



Information Workshop on electronic Product Information (ePI)

5 July, 13.00-16.30 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.

A recoding of the Information Workshop will be published on the EMA website after the event.

Information Workshop on electronic Product Information (ePI)

Chaired by Melanie Carr (EMA) & César Hernández (AEMPS)

Introduction

12:45 – 13:00	Joining and technical checks	15'
13:00 – 13:05	Opening remarks <i>Melanie Carr (Head of Stakeholders and Communication Division, EMA)</i> <i>César Hernández (Head of Department of Medicines for Human Use, AEMPS)</i>	5'

Electronic Product Information (ePI)

13:05 – 13:20	Background of ePI initiative <i>Juan García Burgos (Head of Public Engagement Department, EMA)</i>	15'
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ePI set-up project

13:20 – 13:40	FHIR and the EU common standard for ePI <i>Gustavo Rodriguez (Technical Solution Architect, EMA)</i>	20'
13:40 – 13:50	Q&A	10'
13:50 – 14:10	ePI proof-of-concept prototype <i>Elizabeth Scanlan (Project Manager ePI set-up project, EMA)</i>	20'
14:10 – 14:20	Q&A	10'
14:20 – 14:40	Next steps for ePI and roadmap development <i>Juan García Burgos (Head of Public Engagement Department, EMA)</i>	20'
14:40 – 14:50	Break	10'

Panel discussion

14:50 – 16:20

Q&A with ePI set-up project steering committee & team

90'

Moderated by Melanie Carr & César Hernández

Juan García Burgos, ePI Steering Committee, Head of Public Engagement, EMA

Aleksandra Dacic-Pilcevic, ePI Steering Committee, Head of Customer Advocacy, EMA

Georg Neuwirthner, ePI Steering Committee, Head of IT, AGES

Alexios Skarlatos, ePI Steering Committee, Head of Labelling, EMA

Ana López de la Rica, ePI-HMA contact point, AEMPS

Achilleas Voutsas, ePI Solution Architect, EMA

Gustavo Rodriguez, ePI Solution Architect, EMA

Kerstin Healy, ePI IT Project Manager, EMA

Joaquim Berenguer Jornet, ePI Data Scientist, EMA

Elizabeth Scanlan, ePI Project Manager, EMA

Kim Sherwood, ePI NCA Subject Matter Expert, MPA

16:20 – 16:30

Concluding remarks

Melanie Carr & César Hernández

5'