15 December 2022
EMA/790948/2022
Stakeholders and Communication Division

Industry Standing Group meeting

22 November 2022

Chair: Marie-Helene Pinheiro (EMA), via WebEx

1. Welcome and introduction

The meeting was chaired by Marie-Helene Pinheiro (EMA) who opened the meeting and welcomed all participants.

The chair welcomed all participants noting the good balance of the audience (60 industry stakeholder representatives of the European human pharmaceutical sectors, supply chain sectors and medical device industry; 55 EU Network representatives, namely from CHMP/ETF, CMDh, SPOC WG and ESMP network PO) and encouraging live participation.

The chair also highlighted that, in addition to topics relating to EMA's extended mandate pursuant to Regulation (EU) 2022/123 ("EMA Extended Mandate") , the ISG includes topics of EMA and industry stakeholders' strategic common interest.

2. Medicines and Medical Device shortages

2.1 Update on Medicine shortages activities

- Joao Ferreira (EMA) provided an update on the activities related to monitoring of supply and demand of medicines included in the lists of critical medicines for Covid-19 and Monkeypox public health emergencies established by the Medicines Shortages Steering Group (MSSG).

  The importance of supply related information provided by companies was flagged as essential for enabling the adopting of shortages preventive measures. In addition, the need to have all i-SPOC contacts for supply and availability issues registered on the IRIS platform was reiterated.

- The audience was informed that additional communication activities are being performed/planned to raise awareness and promote compliance with the requirements. Industry associations confirmed the availability to also follow up with their associates. Exploring if also European Medicines Verification Organisation (EMVO) list of companies can be used to raise further registration awareness, was suggested.

- The ISG operational group mandate was presented. The group is the main link between industry and EMA when discussing technical aspects for implementation of EMA's Extended Mandate, including i-SPOC registration and data submission (i.e reporting template and

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

guidance) for ongoing PHEs. The group will be in place while interim IT solutions are being used for the collection of data from i-SPOC Networks.

- Sofia Zastavanik (EMA) provided an update on the set up of the European Shortages Monitoring Platform (ESMP). An overview of the ESMP team and its governance structure was provided highlighting that Medicines for Europe and EFPIA are included as industry subject matter experts (SMEs). ESMP roadmap and minimum viable product are expected to be defined and available in line with the required deadlines (by Q1/2023).
- Industry highlighted some challenges related to the use of the current, interim IT solution when adding required data, especially for nationally authorized products, where different national reporting requirements may apply. Industry further stressed that fragmentation of national demand data (sources) may lead to inconsistency and may have an impact on objectivity and reliability of data. EMA confirmed that specific feedback should be channelled through the ISG operational group to also help informing and defining in the future the ESMP industry's template attributes.
- EMA confirmed that all activities linked availability, including the EMA Extended Mandate and the Joint Action on shortages are being coordinated to promote synergies and avoid duplication.

Follow-up and next steps

Reporting compliance:

- Foster industry's medicinal product reporting compliance and i-SPOC registration: EMA and EU trade associations to raise awareness on incomplete/missing submissions and promote reporting compliance from their affiliated member companies (including national trades associations).
- Importance for industry stakeholders to actively use ISG operational group on medicine shortages as the key platform for feeding back comments on "reporting templates/guidance/data submission tools".
- EMA to continue reporting on ESMP status progress development at next meeting.

See presentation.

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

- Klaus Kruttwig (EMA) provided an update on activities related to monitoring and mitigating shortages of critical medical devices expected to be implemented from 2 February 2023. These include the setting up of the Executive Steering Group on Shortages of Medical Devices (MDSSG) which will be responsible for drafting the list of critical medical devices, monitoring supply and demand, and providing recommendations on preventative measures.
  An overview of the IT framework intended to be used by the Economic Operator Single Points of Contact (EO-SPOC) for registering critical medical devices was provided. It was confirmed that alignment with the Health Emergency Preparedness and Response Authority Directorate General (DG HERA) activities on the medical counter measures list is being sought.
- Once available, EMA will promote IRIS registration of Economic Operators (EOs) by proactively liaising with concerned companies to raise awareness on the reporting obligations.
  MedTech Europe highlighted that as medical device EOs include manufacturers, importers and distributors, there is a potential for inaccurate reporting duplication. It was suggested that

authorised representatives may be an alternative to medical device manufacturers as data source (tbc).

- Strengthen interactions with medical device industry associations was acknowledged, yet leveraging, where possible and adequate with existing DG SANTE meetings, *ad hoc* drafting group no shortages of critical medical devices consisting of EMA, NCAs and HERA, etc.
- It was acknowledged that there is a need to promote engagement with the medical device industry representatives and Economic Operators and to provide more training and guidance on the new obligations.

Follow-up and next steps

- Ad hoc drafting group on shortages of critical medical devices to continue supporting preparations for the implementation of MDSSG and progress to be reported at next ISG meeting; industry stakeholders to be ready to provide input/feedback when consulted.
- EMA and medical device industry to raise awareness of the impact and new responsibilities i.e. the submission of demand and supply data for critical medical device by Q2/2023 of MD operators and facilitate/advice on the means to better reach out to these stakeholders.
- Strengthen the interactions with industry associations in the medical devices sector as well as with Notified Bodies.

See presentation.

3. Update on Medical Devices expert panels implementation

3.1. Update on Medical Devices expert panels implementation

- Silvy da Rocha Dias and Miguel Antunes (EMA) provided update on the activities of the Medical Devices (MD) expert panel activities responsible for Clinical Evaluation Consultation Procedure (CECP) of class III implantable medical devices and class IIb active medical devices and for Performance Evaluation Consultation Procedure (PECP) for class D IVD (In vitro diagnostics), highlighting the small number of submissions since last ISG September 2022 (Medical Devices-Expert Panels) and the need for increased pipeline information to be shared for workload, expertise and resources MD expert panels planning optimisation.
- EMA presented the status development of the **new scientific advice procedure for medical device manufacturers on clinical development strategy and clinical investigation** and informed the audience of the launch of a pilot phase for Q1/2023. The pilot is aimed at gathering experience to shape the future scientific advice procedure after 2024. It was highlighted that as part of the pilot phase, the scientific advice will be free of charge. Additional information and guidance will be shared in advance of a dedicated webinar scheduled in January 2023.
  Medical device industry representatives welcomed the pilot phase.

Follow-up and next steps

- Medical device industry and Notified Bodies to share medical device pipeline information.
- Medical device industry to raise awareness to medical device manufacturers to participate to the SA pilot scheduled to start Q1/2023.

See presentation.

3.2. Early Scientific Advice and Expert Panels Views from MedTech Europe Third Industry

Standing Group Meeting

- Jesús Rueda Rodríguez (MedTech Europe) provided the MD industry point of view on the activities of the MD expert panels within Regulation (EU) 123/2022, namely the Notified Bodies' mandatory consultations, the CECPs of class III implantable medical devices/class IIb active medical devices and PECPs for class D IVDs and the optional MD manufacturers' consultation on their device clinical development. further to a survey performed within their affiliated members. It was highlighted that the process of MDs scientific advice needed to provide certainty on clinical development strategy and proposals for clinical investigations, the establishment of a structured dialogue with clear documentation and timely deliverables.
- The need for resources of MD expert panel was highlighted needing to be carefully planned in the view of the expected number of requests of up to 200. Other feedback provided was related to the specific limited scope of MD expert panels to be complied with, i.e. not to give regulatory advice.
- EMA clarified the scope of the MDs' Expert Panel (as outlined in the legislation) and confirmed that regulatory advice is expected to be provided by competent authorities in accordance with established legal frameworks.
- The MD industry finally expressed the need for a specific interface to be established in case of medical device combination products to bridge the work of and expert panel and the pharmaceutical regulatory process.

Follow-up and next steps

- Medical device industry to keep EMA informed of any pipeline information and/or trends.
- Collaboration to develop and foster the activities of the MD expert panels between EMA and MD industry and NBs to be continued/strengthen including the need for specific interfaces for combination products.

4. Establishment of the Quality Innovation Group and Industry Stakeholder engagement

- Veronika Jekerle (EMA) provided an overview of the newly created Quality Innovation Group (QIG) which is expected to be the point of entry for industry stakeholders to the EU regulatory network to facilitate translation of innovation in manufacturing aspects. The QIG composition, mandate and priority topics were outlined. The audience was informed of the "Listen and learn focus groups" which are expected to be a forum for the QIG and industry/academia stakeholders to share knowledge and experience on innovative products/processes/control strategies/facilities and discuss challenges and possible solutions.
- The first meeting of the "Listen and learn focus group" is planned for 13th March 2023 and a call for abstracts was sent to industry stakeholders through EU trade associations with a deadline for reply by 20th January 2023.
- It was clarified that the current QIG topis' priorities derived primarily from several sources such as the EMA Regulatory Science Strategy to 2025 and stakeholders' responses, overview of ITF meetings, Scientific Advices, information from NCAs but also international regulators. Those currently identified are "continuous manufacturing" and "decentralised manufacture" and "digitalisation in pharmaceutical manufacturing". Future discussion on other topics will be driven by stakeholders' feedback.

Follow-up and next steps

- EMA to launch call for abstracts to industry stakeholders and subsequent invite for the Listen/Learn focus group meeting 13th March 2023. See presentation.

5. Update on EMA Agile governance implementation

- Hilmar Hamman (EMA) presented the progress of EMA's Agile transformation journey from the traditional Waterfall IT Governance Framework towards a SAFe / Agile approach. The purpose of the transformation is to reduce redundancy and duplications and bring benefits including a higher level of transparency, better communication with the network and industry, and focus on value/business outcomes instead of output/costs.
- It was highlighted how important it is for industry to put forward nominations for industry SME roles in the Value Streams for Product Management Service (PMS), Regulatory Procedure management (RPM), eCTD, Union Product Database (UPD) and signal and safety analysis.
- Industry expressed concern that the confidentiality undertaking they are required to sign in the role as SMEs restricts them in effectively acting as a delegate on behalf of their communities/peers. Additionally, they requested the opportunity to provide feedback during the bi-annual participation of industry in Strategic Portfolio Reviews.

Follow-up and next steps

- Complete IT products "Agile" Governance transition in Q2/2023.
- Industry stakeholders to put forward nominations for SMEs in the indicated Product Teams, once call is being sent.
- EMA to follow up on industry SME confidentiality undertaking clarifications and allow for adequate time for industry stakeholders' response and input during the bi-annual System Demos and Strategic Portfolio Reviews to optimise dialogue and feedback during these meetings.

See presentation.

6. IT security at EMA - update on additional measures in place

- Ivo Classen (EMA) provided an update on the measures EMA has put in place following the cyber security attack which was discovered on 1st December 2020. While police investigation is still ongoing, EMA has worked and is continuously working to improve its cybersecurity procedures and has kept its stakeholders continuously informed (Cyber-attack on EMA – update 1, update 2, update 3, update 4, update 5, update 6).
- The Agency is not aware/being informed of more documents made available on the "Dark web" and continues enhancing its cybersecurity systems and processes to mitigate any business risks by implementation of administrative and technical controls to further protect the data managed by EMA.
- The closure of the investigation is expected in 2023 (tbc). EMA will keep all its stakeholders informed. The audience was invited to communicate any suspicious activity/publication promptly to the Agency.

Follow-up and next steps

- EMA to publish updates on the cyber-attack investigations as needed.
- Industry to communicate any suspicious activity/publication promptly to the Agency.

See presentation.

7. CTIS implementation update

- Peter Arlett and his team (EMA) provided an overview of activities related to the Clinical Trial Information System (CTIS) and ACT-EU.
- CTIS is a single submission portal which harmonises the submission, assessment and supervision of clinical trials in the EU/EEA. In terms of engagement, the CTIS forum was held on 12th October 2022 to facilitate stakeholder exchange and share recent experiences with the portal.
- Accelerating clinical trials EU (ACT-EU) was briefly presented as a business change initiative to transform the EU clinical research environment in support of medical innovation and better patient outcomes. Its main objectives and priority actions were presented. In particular, the audience was informed of Priority Action 3 which is the set-up of a multistakeholder platform enabling the discussions on clinical trials.
- It was clarified that the activities linked to ACT-EU do not intend to replace current legal requirements already established at national level. Nevertheless, the Agency is strengthening the support and is providing lead to the outlined priority actions. It was also confirmed that the multistakeholder platform and CITS forum can be used to discuss regulatory problems.

Follow-up and next steps

- Address CTIS issues (no blocking bugs on CTIS core processes) to deliver the system for mandatory use for initial trial applications by 31/01/23
- Deliver CTIS information sessions and trainings
- Follow up on ACT-EU priority actions and engagement

See presentation.

8. Summary of actions and next steps

- The chair thanked the participants and recognised the constructive interaction, open dialogue and participation to the discussion and informed the audience of the publication of high summary report of the meeting which will include all identified actions.
- Feedback on the ISG meetings was also sought and a specific questionnaire will be sent post-meeting to gather such input.
- The 2023 meeting date of the ISG will be communicated in due course.
- ***Post-meeting note:***
  ISG 2023 meetings are: 21st March 2023, 29th June 2023, 21st September 2023 and 23rd November 2023.