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European Medicines Agency

Highlights- 9th EMA-European Federation of Pharmaceutical Industries and Associations (EFPIA) bilateral meeting

Chaired Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The EMA Executive Director and chair welcomed EFPIA delegation underlining the value of the longstanding dialogue, particularly at a time of significant opportunities for the European pharmaceutical sector.

While recognising the complexities of the European regulatory environment, both parties emphasised the importance of presenting Europe as a unified ecosystem and welcomed ongoing efforts to enhance regulatory agility, innovation support and international cooperation.

EFPIA highlighted the rapidly evolving global environment and the importance of ensuring that Europe remains competitive and attractive for medicines research, development and innovation.

2. From strategic dialogue to delivery: accelerating regulatory transformation

Follow ups from EMA meeting with leaders of pharmaceutical companies

EFPIA noted that the European Medicines Agency meeting with senior representatives of pharmaceutical companies had been highly appreciated by senior industry leaders and represented a valuable new format for dialogue. Reflecting on the discussions, EFPIA highlighted that clinical trials as well as discussions on accelerating regulatory transformation in Europe had dominated the exchange, underlining their central importance for European competitiveness and patient access to innovation.

EMA welcomed the positive feedback and reiterated its appreciation for the frank and constructive contributions provided by industry participants and trade associations. The Agency shared details on how the feedback gathered had been consolidated into key areas which have been discussed with Heads of Medicines Agencies (HMA), the European Commission (EC) and internally to identify opportunities within ongoing and future initiatives. EMA highlighted the priority areas where significant

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developments are underway and where the feedback received will used during implementation of the New pharmaceutical legislation (NPL), biotech act and relevant future legislation.

OneVision proposal

EFPIA provided further insights on the ONE Vision initiative, highlighting the importance of moving towards a more integrated and coordinated European regulatory system – reducing fragmentation, better connecting clinical development and regulatory assessment, and strengthening continuity of knowledge and data throughout the product lifecycle. EFPIA highlighted the opportunity to use the implementation of the NPL, the Biotech Act and targeted Medical Device Regulation/In Vitro Diagnostics Regulation (MDR/IVDR) changes to move progressively in this direction, including through streamlined processes, earlier and iterative pre-submission interactions and a stronger coordination role for EMA across the regulatory pathway.

EMA welcomed the further elaboration of the proposal and noted the strong alignment between many of the concepts presented and the Agency's own strategic thinking. EMA highlighted ongoing work related to implementation of the NPL, the Biotech Act, enhanced pre-submission interactions (including the recent launch of the pre-submission interaction model pilot) and lifecycle knowledge management (including the recent phased review pilot and AI-enable knowledge mining tool Scientific Explorer).

The Agency recognised the importance of earlier engagement with developers, better continuity of knowledge throughout development and improved use of digital technologies to support regulatory assessments while noting that a model based on a single individual overseeing an entire product lifecycle could present scalability challenges. Such challenges are also being discussed by the HMA/EMA Strategic Resource Oversight Group, focusing on capacity and capability building at national competent authority (NCA) level.

Both sides recognised that digital solutions, structured data and AI-enabled tools may offer more sustainable mechanisms to preserve institutional knowledge and facilitate access to regulatory history.

EMA international leadership

Recognising the extensive and longstanding collaboration already in place between the EMA and the US Food and Drug Administration (FDA), EFPIA highlighted several successful examples, including the Mutual Recognition Agreement, joint guidance and reflection documents, and collaborative assessment initiatives. EFPIA suggested that these existing mechanisms could be further expanded, particularly in the areas of work-sharing programmes, regulatory science, increased reliance and additional joint publications, and invited EMA's views on how such cooperation could evolve and how industry could support these efforts.

EMA emphasised that collaboration with FDA remains strong and active across a broad range of areas. The Agency highlighted ongoing cooperation on several areas, including artificial intelligence, novel manufacturing approaches, rare disease development, and 3Rs, as well as other extensive engagement opportunities through both bilateral mechanisms and multilateral international forums. EMA highlighted the many collaborative activities currently underway, including the parallel scientific advice, the fellowship programmes, and collaborative assessments involving other international authorities. Both sides also recognised the value of increasing the visibility of this extensive international cooperation.

3. EPIA position on New Pharmaceutical Legislation: priorities and opportunities

EFPIA emphasised that implementation of the NPL represents a critical test of Europe's ambition to strengthen competitiveness, innovation and regulatory agility. While recognising the opportunities

offered by provisions such as phased review, accelerated timelines and other modernisation measures, EFPIA cautioned that these benefits must be balanced against the additional regulatory complexity and operational burdens introduced by the legislation. EFPIA stressed the importance of ambitious and pragmatic implementation, robust change management and close collaboration between regulators and industry to ensure that the new framework delivers tangible benefits without creating unnecessary complexity. The importance of digital transformation and regulatory data infrastructure and the need to build upon existing initiatives and data platforms were highlighted.

EMA reaffirmed its commitment to transparency and stakeholder engagement throughout the implementation process and highlighted the centralised procedure and future committee/expert model among the early priority areas. EMA confirmed the intention to update and consult stakeholders through the agreed platforms (Industry Standing Group, Industry stakeholder platforms), consultation mechanism and, where possible, pilot phases once alignment within the network is reached.

EFPIA was encouraged to share practical proposals early in the process.

4. EFPIA position on upcoming EU legislation and policy initiatives

EFPIA welcomed the proposed Biotech Act, describing it as a positive step towards modernising Europe's clinical trial ecosystem and addressing long-standing challenges related to fragmentation, duplication and inconsistent assessment practices. EFPIA highlighted its strong support for measures aimed at shortening clinical trial authorisation timelines while maintaining high standards of scientific assessment and patient safety and stressed that successful implementation of these reforms will require corresponding changes to the supporting digital infrastructure, particularly CTIS.

EMA confirmed broad alignment with many of the objectives outlined and noted that preparatory work is already underway through existing governance structures, including the CTIS Task Force on implementation aspects.

5. EFPIA research and insights

Topic not discussed.

6. Conclusions and next steps

Both parties noted the strong level of alignment demonstrated throughout the discussion and the shared ambition to use the current challenging geopolitical environment as an opportunity to strengthen Europe's attractiveness for medicines research, development and patient access.