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European Medicines Agency

Highlights- EMA-IPFA and PPTA Global bilateral meeting

12th November 2024 – Chaired by Marie-Hélène Pinheiro, EMA Corporate Industry stakeholder Liaison

1. Welcome and Introductions

The chair welcomed IPFA and PPTA delegation and encouraged an open dialogue on topics of common interest.

2. Key priorities for the next 3-5 years and pipeline trends

IPFA key priorities for the coming years were presented highlighting the focus on ensuring the quality of plasma derived medicinal products and on promoting to the contribution of plasma collection by the public sector. Collaboration with other stakeholders' organisations and initiatives to manage and support the supply of plasma derived medicines, especially immunoglobulins, was also noted.

PPTA's 3-year strategy was also outlined, highlighting as a key goal the establishment of a collaborative environment enabling global plasma supply and patient access to plasma derived medicinal products. The focus on advancing the regulatory and policy framework for the benefits of medicines access, participation in international initiatives and dialogue with the EMA and other global authorities was also highlighted. Both PPTA and IPFA were asked to notify EMA of any upcoming novel manufacturing methods that may necessitate regulatory changes, thus emphasizing the importance of early engagement with MAHs on such innovation.

3. PPTA/IPFA position on the new EU Pharmaceutical legislation

IPFA and PPTA shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation emphasising the need to ensure alignment with the provisions of the Regulation (EU) 2024/1938 of the European Parliament , the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation)

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and of the new variation regulation requirements for areas linked to medicine shortages, good manufacturing practice (GMP) inspections requirements, where appropriate.

Given the nature of plasma derived medicinal products, a call for a more tailored approach to address medicines shortages monitoring and mitigating activities was flagged.

It was clarified that EMA, not being an official party to the legislative process, was not able to comment on the proposals made. Nevertheless, given the specific mandate for shortages management in crisis preparedness and management, EMA is promoting an open dialogue with stakeholders and therefore IPFA and PPTA were encouraged to contribute to relevant discussions held at the Industry Standing Group (ISG) with their perspectives and to participate to relevant pilot and training initiatives. More specifically the pilot implementing the shortage prevention and mitigation plans planned for 2025 and the upcoming European Shortages Monitoring Platform (ESMP) training session on routine shortage reporting for marketing authorisation holders of centrally authorised products (CAPs). IPFA/PPTA were also advised to directly engage with the Good Manufacturing Practice (GMP)/Distribution Practice (GDP) Inspectors Working Group secretariat for specific GMP matters as part of their Interested Party meetings.

Finally, acknowledging PPTA and IPFA's offer to provide a comprehensive overview of the PDMP supply chain for a better understanding of this industry shortages and vulnerabilities requirements' specifics.

4. PPTA/IPFA impact analysis and position of SoHO Regulation

PPTA/IPFA provided its impact assessment on the SoHO Regulation.

The EMA thanked PPTA/IPFA for their analysis and clarified the scope for EMA is limited and, amongst other points, includes the requirement for the SoHO Coordination Board (SCB) to consult the Agency on the coordination of 3rd country GMP inspections upon request, and to support harmonised implementation of standards and technical guidelines regarding the Plasma Master File (PMF) certification under Directive 2001/83/EC.

For additional clarifications on the SoHO Regulation and the respective role on the drafting of guidelines by the 'experts bodies', IPFA and PPTA were encouraged to approach the European Commission and other relevant blood authorities, who are currently preparing for the implementation of the new regulation in 2027.

5. EMA update on immunoglobulin activities

EMA activities linked to shortage management and availability of immunoglobulin at the level of the Medicine Shortage Single Point of Contact (SPOC) working party, related subgroup and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), including the international collaboration, were outlined. It was noted that the discussions occurred during the HMA/EMA multi-stakeholder workshop on shortages (01 March 2023) and information has recently been published in the shortage catalogue.

6. Conclusions and next steps

The open exchange of views on regulatory and legislative requirements, challenges and priorities for plasma-derived medicinal products was welcomed and encouraged to continue.