26 June 2023
EMA/294473/2023

Highlights - 5th Industry Standing Group (ISG) meeting

26 June 2023 – chaired by Marie-Helene Pinheiro

A. EMA extended mandate topics

1. Welcome/ Introduction

The chair welcomed all participants and adopted the agenda without any additions.

2. ISG Mandate update

- Marie-Helene Pinheiro provided an update on the ISG mandate following 1 year since the kick off meeting. It was highlighted the evolution of the topics covered from the initial focus on the EMA extended mandate implementation to the discussion of strategic topics of common interest and cross-Industry sectors interests. Further to the successful experience of the pilot, the ISG is being formalised as a standard group dedicated to interaction with industry stakeholders and the updated mandate will be published. Consequently, ISG members will be asked to confirm their membership. The date of the next ISG meeting (21st September 2023) was communicated and a call for topics was launched .

Actions arising:

- ISG members to provide topic proposals by the 20th of July.
  Post-meeting note: Deadline for topics proposals by 31st July 2023.

Link to presentation.

3. Medicine shortages and Medical Devices

3.1. Medicines shortages activities

3.1.1. Review activities and discontinuation of the ISG operational group on medicines shortages

- Joao Ferreira (EMA) provided an update on Industry's SPOC Covid-19 and Monkey Pox reporting activities noting that, following WHO declaration of end for both Public Health Emergencies (PHEs),

reporting obligations for companies have ceased to apply.
Nevertheless process improvement activities will continue during Q3 2023 in order to be better prepared for future PHEs.
The need for Marketing Authorisation Holders (MAHs) to continue to register dedicated Medicines shortages industry-Single Point Of Contact (i-SPOC) was also stressed as the numbers are still considered very low and could undermine any future PHE preparedness/actions.

Actions arising:

- EU Industry trade organisations to promote i-SPOC registrations within their members, especially through their National industry (Trade) Associations members.

Link to presentation.

3.1.2. Joint EMA/HERA exercise on the monitoring of a subset of antibiotics in preparation for the autumn/winter 2023-2024

- Emilija Matelyte (EMA) provided an overview of measures taken by EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and its Medicine Shortages SPOC WP (SPOC WP) to monitor the shortage of antibiotics across the EU throughout autumn and winter 2022/2023 which included international cooperation, engagement with the key players in the supply chain and communication with stakeholders including community members, amongst others.
- To ensure preparedness for the upcoming autumn/winter 2023/2024 season, a joint European-level (EMA/HERA) exercise has been initiated with an aim to identify any potential gaps between the supply and demand, so that EU-level actions, if needed, can be undertaken proactively to ensure sufficient supply for European patients. The subset of antibiotics to be monitored have been agreed upon by the SPOC WP, MSSG and the HERA Board and interactions with the relevant MAHs (of those active substances) are ongoing. EMA presented the roadmap and methodology for the exercise. It was highlighted that while the technical tools to match the supply and demand have been developed, the supply data from industry is still required to complete the exercise. ISG members were asked to promote cooperation with EMA/HERA in the exercise to their relevant member organisations.

Actions arising:

- Industry trade organisations to encourage their affiliate members to take part in the EMA/HERA joint exercise.

Link to presentation.

3.1.3. Update on ESMP development progress status and ESMP Roadmap

- Sofia Zastavnik/Pedro Pina Ferreira (EMA) provided a progress update on European Shortages Monitoring Platform (ESMP) roadmap and highlighted the business priorities included in the Product Increment (PI) planning for the next quarter. It was noted how all the activities are supported and include input by the nominated Industry Subject Matters Experts (SMEs). The actual scope of the IT deliveries for the ESMP for Q3 will be decided during the PI planning event (28th and 29th June), depending on the complexity of the items that need to be delivered and the capacity and velocity of the IT development teams. The scope of deliveries that was committed to during the PI planning event will be provided at the next September 2023 ISG meeting.

Link to presentation.

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

3.2.1 Update on the" Critical Medical Devices Shortage Reporting System" development

- Klaus Kruttwig/Pedro Pina Ferreira (EMA) provided an update on the development activities linked to the Critical Medical Device Shortages (CMDS) system. The minimum viable product (MVP) is expected to be released in July 2023. In this context, user testing were performed with relevant economic operators and results are currently being analysed. Further interactions with with industry associations in the medical devices sector as well as with notified bodies are foreseen. Specifically further user testing with national competent authorities and notified bodies will take place in Q3 2023 to identify opportunities for improvement.
  An update of the of the user test of the webform relevant for economic operators was provided. Relevant economic operators were invited for a user test of the economic operators webform via the EMA-HERA JICF Working Group
- It was clarified that the 3 web forms developed were tailored based on the requirements applicable to the relevant economic operators and notified bodies and national competent authorities. Therefore no duplication of reported information is foreseen. It was also clarified that only the categories of critical medical devices included in the public health emergency critical devices list, adopted by the Executive Steering Group on Shortages of Medical Devices (MDSSG) will be subject to reporting requirements.
- For the medicinal products MSSG will identify the list of critical medicinal products, once a PHE is declared. In case of medicinal products in combination with medical devices (combination products), both EMA Executive groups (MSSG and MDSSG) are expected to be involved. The reporting requirements will be aligned with the underlying legal frameworks and reporting on pharmaceutical products will be performed in the ESMP, whereas reporting on categories of critical medical devices will be performed in CMDS.

Link to presentation.

3.3 Medical Devices expert panels

- Silvy da Rocha Dias (EMA) provided an update on the activities of the expert panels which have been in operation for 2 years. It was noted that for Clinical Evaluation Consultation Procedure (CECP) only 63 files were submitted so far. Such figures are not in line with the European Commission survey forecast predictions of 2022 for the current year.
  As there is need to have a better understanding of the forecast of applications for high-risk devices for 2023/2024, a new survey is being launched in July 2023 by the European Commission (EC).
- ISG members were also informed of the launch of the 2nd phase of the Scientific Advice pilot for certain high-risk MD/IVDs on the 19th of June 2023 with application deadline of 15th of September 2023.

- The scope and terminology used for the mandatory and *ad hoc* functions of the expert panels was clarified as follows:
  - **Mandatory requirements** under the Regulations on Medical Devices (Regulation (EU) 2017/745) and on In Vitro Diagnostic Devices (Regulation (EU) 2017/746): notified bodies are

required to consult the expert panels before issuing a CE certificate. In this context the expert panels provide:

  - An **opinion** on the notified body's assessment of the manufacturer's clinical file of all class III implantable medical devices and class IIb active medical devices destined to administer or remove a medicine medical devices (the clinical evaluation consultation procedure - CECP);
  - A **view** on the manufacturer's performance evaluation report of all class D *in vitro* diagnostic medical devices (the performance evaluation consultation procedure - PECP).

- ***Ad hoc* functions to the Medical Device Coordination Group (MDCG)**: The Expert Panels are consulted by the MDCG on different issues. Most frequently these are questions on the performance of IVDs or on the clinical/epidemiological characteristics of the infectious agents they detect.
- ***Ad hoc* functions for medical device manufacturers:** EMA is running a pilot on the provision of scientific advice to manufacturers for class III or the class IIb medical devices mentioned above on their intended clinical development strategy and/or proposals for clinical investigation prior to certification.
- Additional details are available the Medical Devices corporate webpage.

Actions arising:

- EU Industry trade organisations/Notified bodies to raise awareness within their respective members at EU and National and international, where relevant.

Link to presentation.

B. Other cross-stakeholders strategic topics

4. ACT EU and CTIS update

Peter Arlett (EMA) provided an update of ACT EU activities highlighting the focus for 2023:

- Clinical Trials Information Systems (CTIS) implementation: since 31 January 2023 CTIS is now mandatory for all Clinical Trial applications. The majority of system bugs were addressed and a new survey is expected to be launched in September 2023 in order to monitor the progress. In addition, ISG members were invited to take part to the current public stakeholder consultation on transparency rules for the operation of the Clinical Trials Regulation and its Clinical Trials Information System.
- Creation of the multi stakeholder platform: ISG was informed of the key points arising from the recent ACT EU multi stakeholder platform kick off workshop held on the 22nd and 23rd of June. It was highlighted how a call for nomination to be part of the multi stakeholder advisory group will be launched soon. Under this umbrella, additional multi-stakeholder workshops will be organised in 2023 (ACT EU Multi-stakeholder workshop on ICH E6 R 3 on the 13-14 July; Clinical trial data analytics in autumn with the aim of identifying research priorities; Methodologies workshop in November aiming at discussing key topics and guidance needs)
- Support of academic sponsors conducting large multi-national clinical trials.

Link to presentation.

5. Pharmaceutical legislation review

- Lilia Luchianov (EC) provided highlights on the EU Pharmaceutical reform. The proposal is divided in 4 packages including a chapeau communication between new regulation and new directive and council recommendation on antimicrobial resistance. The proposal is built around 6 main political objectives:

1. access to medicines: in order to ensure that all EU member states have the same access to medicines, incentives are provided to promote innovation and market access;

2. availability of medicines: better shortage monitoring and prevention included in the proposals in addition to other activities outside of the pharma package (HERA, Important Projects of Common European Interest (IPCEI), European Critical Raw Materials act).

3. affordability of medicines: the proposal includes incentives to increase competitions and reduce prices with earlier market access and enhanced transparency for R&D and Clinical Trials.

4. ensure competitive regulatory framework: the proposal includes solutions aiming at speeding up marketing authorisation activities with more pre-authorisation support and educed regulatory burden.

5. Environmental sustainability: measures aiming at the reinforcement of the Environmental Risk Assessment with stricter rules and promotes the use of electronic leaflet/submissions are included.

6. Combating Anti Microbial Resistance (AMR): the proposal includes measure for monitoring the use of antimicrobials and provide incentives to innovation through a voucher mechanism.

- Industry trade associations flagged the need of a balanced approach in order to promote innovation and ensuring at the same time affordability and patent protection. Specifics industry stakeholders' sector concerns and supports to EC legislative proposal were highlighted by EFPIA, Medicines for Europe, AESGP, EuropaBio, Vaccines Europe, Eucope, IPFA and MPP i.e. :
  - Support to EU Regulatory system simplification, support medicines' affordability principles, new regulatory sandbox proposal, towards mandatory ePI, timelines for implementation of EMA Committees' reorganisation etc.
  - Concerns in relation to Regulatory Data Protection duration, obligatory prescription for all antimicrobials, incentives proposal appropriateness etc.

- It was highlighted that once the EC legislative proposal will be adopted by the Parliament/Council, EMA together with the European Commission and MSs, as relevant and appropriate, will develop relevant (industry) stakeholders' implementation plan and that ISG will be the fora for key dialogue/discussions where Industry stakeholders interaction will take place.

Link to presentation.

6. Transition to new EMA Working Party Governance –status update

- Silvy da Rocha Dias (EMA) provided insights on the re-organisation of the EMA working parties initiated in 2020. 5 domains (quality, non-clinical, clinical, methodology, veterinary) have been established supported by Working Parties (WPs), Operational Expert Groups (EOGs) and Drafting Groups (DGs) who follow a 3 year rolling strategic plan. The European Specialised Expert Community (ESEC) also supports training and knowledge sharing. In addition, at domain level, a

systematic and structured stakeholder engagement is foreseen in support of strategic priority planning and guideline generation/revision. Additional specific engagement on specific deliverables foreseen at WP level.

Link to presentation.

7. Quality Innovation Group

- Evdokia Korakianiti (EMA) provided an update on the activities of the Quality Innovation Group (QIG) established in 2022 as main vehicle to ensure that innovation and related knowledge is secured within the EU. The QIG is the interface between all key players (Industry, International Partners, Academics, Network) and as such it provides support to developers through regulatory advice. Challenges with specific technologies are discussed in specific Listen and Learn Focused Group (LLFG) meetings in order to develop learnings, guidance and training. Since its establishment, the QIG has been working on an agreed workplan which, for 2023 focuses on continuous and decentralised manufacturing, automation and digitalisation.
- It was highlighted that QIG activities needs the cooperation of Industry stakeholders in order to promote innovation on quality and manufacturing in Europe. Please see further details in the following published report from the 1st LLFG on Continuous Manufacturing (particularly focus on BIO and end-to-end) and Decentralized Manufacturing (link).
- In addition, the **2nd Quality Innovation Group (QIG) lesson and learnt focus group** with stakeholders (industry and academia) was announced to take place on 12 & 13 October 2023 with the objective to focus on **Digital Novel Technologies applied to manufacturing and/or quality control testing (e.g. Artificial intelligence, machine learning, digital twins, robotics, internet of Things (IoT), virtual reality etc.)**.

Actions arising:

- EU Industry (trade) associations invited to share the information with affiliated members in order to promote participation to QIG and LLFG activities.

Link to presentation.

8. A.O.B or Tour de Table

NA

9. Summary of actions and next steps

The chair thanked all participants and reminded the next ISG meeting scheduled for the 21st of September 2023 in virtual format with deadline for topic suggestion of 20th July 2023.

Post-meeting note: New deadline for topics suggestions will be the 31st July 2023.