7 February 2023
EMA/45560/2023

Highlights of EMA-EFPIA bilateral

07 February 2023 – chaired by Marie-Helene Pinheiro

1. Welcome and introduction

EMA Executive Director welcomed the participants and highlighted how these types of meetings are an important occasion to exchange views on opportunities and challenges and to reinforce the collaboration on common priorities.

2. Report on Factors affecting the location of biopharmaceutical investments and implications for European policy priorities

- The key findings impacting the speed of growth of biopharma investments in the EU were discussed along with the policy recommendations suggesting a more competitive and attractive European market.
- The report on Factors Affecting the Localisation of Biopharmaceutical Investments and Implications for European Policy Priorities recommends establishing EU policies that can better incentivise R&D innovation hub, promote small-mid size companies, invest in ATMP research and development activities, develop adequate the regulatory pathways and evidence requirement in order to promote market access.
- Discussion took place about existing innovation hubs in Europe in terms of life science investments, not specifically identified in the report. In addition, amongst all the initiatives promoting innovation, EFPIA was invited to actively participate to the work of the Quality Innovation Group (QIG) whose aim is to support developers that intend to use advance technology in their manufacturing approaches by understanding and addressing the current challenges through an adequate regulatory environment.
- It was also highlighted that the review of pharma legislation is expected to address some of the points of the report but no further discussion took place since the European Commission proposal was not yet published.

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3. IVDR implementation challenges from pharma industry perspective

- EFPIA discussed the impact of the implementation of the In Vitro Diagnostic Regulation (IVDR) for clinical trials of IVD devices in terms of delayed timelines and access for patients and expressed the concern in general what this does to the attractiveness of the European clinical research ecosystem, despite good initiatives being in place, such as ACT EU.
- EMA also clarified that the majority of the IVDR implementation is out of the Agency's remit and invited EFPIA to keep engaging with the relevant authorities responsible for IVDR implementation (i.e. EC, National Competent Authorities).
- EMA highlighted how the EC, EMA and HMA initiative Accelerating Clinical Trials in the EU (ACT EU) is considered an opportunity to modernise clinical trials in the EU. In this context, EFPIA was invited to participate to the ACT EU multi-stakeholder platform public consultation launched on the 3rd of February.
- In terms of development programmes for drug-device combinations or medicinal products alongside companion diagnostics, EMA acknowledged the challenges presented and referred to the on-going discussions as part of the R&D stakeholders platform. EFPIA was recently invited (alongside other trade associations) to nominate representatives for a dedicated focus group on scientific advice on medicines development including companion diagnostic or medical device combination. This is an opportunity for active engagement in shaping a pilot for such Scientific Advice.

4. EMA Mandate Extension – Drug shortages: European Shortage Medicines Platform (ESMP) implementation

- EFPIA presented some proposals to prevent and mitigate shortages highlighting the importance of adopting an inter-operable EU shortage system, a risk-based approach, flexibility, transparency and maintaining a resilient supply chain. This included recommendations to use, where and as appropriate some of the EMVS data.
- EMA informed EFPIA that as part of ESMP development planning, a feasibility study was performed including the possibility to use other existing IT tools/systems, such as EMVS. Based on the results of that assessment, the EMVS database would not supply all of the required information laid out in the Regulation (EU) 2022/123 even if the access issue was legally solved. Nevertheless, it was considered to be a potentially interesting source of information to complement the ESMP system and when it established together with other information systems that exist in Europe e.g. volume of sales data per product per Member State. Submitting the same data once and using it for multiple purposes, would be efficient, if possible and appropriate.
- EMA is aware of some pilot initiatives being taken by Trade Associations in conjunction with one or more Member States to investigate the potential use of the EMVS data sets to address the challenge of supply and availability of medicines in Europe with the particular view to anticipate and prevent shortages. EMA is interested to hear of the progress of this work and invited EFPIA to provide information both on their past workshops and planning for future workshops. The recent public health challenge of antibiotics shortages in Europe and globally was discussed and identified as a potentially interesting use case with which to explore the utility of the EMVS data set as part of this pilot exploration. EFPIA committed to pursue this and report back outcomes accordingly.

5. COVID-19 pandemic lessons learnt and Resourcing/Viability of the European Medicines Regulatory Network

- EFPIA informed about the feedback from a survey across its members on the COVID-19 lessons learnt and highlighted how the regulatory flexibility was considered an important tool enabling speeding up the scientific dialogue, market authorisation, post approval changes and clinical trials. International agreement of guidance coordinated via ICMRA was also highlighted as a key successful forum during the Pandemic.
- An update on EMA lessons learnt from the COVID-19 response was briefly presented and discussed. Amongst the follow up actions, mobilisation of experts through the Emergency Task Force and work to monitor and coordinate MSs activities in identifying and mitigating shortages have been formalised through EMA's extended mandate. Some of proposals related to availability of data, clinical trial design, and use of RWE are being addressed through ACT EU and DARWIN, EMA/ECDC vaccine monitoring platform. The establishment of regulatory tools enabling rapid approval of medicines during crisis and the considerations on improving the use of resources and increasing the support to EU-level coordination (e.g.assessment report revamp, submission predictability focus group, capacity building, strengthening MNATs and cross-NCA training programmes), were also highlighted. EFPIA was informed that further details of the EMA COVID-19 Lesson learned will be shared at the next ISG meeting on 21st March 2023.

6. Future proof EU Regulatory System: Agile Committee and WGs structure

- EMA provided overview on the progress of working party revision. It was clarified that the working parties will be involved on an ad hoc basis in terms of product assessment and only when the CHMP requires a steer on specific points. Clarifications were provided on the composition of the methodology working party. Further detailed on Industry stakeholders' engagement are being developed and industry will be updated further once available. Status update of the new WP governance implementation will also be given to all Industry stakeholders at the next ISG March meeting.

7. New HTA Regulation: EMA collaboration and implementation progress

- EFPIA recognised the objectives of the new HTA Regulation and expressed the desire to be actively involved in the implementation of the regulation given its impact on development programmes.
- EMA noted the ongoing implementation activities by the European Commission as secretariat of the HTA Coordination group. The importance of Industry efforts to bring internally together regulatory affairs and market access was highlighted. EMA confirmed its commitment to support the implementation of the new HTA regulation in close collaboration with the European Commission and also guided by work plan with the EUnetHTA 21 consortium.

8. AOB

No AOB added.