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European Medicines Agency

Highlights – 3rd EMA-IPFA-PPTA bilateral meeting

9 February 2026 – Chaired by Steffen Thirstrup, Chief Medical Officer

1. Welcome and introduction

The Chair welcomed the IPFA and PPTA delegations and expressed appreciation for the opportunity to engage in an open dialogue with organisation representing blood and plasma derived medicines. The importance for discussing sector priorities and challenges was acknowledged.

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

The IPFA and the PPTA presented an overview of their strategic priorities for the coming years emphasising the importance of ensuring availability of plasma and blood derived medicines. Key priorities are, amongst other, the implementation of the Substance of Human Origin (SoHO) Regulation, the evaluation of the impact represented by the revised pharmaceutical legislation and critical medicines act. The need for ensuring coherence, harmonisation and mutual recognition was highlighted.

3. IPFA and PPTA position on SoHO regulation implementation

The IPFA and the PPTA provided an overview of activities undertaken to adequately implement the SoHO regulation and flagged certain areas where more clarity on requirements and timelines was sought. Support from the Agency was welcomed to enhance coordination across national competent authorities.

The Agency acknowledged the points raised and provided an update on current guideline development, expected timelines, and ongoing engagement with stakeholders within Agency's remit.

The IPFA and the PPTA also engage with the national competent authorities (including engagement with the CMDh - Coordination Group for Mutual Recognition and Decentralised Procedures - Human) and closely follow the activities of relevant working parties and groups (such as the GMDP Inspectors

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Working Group and Biologics Working Party) and contribute to relevant stakeholders' consultations. The EMA acknowledged and reinforced encouragement for these interactions.

4. Regulatory alignment for plasma supply chain

The IPFA and the PPTA provided their position on the implications of current and forthcoming European legislation, including the Critical Medicines Act, the revision of pharmaceutical legislation, and the Biotech Act, on the plasma-derived medicinal product sector.

The importance of ensuring that the specificities of this sector are taken into account in terms of requirements were flagged to safeguard the plasma collection and supply chain. The challenges and complexities linked to supply from emerging markets were briefly discussed and the support from the Agency was welcomed.

The Agency welcomed the points raised and confirmed the intention to work with the network as well as stakeholders to ensure adequate implementation of all legislative requirements. The Industry Standing Group was flagged as main forum for receiving updates on the implementation of the revised pharmaceutical legislation.

5. Emergency preparedness activities

The activities of the PPTA Emergency and preparedness task force activities were outlined. Collaboration with the MSSG, the US FDA, EDQM (European Directorate for the Quality of Medicines and HealthCare) and engagement with HERA (Health Emergency Preparedness and Response) Industrial Cooperation Forum were flagged.

The IPFA also outlined the activities undertaken to address emerging agents and pandemic preparedness. Both associations proposed a joint workshop to enhance coordination between industry and regulatory authorities.

The Agency welcomed the overview provided and expressed openness to future collaboration and integrating recent crisis learnings. The role and activities of the SPOC (Medicines Shortages Single Point of Contact) Working Party the SPOC WP subgroup on crisis monitoring and preparedness, and routine engagement with industry and Member States to detect early signals, prevent shortages, and enable coordinated action during major events or public health emergencies were stressed.

The EMA shared plans to convene a public workshop in the 2nd half of the year on immune thrombocytopenia in line with the haematology work plan for 2026. Details and agenda will follow.

6. AOB

Participants discussed technical points linked to Variant Creutzfeldt-Jakob disease, EudraVigilance database, Scientific Data Requirements for PMF (Plasma Master File) guideline and the revision of Chapter 9 of guideline of epidemiological guideline.

7. Conclusions and next steps

The meeting provided an opportunity to focus the dialogue on the specificities of the plasma derived medicines sector.