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European Medicines Agency

Highlights sixth EMA-EFPIA bilateral meeting

06 February 2024 - Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The chair and EMA's Executive Director welcomed EFPIA delegates to the 6th bilateral meeting acknowledging the important timing for discussing challenges on medicine availability and innovation and explore solutions that could enable the modernisation of the regulatory system.

Likewise, EFPIA's Director General highlighted the importance of a constant exchange and collaboration which go beyond the present meeting and are valuable to improve, harmonise at global level and ensure a strong legislation and competitive regulatory framework.

2. The pharmaceutical legislation review and its implications for the EU regulatory framework

EFPIA shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation. The importance of ensuring a flexible approach that can remain applicable also for future scientific developments was flagged as essential.

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. Therefore EFPIA was referred to the European Commission. To promote regulatory understanding EFPIA was also encouraged to further contribute by flagging topics and bringing case studies, such as the use of the Platform Technologies, to the upcoming technical discussions of the listen and learn focus group of the Quality Innovation Group (QIG).

3. Interface between medicines and chemical/food/environmental agenda

EFPIA expressed concerns on the impact that recent changes in EU legislation and policies (such as new environmental requirements and restrictions to the use of titanium dioxide and Per- and polyfluoroalkyl substances) may have on the pharmaceutical sector in terms of medicines availability and feasibility of manufacturing in the European Union. EFPIA also flagged the need to have tailored

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benefit/risk considerations and to allow case studies discussion with all concerned stakeholders and global regulators.

EMA acknowledged the concerns shared and flagged the need to have further discussion on specific examples and scientific evidence. In this context it was flagged that the challenges for our environment need to be considered and that sustainable medicine development and manufacturing is a strategic EU priority, as part of the EU Green Deal. Industry was invited to discuss technical enablers for green manufacturing and innovative methods that can support such transition with the Quality Innovation Group.

4. Implementation of the HTA regulation with a main focus on EMA-HTA interactions

EFPIA welcomed their dialogue with HTAs on key areas linked to the implementation of the Health Technology Assessment (HTA) regulation and the engagement by EMA on aspects relevant to the regulatory/HTA interface.

EMA stressed that the primary responsibility of the implementation lies with the European Commission and the HTA coordination group, and clarified its contribution in supporting these implementation activities by working closely with them and also by facilitating multi-stakeholders discussions in line with Agency's remit.

5. EU Critical Medicines List, Drug Shortages Monitoring Platform and European Medicines Verification System

The progress on the European Shortages Monitoring Platform (ESMP) was discussed outlining the need to ensure that the system is in place by the legal deadline (February 2025) and also the valuable contribution of EFPIA subject matter expert in the development of the product.

It was clarified that a successful pilot on the availability of antibiotics in preparation for the next autumn/winter season could help understand the potential use of EMVS data.. In addition, it was confirmed that in a hypothetical future, EMVS should be viewed as an additional or supplementary data source, rather than a replacement for the ESMP.

The EMA confirmed its complementary involvement in the Critical Medicines Alliance consultative mechanism recently launched on the 16th of January and led by the European Commission and the Health Emergency Preparedness and Response (HERA).

The EMA also clarified that shortages prevention plans should be part of industry business continuity plans to ensure availability of medicines and that work is ongoing in order to ensure adequate guidance to industry stakeholders.

6. EFPIA position on interface between medical device and pharmaceutical legislation

EFPIA appreciates the initiatives (such as the COMBINE project, led by the European Commission) aiming to provide clarity support on the complex interphase between the medical device and pharmaceutical legislations.

The EMA confirmed its contribution in line with its remit outlined in the regulation (EU) 2022/123 extending Agency's mandate. In this context the recent experience with the ongoing and successful expert panel pilot on scientific advice for certain high-risk medical devices was discussed and more details will be provided during the next Industry Standing Group meeting scheduled for March 2024.

EFPIA was invited to share any tangible example outlining the challenges experienced by members in order for the EMA to explore possible guidance.

7. AOB

No AOB.

8. Conclusions and next steps

The bilateral meeting was an opportunity to discuss the challenges and opportunities for the pharmaceutical ecosystem. The value of having constant dialogue and engagement enabling both parties to understand each other perspectives was recognised