

# Harmonised ePI for EU medicines

PCWP/HCPWP joint meeting

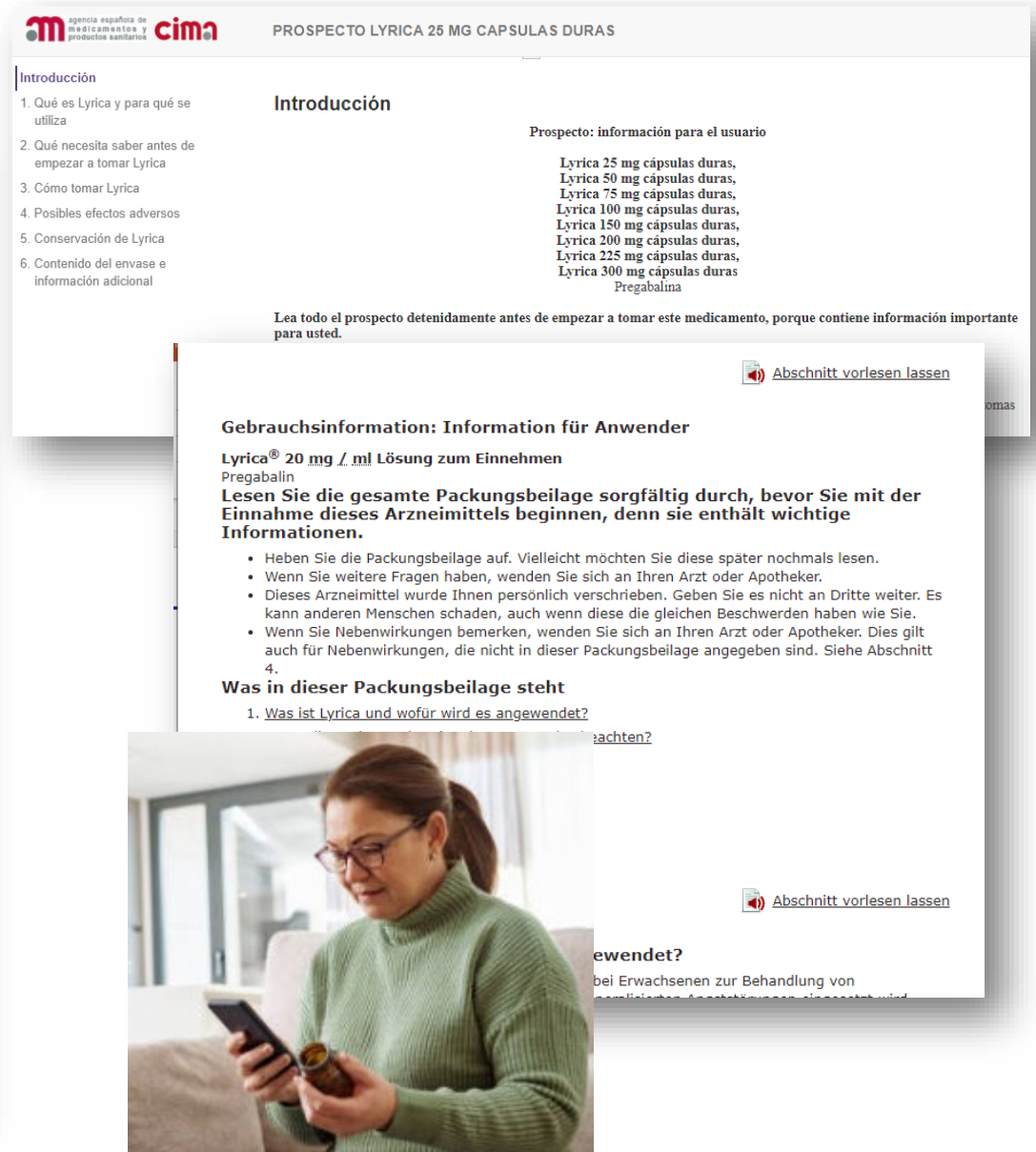
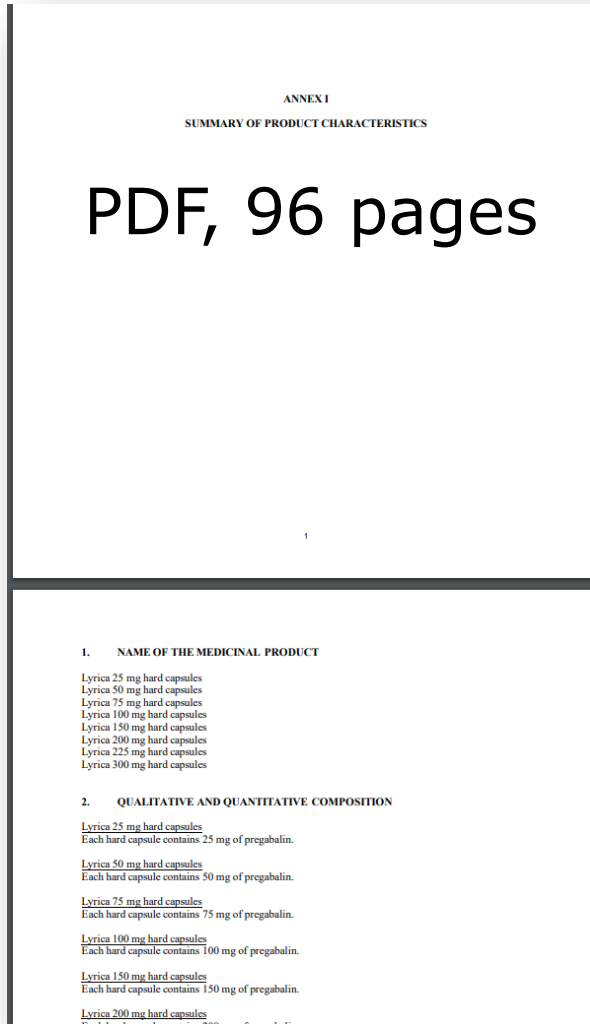
01 April 2025

Presented by Elizabeth Scanlan, ePI Product Owner



# ePI definition

**ePI** is authorised, statutory product information for human medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



# Benefits for patients, healthcare professionals, regulators & companies

- Patient apps
- Digital & Video content
- Accessibility features
- Update alerts
- Targeted searches
- Rapid updates
- Link to national language ePI
- Timely access to up-to-date information in patient's language at point of need
- Support mitigation of medicine shortages
- Optimise signal validation
- Administrative efficiencies



# EMA-HMA-EC: progress of ePI initiative

## Key principles

**2020:** ePI is authorised summary of product characteristics, package leaflet and labelling created using the EU ePI Common Standard. ePI optimises dissemination via the web, e-platforms and print.

**Benefits** of up-to-date timely information



## EU ePI Common Standard

**2021: Harmonisation** using EU ePI Common Standard based on FHIR: a set of XML (and/or JSON) health data resources, plus a REST API for accessing them



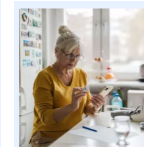
## ePI at PLM Portal

**Creation and management** by companies & regulators, storage in FHIR repository



## Pilot

**2023-2024:** Creation of ePI in real procedures by EMA, AEMPS, DKMA, MEB and MPA



Successful pilot paves the way for implementation of ePI

16 December 2024

Report outlines recommendations and next steps

News Human Product information



# ePI at the Product Lifecycle Management portal

The screenshot displays the Product Lifecycle Management Portal interface. At the top, there is a navigation bar with the EMA logo and the text 'Product Lifecycle Management Portal'. Below this, a secondary navigation bar lists various services: 'Electronic application forms', 'Electronic product information', 'Products Management Service', 'SPOR', 'IAM', 'IRIS', and 'Forum'. A light blue banner below the navigation bar contains a message from the eAF team regarding the use of web-based eAFs for all EU products and procedures starting from 11th February 2025. The main content area is divided into three columns. The first column, titled 'Electronic application forms (eAF)', describes it as a secure online portal for managing eAFs and includes buttons for 'Create new eAF', 'eAF list', and 'eAF guidance'. The second column, titled 'Electronic product information (ePI)', describes it as a streamlined management tool for product information and includes buttons for 'Create new ePI', 'ePI list', 'Published ePIs', and 'ePI guidance'. The third column, titled 'Product Management Service (PMS)', describes it as a user interface for product data management and includes buttons for 'Owned Products' and 'PMS guidance'. At the bottom, a 'Quick links' section provides shortcuts to news and release notes for eAF, ePI, and PMS.

From the same portal, applicants can manage ePI, electronic application forms and product data.

ePI features:

- ePI authoring & management
- Rich-text editing
- ePI export to FHIR/Word
- Repository & API

# ePI pilot objectives

-  **Enable EMA & national regulators using ePI in live procedures to assess tooling and business processes**
-  **Collect feedback from companies creating ePI & medicine information providers using the API**
-  **Support ePI team in determining outstanding functional requirements & inform roadmap to implementation**

# ePI pilot outcomes



All 23 companies and 5 regulators **successfully created and published ePI** in real regulatory procedures with no blockers



**KPIs** on ePI creation, management and portal usability met



**Recommendations made** in categories:  
Guidance, Business Processes and PLM Portal



**Plan to go live for EMA CAPs first,**  
then early adopter NCAs



# Pre-implementation work



**Actions from pilot** recommendations, including

- ❖ Guidance to be created
- ❖ Business processes to be elaborated
- ❖ PLM portal features to be developed



**User Acceptance Testing**

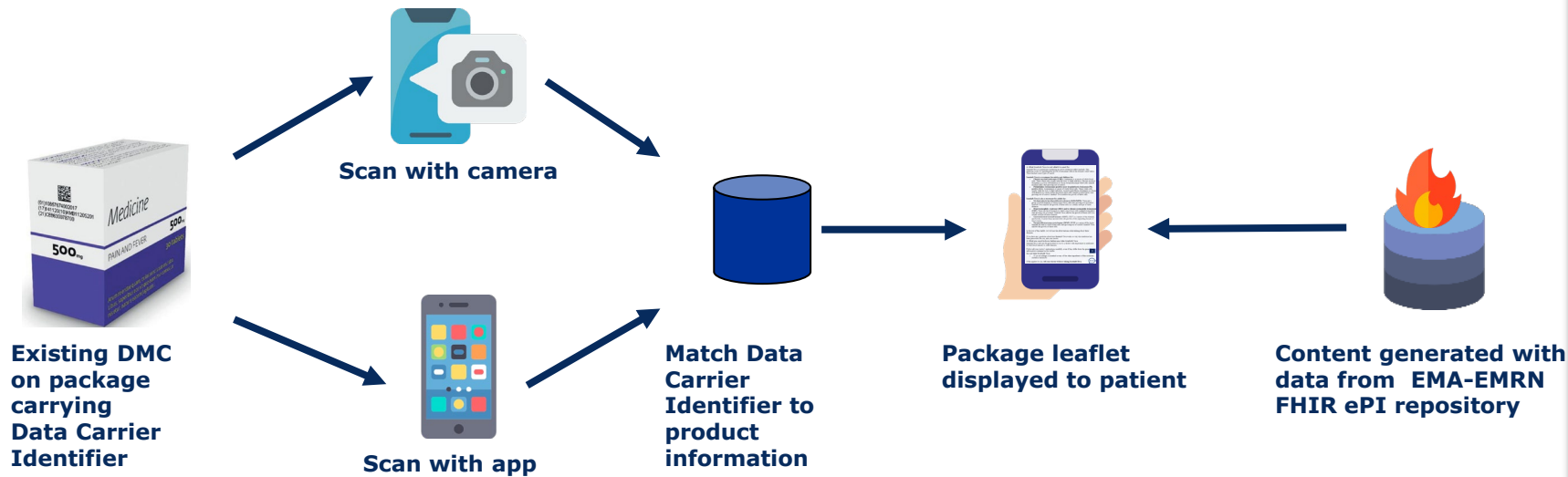


ePI access from medicine package: public consultation on **Reflection paper** (Q2 2025)



**Road map for phased implementation** – working towards centrally authorised products (CAP) go live first, assess national competent authorities (NCA) readiness

# How will MAH provide ePI to patients?



  
 EUROPEAN MEDICINES AGENCY  
 SCIENCE MEDICINES HEALTH

1 31 March 2025  
 2 EMA/95076/2025  
 3 European Medicines Agency

4 Reflection paper on linking to electronic product information (ePI) from EU medicine packages  
 5  
 6 Draft

Start of public consultation	31 March 2025
End of consultation (deadline for comments)	30 June 2025

7  
 Comments should be provided using this [EUSurvey form](#). For any technical issues with the form, please contact the [EUSurvey Support](#).

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Keywords	Electronic product information, ePI, summary of product characteristics, package leaflet, DataMatrix, data carrier identifier, patients, healthcare professionals
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- ❑ Data matrix code (already on the box and used for anti-falsification) preferred to adding additional QR code
- ❑ Availability of EU wide solution is desirable in cross-industry collaboration



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# Thank you

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