.

4. Update on the implementation of New Fee Regulation (EU) 2024/568

EMA presented the activities implementing the Regulation (EU) 2024/ 568 (New Fee Regulation) published on the 7th of February 2024 whose aim is to have a simplified, single union remuneration proportioned to Member States required workload and actual costs.

ISG members were provided with a high-level overview of the changes impacting Industry stakeholders and were informed about further guidance , the IT invoice processing development roadmap and relevant engagement and communication opportunities planned for 2024 for human and veterinary pharmaceutical industry stakeholders. Industry stakeholders were encouraged to join the quarterly system demo planned for the 26th of March 2024 as well as to other future events elaborating on operational and technical aspects of the new fee regulation.

It was clarified that this New Fee Reglation, apply to the current EU Pharmaceutical Legislation and that the on-going reform of the EU pharmaceutical legislation would lead to other amendments in the future.

Actions arising:

- Industry stakeholders to consider participation to engagement events as described in the EMA presentation (see bellow link).
- *Post-meeting note:*
  - *26th March 2024 System Demo video recording.*
  - *4th July 2024 Industry Platform on R&D*
  - *22nd October Industry Platform on Pharmacovigilance*
  - *Q2/Q3 Veterinary stakeholders dedicated meetings*
  - *Q3/Q4 Small-Medium Enterprises Info Day*
  - *November 2024 Next EMA Strategic Portfolio Review*

Link to presentation.

5. COVID lessons learned

EMA provided an overview of the HMA-EMA joint report on COVID-19 lessons learned published in December 2023. It was highlighted that the report focuses on the analysis of the lessons learned covering several aspects including support to the development and approval of medicines, regulatory framework and procedures, network coordination and resourcing and transparency, stakeholder engagement and communication.

Generally, the close cooperation between Member States, the regulatory response and flexibility adopted and the increased level of transparency enabled a prompt and engaged response to the crisis resulting in the approval of 8 new vaccines and 8 new therapeutics.

It was also flagged how the opportunities for improvement identified in the report are being already implemented in current activities with several initiatives (e.g., ACT EU, DARWIN, formalisation of the Emergency Task Force) and proposed changes in the legislations (e.g., EMA extended mandate, reform of the EU pharmaceutical legislation).

Important activities were also noted in terms of ensuring adequate network resourcing and expertise and in ensuring adequate and timely, evidence-based communication and infodemic management to address mis- and dis- information. This topic is further addressed in topic 7 below.

It was clarified that additional discussions relating to operational and technical aspects are expected to be addressed in the context of the Industry stakeholders platform meetings on the Centralised Procedure.

Actions arising:

- Industry stakeholders invited to consult the report.
- EMA to consider need for additional discussions on operational aspects (for process improvement, without need for legislative changes) as part of relevant EMA-Industry Stakeholder meetings.

Link to presentation.

6. European Medicines Agency Network Strategy (EMANS) mid-point report and plans for 2028 update

EMA presented an overview of progress made in implementing the European Union Medicines Agencies Network Strategy to 2025 following publication of its mid-point report in December 2023.

In addition plans for a 3 year update of EMANS to 2028 in view of the future changes that will be brought by the EU pharma legislation review were presented.

The update will take into account the lessons learnt from COVID-19 and will further refine the focus areas already present in the current strategy in order to capture new themes (i.e. Artificial Intelligence, innovation and competitiveness) applicable to both human and veterinary medicines.

Work on the review and update of EMANS will take place during the course of 2024 with a public consultation currently planned over the summer.

It was clarified that, environmental aspects are not planned as a specific focus area, however, it may be covered in more general terms.

Actions arising:

- Industry stakeholders invited to contribute to the public consultation which is tentatively planned for launch this summer (date to be confirm).

Link to presentation.

7. Presentation from industry on misinformation-miscommunication in medicines

Industry stakeholders were invited to present and share their experience and plans to address mis-information and mis-communication. Vaccines Europe and AESGP provided their perspectives and with some recommendations.

It was reported how during a period of crisis (e.g. COVID-19, H1N1 pandemics, ibuprofen case) any communication gap can give raise to rumours (unverified information), mis-information (accidental falsehood) and dis-information (deliberate falsehood) and how fundamental it is to build a network of consistent, science-based communication as part of a resilient health system.

Working in cooperation with a multi-stakeholder network (including patients and health care professionals) in order to ensure that consistent messages are given and adapting the communication to modern tools (i.e. social media, use of mobile phones), was flagged as a crucial investment allowing to build trust with the audience and ensure that reliable science-based information reaches a wide audience.

The benefits of early engagement with Industry stakeholders were highlighted to support early detection of any new infodemic information.

EMA thanked industry stakeholders for sharing their experience and recommendations and acknowledged the need to cooperate in order to tackle mis- and dis- information. Several

initiatives involving national, international regulators, patients and healthcare professionals were highlighted, , as well as the engagement with the Patients and Consumers Working Party and the Healthcare Professional Working Party.

At EMA the vaccines outreach strategy has been developed in 2019 and is currently being updated. The goal is to increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions. The cooperation with ECDC and EC to improve access to information via the European vaccines information portal and additional activities to tackle false narratives and increase knowledge including press briefings live streaming, public engagement and social media presence were also highlighted.

In parallel, EMA is developing a framework to tackle more effectively false narratives (mis- and disinformation), with the goal to put in place a systematic and proactive approach to dealing with false narratives.

EMA is working closely with its regulatory partners and recognises the importance of involving also stakeholders, including industry stakeholders in this process. In that context, ISG members were also invited proactively report any information or concerns linked to mis-information and dis-information.

Actions arising:

- Industry stakeholders invited to flag to EMA or other relevant authorities any signal of mis-information and dis-information.
- EMA is working on a framework to address false narratives (mis- & dis-information) and will involve relevant stakeholders as appropriate.

8. International activities update

EMA provided an update on the following EMA international activities:

- ***African Medicines Agency (AMA): update on the EMA support to AMA and the pilot of the Continental Listing of Medicinal Products*:** the Agency's project to support AMA is ongoing and is expected to be delivered by 2027. Currently EMA is providing scientific and technical support to ensure AMA operationalisation, strengthen African scientific and regulatory expertise and coordinate alignment of the European efforts. As already communicated, a pilot phase on continental listing of medicinal products is due to start in May 2024 and EMA has shared this information with relevant industry Stakeholders.

Link to presentation.

- ***Update on the opening procedures at EMA to non-EU authorities (OPEN)*:** Industry stakeholders were reminded that the scope of the framework was expanded in July 2023 to include anti-microbial resistance, PRIME, other products that address a high unmet medical need and medicines responding to public health emergencies. Industry stakeholders are now able to suggest for consideration the OPEN partners' in their MAA

application/Pre-Submission meetings when requesting to be part of OPEN initiative. Once again, the importance of ensuring alignment of MAA regulatory submissions in all the regions was highlighted. The impact of EU MAAs' submission delays in OPEN activities was also highlighted as this makes the attempt to a plan the alignment of submissions across OPEN partners more challenging.

Link to presentation.

- ***EU enlargement (Instrument for Pre-accession Assistance [IPA] program implementation): Update on EMA engagement with candidate and potential candidate countries*:** ISG members were informed of EMA engagement and support activities aiming at facilitating potential new EU candidate countries to align with EU requirements for human and veterinary medicines in terms of assessment capacity, scientific cooperation, preparedness and harmonisation of medicine regulations with EU rules as part of the 2024-2026 IPA III programme.
  Observer-ship of candidate and potential candidate countries to selected EMA working Parties activities and the confidentiality rules applied were highlighted.

Link to presentation.

9. Presentation from industry on cross-sectoral legislations and policies affecting EMA and medicines development

EFPIA, Vaccines Europe and AESGP provided an overview on how the EU legislative landscape relevant to medicinal products is becoming increasingly complex due to the interference/overlap of different industrial sectors and stakeholders involved. It was flagged how the interplay between the pharmaceutical, chemical, food and environmental legislation can bring complexity and challenges for both medicines development and regulatory assessment. Related misalignment and discrepancies could lead to unintended consequences such as undermining Research & Development (R&D) and medicines availability.

The EMA acknowledged the points made and invited Industry stakeholders to keep engaging directly with the relevant authorities, EU institutions and Agencies and continue to pro-actively flag all potential concerns which may impact medicinal products development, evaluation and/or marketing to EMA. It was confirmed that the EMA is continuing to strengthen the cooperation with other agencies both at strategic and operational level in order to identify early any potential impact of new regulatory requirements/legislative changes.

Industry stakeholders expressed interest and availability to be further involved in future discussions.

Actions arising:

- Industry stakeholders to keep engaging directly with the relevant authorities, EU institutions and Agencies and continue to pro-actively flag all potential concerns which may impact medicinal products development, evaluation, marketing to EMA.

10. Announcement of EMA-Industry Early engagement fostering innovation survey launch

EMA announced the recent launch of the industry early engagement fostering innovation survey which aims at monitoring the adequate implementation of the Framework for interaction between the European Medicines Agency and industry stakeholders. The survey is targeting all pharmaceutical companies and network representative attending any of the following meetings from 1st January -15th December 2024, namely:

- Innovation Task Force Briefing Meetings (ITF BM)
- Portfolio and Technology Meetings (PTM)
- Small-, Medium- Sized Enterprises briefing meetings (SMEs)
- Quality Innovation Group (QIG) (Listen & Learn (LL) focus group and targeted companies' (1:1) meetings)

Following the analysis of the results, a consolidated report is expected to be published on the EMA corporate website early 2025.

11. Close of the meeting and next steps

The chair closed the meeting summarising the key highlights and action points arising as highlighted above.
The next ISG meeting will be on the 28th of June, 09.00AM-1:00PM and is planned in hybrid format (subject to sufficient onsite participation).