8 July 2025

European Medicines Agency

Highlights 8th EMA-EFPIA bilateral meeting

08 July 2025 – Chaired by Sabine Haubenreisser, Principal scientific administrator, Public and stakeholders engagement department

1. Welcome and introduction

The Chair and the EMA Executive Director welcomed the EFPIA delegation, emphasising the importance of continuing the open dialogue in preparation for the anticipated legislative changes and in view of the advancements in science and technology. They also emphasised the importance of ensuring cooperation, simplification and streamlining of procedures for the benefit of European patients.

2. Introduction to EFPIA's Regulatory Road to Innovation (RRI) 2030

EFPIA presented their strategy "Regulatory Road to Innovation to 2030", highlighting short and mid-term priorities (such as the implementation of the General Pharmaceutical Legislation (GPL) and relevant delegated acts) as well as anticipating long-term priorities, beyond 2030, to embrace the progress in scientific technology and digital transformation.

Proposals for a sustainable network strengthened by international collaboration, a focus on scientific progress, as well as digitalisation across the product lifecycle, were presented as key enablers for consolidating Europe's position as a hub for innovation.

The EMA noted general alignment between the RRI 2030 and the thematic areas reflected in the European Medicines Agencies Network Strategy 2028 and briefly outlined ongoing activities aiming at translating the EMANS provisions into multi-annual workplans.

EFPIA was encouraged to present specific proposals within the context of the established stakeholders' platforms for interaction and engagement events. EFPIA members were invited to engage in a dialogue with the Agency on innovative technologies through the available channels (e.g. interested parties, early engagement tools and scientific advice).

EFPIA highlighted the cumulative impact represented by pharmaceutical, chemical, food, animal and environmental legislations and the need to strengthen the dialogue amongst authorities and stakeholders to avoid impacts on availability of medicines.

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EMA acknowledged the complexities of interlinking several legislative policies and underlined the importance of its ongoing engagement with relevant European Authorities (such as EFSA and ECHA).

EFPIA was invited to proactively flag any anticipated challenges or concerns to the Agency.

3. EFPIA position on revision of the General Pharmaceutical Legislation, Biotech ACT and European Lifesciences Strategy

EFPIA presented its position on the expected challenges posed by the implementation of the revised pharmaceutical legislation and related delegated acts, highlighting the need to raise awareness among companies on the anticipated changes, timing and their potential impact on their activities.

The EMA confirmed its intention to ensure transparency and engagement with stakeholders regarding implementation activities and welcomed EFPIA to advise on any specific area and priorities requiring particular attention in order to ensure companies readiness.

4. EFPIA position on vulnerability assessment and solidarity mechanism

EFPIA expressed support in being further involved in the vulnerability assessment methodology and asked clarifications on how stakeholders feedback was incorporated into the criteria to develop the Union List of Critical Medicines (ULCM).

The EMA confirmed the intention to keep working with stakeholders, as already done with the Critical Medicines Alliance, the structured dialogue and the consultations on the ULCM. Additional engagement was confirmed.

5. Conclusions and next steps

The continued constructive dialogue and focused collaboration in specific areas in the margins of available fora was welcomed and encouraged.