



Exploratory Workshops on electronic Product Information (ePI)

6, 7 and 8 July, 13.00-17.30 CEST

Virtual meeting

Background and objectives

EMA, national competent authorities and the European Commission are conducting an electronic product information (ePI) set-up project throughout 2021. ePI is authorised, statutory product information for medicines (the summary of product characteristics [SmPC, intended for healthcare professionals], labelling [outer and inner packaging information] and package leaflet [PL, for patients / consumers]) in a semi-structured format created using the EU Common Standard. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.

An EU Common Standard for ePI refers to the technical features of ePI to be agreed by regulators and stakeholders. To facilitate stakeholder consultation on the draft EU Common Standard for ePI, EMA is hosting half-day virtual workshops designed to inform on the standard and explore its future use. Feedback from the workshops will contribute to ensuring that the adopted EU Common Standard meets the needs of its future users to access, view and disseminate product information in electronic format, ePI.

Exploratory Workshops on electronic Product Information (ePI)

Chaired by Aleksandra Dacic-Pilcevic (EMA) & Georg Neuwirther (AGES MEA)

Introduction

12:45 – 13:00	Joining and technical checks	15'
13:00 – 13:05	Opening remarks <i>Aleksandra Dacic-Pilcevic (Head of Customer Advocacy and Delivery Department, EMA)</i> <i>Georg Neuwirther (Head of IT, AGES MEA)</i>	5'

Electronic Product Information (ePI)

13:05 – 13:35	Description and demonstration of use of ePI API <i>Achilleas Voutsas (Technical Solution Architect, EMA)</i>	30'
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Breakout sessions

13:35 – 13:45	Introduction to breakout session <i>Kerstin Healy (IT Project Manager ePI set-up project, EMA)</i>	10'
13:45 – 16:30	Breakout sessions: <ul style="list-style-type: none">• Groups work on tasks using the ePI API• Groups discuss their use cases for the ePI API and the EU Common Standard	165'
16:30 – 16:40	Break	10'
16:40 – 17:25	Feedback from each breakout session	45'

Conclusion

17:25 – 17:30	Concluding remarks <i>Aleksandra Dacic-Pilcevic (EMA), Georg Neuwirther (AGES MEA)</i>	10'
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