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European Medicines Agency

Highlights – Seventh EMA- EFPIA bilateral meeting

29 November 2024 – Chaired by Marie- Hélène Pinheiro, EMA Industry Stakeholder Corporate Liaison

1. Welcome and introduction

The chair and EMA Executive Director welcomed EFPIA delegation in the spirit

of continuous open and direct dialogue and discussions.

2. Views from EFPIA on new legislative proposals

EFPIA shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation further to Parliament and Council on-going discussions, flagging the need to ensure a competitive, efficient and agile EU regulatory framework. Considerations on network resources, process efficiency and interplay with other legislations were made.

The EMA noted the points made and shared same commitment in ensuring a regulatory framework that delivers timely medicines to EU patients while ensuring the highest standards of quality, safety and efficacy. It was clarified that EMA, not being an official party to the legislative process, was not in position to comment on any of the proposals made. EFPIA was encouraged to also bring their views to the European Commission and other revenant authorities as needed.

3. EU Network resource sustainability discussion

EFPIA shared its perspectives on how to ensure the sustainability of network resources, including its views on the Quality Review Document (QDR) template updates, and shared some proposals to improve the system.

The EMA confirmed the ongoing dialogue with the regulatory network in order to address Member States' challenges related to network sustainability and expertise management and welcomed further discussions on proposals to improve system efficiency. EFPIA was reminded of the ongoing discussions to improve predictability of submissions and was encouraged to participate in the public consultation on the QDR template once launched.

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4. EFPIA discussion on EMAN strategy update to 2028

EFPIA provided its preliminary feedback on EMAN to 2028 expressing commitment towards pharmaceutical innovation. The areas of activity of the EFPIA strategy (Regulatory Road to Innovation) were outlined highlighting the strategic objectives of ensuring simplification and adaptability, digital transformation, innovation and competitiveness for the benefit of patients and healthcare systems.

The EMA welcomed the preliminary feedback received and encouraged EFPIA to provide more details on the specific challenges faced and recommendations for appropriate solutions as part of the public consultation ending on 30th November 2024. As presented during the 11th Industry Standing Group meeting, the feedback received from stakeholders on the EMANS to 2028 will be discussed in a dedicated workshop expected to be hosted in February 2025.

5. Clinical Trials Ecosystem

EFPIA acknowledges the positive results achieved so far in the area of clinical trials through the ACT EU initiative and the Clinical Trials Regulation (CTR) and related CTIS implementation, including the revised CTIS transparency rules.

The establishment of dedicated focus groups and interactions with relevant working parties (e.g. Methodology Working Party) to enable relevant stakeholders to actively work on and take forward specific deliverables of the ACT EU initiative was considered key by EFPIA.

The need to also ensure the effectiveness of the CTIS and to discuss future changes to the legislative framework at the level of the Multi-stakeholder platform (MSP) was also flagged.

As already indicated during the recent MSP annual meeting, the EMA confirmed that work is ongoing to integrate the identified stakeholder priories into the ACT EU multi-annual workplan and into other relevant initiatives in order to define concrete deliverables where stakeholder can be involved together with relevant ACT EU and network partners.

Both parties shared a sense of urgency to address current challenges given the potential impact on the current European clinical trial ecosystem.

6. EFPIA presentation on cumulative impact assessment of the Green-related files

As presented during the 11th Industry Standing Group meeting, EFPIA provided an assessment of the cumulative impact of several policies related to the Green deal files, highlighting the potential impact of pharmaceutical and non-pharmaceutical legislations on the availability of innovative medicines in Europe.

The EMA welcomed the detailed analysis carried out and challenges highlighted in terms of pharmaceutical impact, and highlighted the need to be shared such insight also with relevant counterparts at the European Commission, as appropriate.

7. Update on EFPIA's 3 baskets approach to the Commission Road map towards phasing out animal testing for chemical safety assessments

EFPIA highlighted its continued commitment for its members to move away from animal testing and the support to the European Commission roadmap for phasing out animal testing in chemical safety assessments. Both EMA and EFPIA recognised the value of the continued collaboration via the 3RsWP IP meetings and platforms such as the EPAA (European Platform for Alternative Approaches to Animal Testing).

8. Bringing EU positions to ICH

Exchanges on ways to foster European topics priorities at ICH level was discussed.

9. Conclusions and next steps

Both parties welcomed the open and continued dialogue on concerns and opportunities for improvement in order to ensure a sustainable, efficient and competitive European pharmaceutical environment.