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 draft agenda

Chaired by Francesca Day (EMA – Head of Therapeutic Area department) and Aimad Torqui (Head of Division – MEB.NL)

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

08:45 Joining and technical checks

09:00 Welcome and opening speech

Welcome and opening remarks by EMA Executive Director & Head of Agency (BfArM) 5 min
Emer Cooke (EMA) and Karl Broich (BfArM) **10 min**

09:15 EMA Statistics on Submission Predictability and problem statement

Presentation
Enrico Tognana (EMA) **20 min**

09:35 Best Practice approach using current guidance

Presentation
Francesca Day **20 min**

09:55 Views & concerns from Member States on Submission Predictability

Presentation
Ingrid Landberg (MPA-SE) and Günter Waxenecker (AGES-AT) **40 min**

10:35 Update on Rapporteur appointments

Presentation
Alberto Gañán Jiménez (EMA) **10 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 present their viewpoint on submission predictability

20 min

11:40 Case studies: Innovators, Generics and Biosimilars

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?

35 min

13:20 Closing remarks

Wrap up and next steps **10 min**

Francesca Day (EMA)