



Joint HMA/EMA multi-stakeholder workshop on submission predictability

25 September 2024, 09:00 – 13:30 (CET/CEST)
Virtual meeting/ EMA, Amsterdam

The event will gather representatives from national competent authorities, the European Medicines Agency, and industry stakeholders. The workshop aims to raise awareness and foster mutual understanding of how changing submission dates for initial centralised Marketing Authorisation Applications (MAAs) affect EMA and network resources, workload, and expertise planning. Additionally, it will provide a platform for industry stakeholders to share best practices for submissions and discuss strategies to enhance the predictability of MAAs submissions and overall network resource management.

In particular, the objectives of this workshop are to:

- To showcase data and trends on submissions predictability – problem statement
- To share best practices approach for submission of initial marketing authorisation applications
- To create awareness of the impact from a resource perspective when changing submission dates
- To strengthen cooperation and communication amongst stakeholders
- To discuss strategies to improve submission predictability

Multi-stakeholder workshop on submission predictability agenda

Chaired by Francesca Day (EMA - Head of Therapeutic Areas Department) and Aimad Torqui (MEB-NL Head of Division)

25 September 2024, 09:00 – 13:30 (CET/CEST)

08:45 Technical check and welcome by the Chairs

09:00 Opening remarks

Welcome and opening remarks by EMA Executive Director & President of BfArM

Welcome, objectives and importance of the webinar
Emer Cooke (EMA) and Karl Broich (BfArM)

15 min

09:15 EMA Statistics on Submission Predictability and problem statement

Enrico Tognana (EMA)

20 min

- Data and trends for submission predictability
- 2023 close monitoring exercise and results
- Case studies – examples of poor submission planning

09:35 Best Practice approach using current guidance

Jaime Oliva (EMA)

25 min

- How to plan and submit a MAA – EMA perspective
- Reinforcement of communication – timepoints and mechanisms for notifying of delays, including a detailed justification
- Awareness of the guidance we have in place

10:00 Views & concerns from Member States on Submission Predictability

Ingrid Landberg (MPA-SE) and Günter Waxenecker (AGES-AT)

30 min

- Case studies - impact on the network when changing submission date and potential consequences for industry
- Specific considerations for Multinational Teams (MNAT)

10:30	Update on Rapporteur appointments	
	<i>Alberto Gañán Jiménez (EMA)</i> • Ongoing process improvements and initiatives at EMA • Overview of the Rapporteurs' appointment and resource impact when changing submission dates • New fee regulation 2025 - provisions for delayed submissions	15 min
10:45	Q&A session	
		15 min
11:00	Slido questions for Industry	
		5 min
11:05	Coffee break	
		15 min
11:20	Industry representatives' viewpoints on submission predictability	
	<i>Pedro Franco (EuropaBio)</i> • Highlight the underlying reasons for postponing submissions • Sharing insights on strategies to mitigate delays and improve predictability	20 min
11:40	Case studies: Innovators, Generics and Biosimilars	
	<i>Andrew Modley (Medicines Europe), Stefan Schwoch (EFPIA), Alexandra Oger (EFPIA), Rebecca Lumsden (Vaccines Europe)</i> • Presentation of case studies illustrating planning and predictability of submissions • Discussion on the challenges and considerations in planning submissions to multiple regulatory agencies worldwide • Exchange of experiences and strategies employed by sponsors in ensuring predictability for global submissions • Lessons learnt and best practices	60 min
12:40	Slido questions for industry	
		5 min

12:45 **Panel Discussion: Q&A Exchange of Ideas - how can we improve submission predictability?**

- Sharing best practices
- Tips and hints
- Enhance communication
- Earlier dialogue/interaction
- Do we need new tools?

35 min

13:20 **Closing remarks**

Wrap up and next steps

10 min

Francesca Day (EMA)

Aimad Torqui (MEB)