2025 EMA Information Day on submission predictability of initial marketing authorisation

03 December 2025
13:30 - 17:30 CEST | Virtual Event

PROGRAMME COMMITTEE

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Representing EFPIA
VP Global Regulatory Affairs EMEA, Eli Lilly and Company Limited, UK

Menno van der Elst
Head of EU Committees Department
MEB, NL

Günter Waxenecker
Head of the Austrian Medicines and Medical Devices Agency, Austrian Medicines and Medical Devices Agency (AGES), AT

| OVERVIEW

Assuring the EU regulatory network's sustainability is key to the functioning of the EU regulatory system. The frequent changes to intended submission dates for initial marketing applications of medicinal products via the centralised procedure pathway, as well as the unpredictability of post-marketing submissions, have a substantial impact on the resources planning within the EU regulatory network and create extra pressure within the system.

The European Medicines Agency (EMA) facilitates this information day with the aim to enhance a common understanding, raise awareness of the challenges for the EU regulatory network and to share best practices for planning and preparing submissions, as well as communicating changes.

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 07 November 2025 latest to emaevents@diaglobal.org

| KEY TOPICS

- Overview on data and trends regarding submissions predictability
- Best practices approach for submission of initial marketing authorisation and post-marketing submission applications
- Impact analysis on resources when changing submission dates
- How to strengthen cooperation and communication amongst stakeholders

| TARGET AUDIENCE

This event is designed for professionals involved in the preparation of initial centralised approved marketing authorisation submissions of medicinal products as well as post-marketing submission applications:

- Marketing Authorization Holders (MAH)
- Contract Research Organisation (CROs)
- Sponsors of clinical trials
- Consultants

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AGENDA | 03 December | 13:30 – 17:30 CET

13:30 **WELCOME NOTE**

SESSION 1 Submission Predictability in Initial Marketing Authorisation: A Regulatory Authority Perspective

Session chair: Francesca Day, European Medicines Agency (EMA), EU

This session explores the issue from the viewpoint of regulatory authorities. EMA will present statistical insights to define the scope of the problem, followed by the MEB's perspective on common challenges and their impact. The session concludes with real-world case studies illustrating how regulators are working to reduce delays and improve submission predictability through increased transparency, guidance, and collaboration.

13:40 **Problem statement: EMA statistics on submission predictability**
Enrico Tognana, European Medicines Agency (EMA), EU

14:00 **Views, concerns, and experience from MEB**
Menno van der Elst, MEB, NL

14:20 **Predictability Matters: Tackling Delays and Uncertainty in Regulatory Submissions with Case Studies**
Günter Waxenecker, AGES, AT

14:40 **Q&A**

15:10 **BREAK**

15:40 **SESSION 2 – Submission Predictability in Initial Marketing Authorisation: An Industry Perspective**

Session chair: Aimad Torqui, MEB, NL

This session examines submission predictability from the industry's perspective, highlighting the challenges and uncertainties faced during the development of a Global Submission. It will illustrate effective case studies where submission dates were adjusted while keeping all key stakeholders and regulators informed in advance. Drawing on available insights & learnings and guidance, the industry will share best practices for planning a submission, strengthening dialogue with regulators and improving predictability of submissions for all stakeholders..

15:40 **Industry representatives' viewpoints & learnings on submission predictability**
Pedro Franco, representing EuropaBio

16:00 **Cases studies on submission predictability**
Stefan Schwoch, representing EFPIA

16:20 **INDUSTRY BEST PRACTICES ON SUBMISSION PREDICTABILITY**
Rebecca Lumsden, representing Vaccines Europe

16:40 **Q&A AND PANEL DISCUSSION**

17:20 **WRAP UP**

17:30 **END OF THE INFORMATION DAY**