



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Perspective of EPL and PM regarding interactions with applicants

Experience from recently completed MAA evaluations



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An agency of the European Union





Management of applicants' queries providing relevant expertise (1/2)

Procedure Manager

- Act as a primary contact point
- Co-ordinate/ collaborate closely with the product team
- Respond/ ensure response is provided
- Maintain procedural-regulatory oversight



Management of applicants' queries providing relevant expertise (2/2)

EMA Product Lead

- Maintain the product and therapeutic area oversight
- Attend committee meetings and facilitate cross-committee discussions and consistency
- Act as scientific focal point for the product team members' input throughout the procedure



Case scenarios

Examples for interactions between the applicant and the PM/EPL at critical steps during the MAA evaluation:

1. Preparation and conduct of an **Oral Explanation** (OE)
2. Finalisation of the review and preparation of a **positive Opinion**

→ Description of experience from real-life cases



Take home messages – Contact points

- PM is the primary contact point (in case of doubt contact/inform PM)
- PM will guide the applicant through the procedure/ensure that questions are addressed
- PM will either directly address questions or request input from the product team
- EPL facilitates discussion on scientific evaluation at key milestones and ensures feedback from committee discussions, where necessary
- In general, direct contact with the EPL and other product team members increases towards the end of the procedure
- When interacting with team members, the PM should be always in copy to ensure procedural/ regulatory oversight



Best practices displayed by applicants as critical success factors

- Transparent, pro-active and aware of existing guidance
- Be available at key time points or provide back-up, ensure timely feed-back and have decision makers available at key time points.



Two-way communication key to the success!