



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 December 2023
EMA/565009/2023

Highlights – EMA-IPFA-PPTA first bilateral meeting

8th December 2023 – Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The chair welcomed the Plasma Proteins Therapeutics Association (PPTA) and the International Plasma and Fractionation Association (IPFA) to the meeting.

The objective of the meeting was to exchange on the type of topics of mutual interests and discuss the modalities of the EMA and PPTA/IPFA future industry stakeholders engagements options.

2. IPFA/PPTA present list of topics of interest

PPTA/IPFA started their presentations by providing updates on their respective organisations' membership status and scopes and highlighted the importance of ensuring that plasma is available for the European patients. The recently appointed PPTA Director General, Anita Brikman was also introduced.

In addition, IPFA/PPTA highlighted information on the scope and areas of mutual interest which would benefit from either technical, regulatory political and strategic discussion with the Agency. IPFA/PPTA illustrated these with examples of complex situations where cross multi-disciplinary input would benefit from a more integrated approach discussion level in view of their potential consequential interlinks.

3. Presentation on EMA engagement with Industry stakeholders taken into account its framework and the new Working Party governance

EMA gave an holistic overview of the Agency's Industry stakeholders interactions in line with its Industry Stakeholder framework ([link](#)) and taking into account EMA New Working Party's governance / changes, pointing out where possible PPTA/IPFA engagement could be foreseen for information sharing, consultation, involvement and /or cooperation and participation.

EMA highlighted the current existing IPFA/PPTA membership both at strategical and operational level such as part of the Industry Standing Group (Strategic) and or as interested parties of the Haematology Working Party (HAEMWP) for clinical aspects, Biotechnology Working Party (BWP) for quality aspects, but also the Non-Clinical working party (NCWP) and the Inspection Working Group

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(IWG) which may be for a to consider also in the future, where and as appropriate. In addition to clarifications on the scope of each of the forum, specific contact details were also provided.

EMA also clarified the possibility for interactions on topics related to shortages and pointed out the participation of IPFA/PPTA in the breakout session on immunoglobulins during the HMA/EMA Task Force on Availability of Authorised Medicines workshop on shortages held in March 2023 ([link](#)).

4. Discussion

IPFA/PPTA welcomed the EMA presentation clarifying ways of interaction.

5. Summary of follow up items

Both parties acknowledged the shared goal to ensure optimal use of the relevant industry stakeholder forum of interactions according to the scope and level of discussion topics. Consideration for an annual EMA-PPTA & IPFA bilateral meeting was also discussed provided the scope and topics of mutual strategic interest could be identified.