EMA
EUROPEAN MEDICINES AGENCY

Harmonised ePI for EU medicines

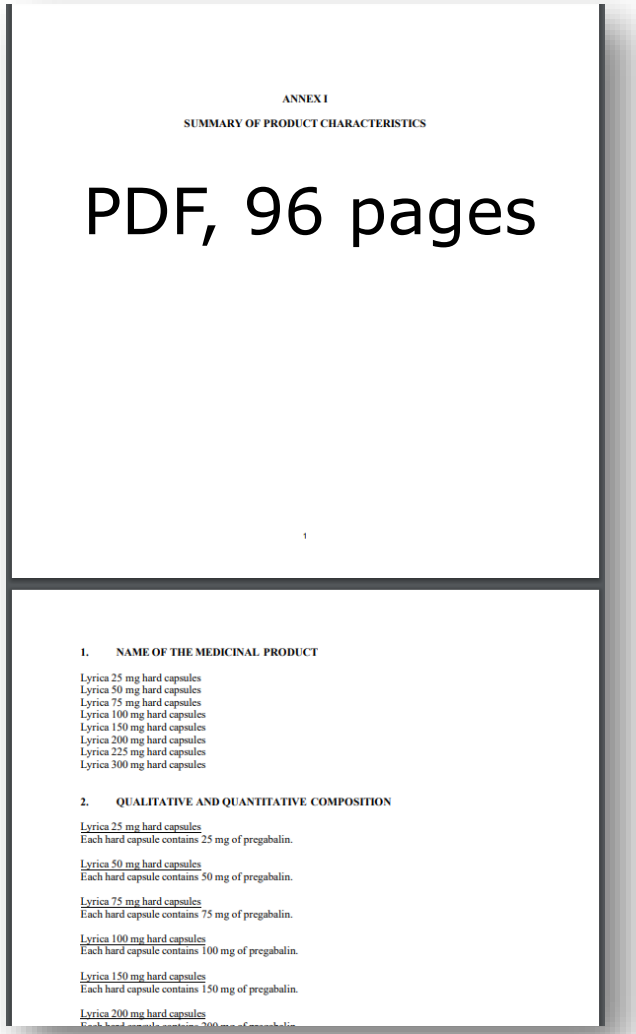
PCWP/HCPWP joint meeting

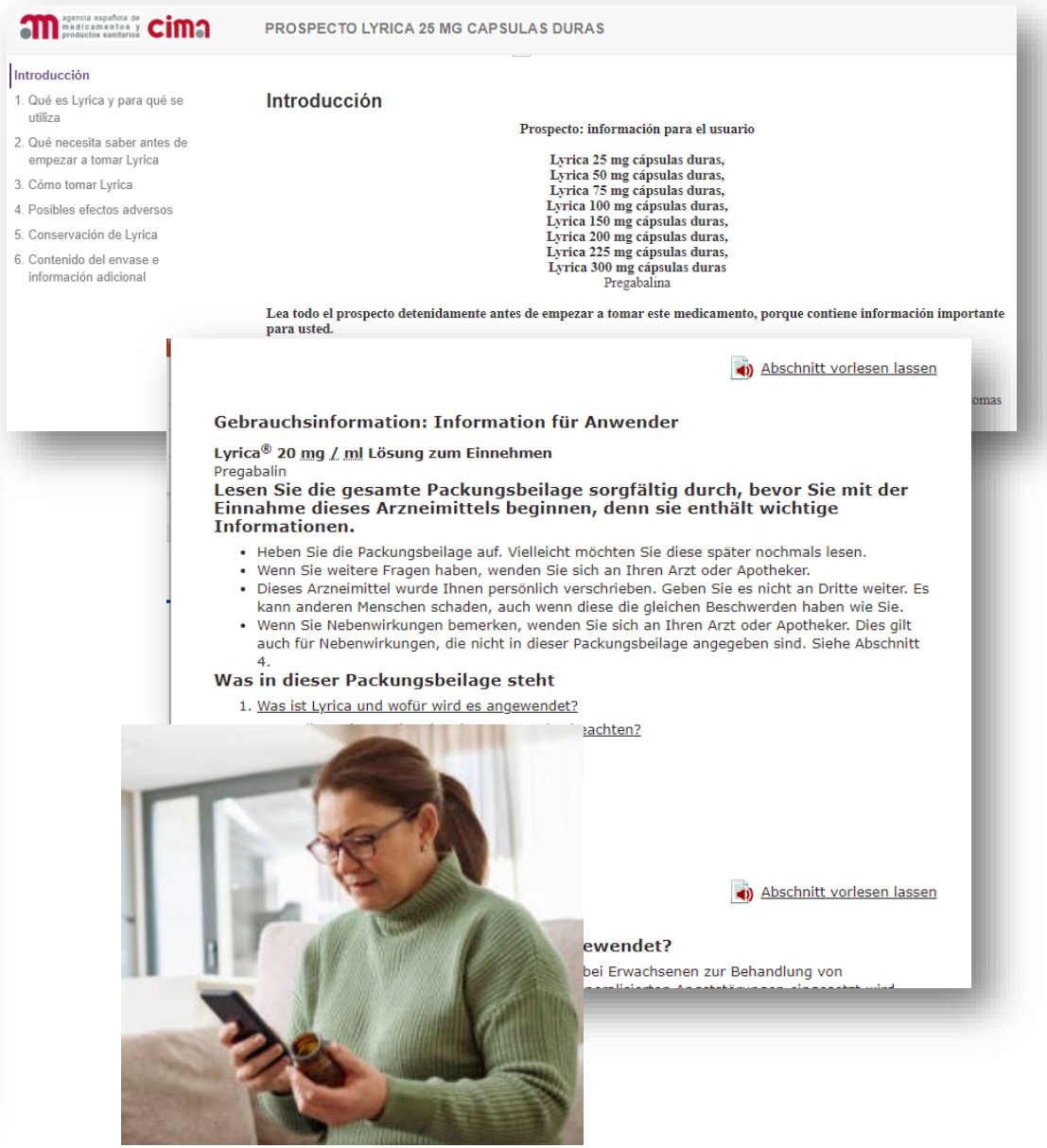
01 April 2025

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

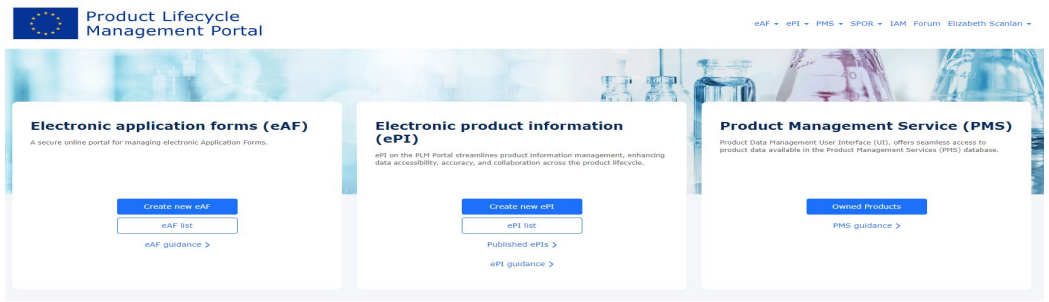
EU ePI Common Standard

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

FHIR

ePI at PLM Portal

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

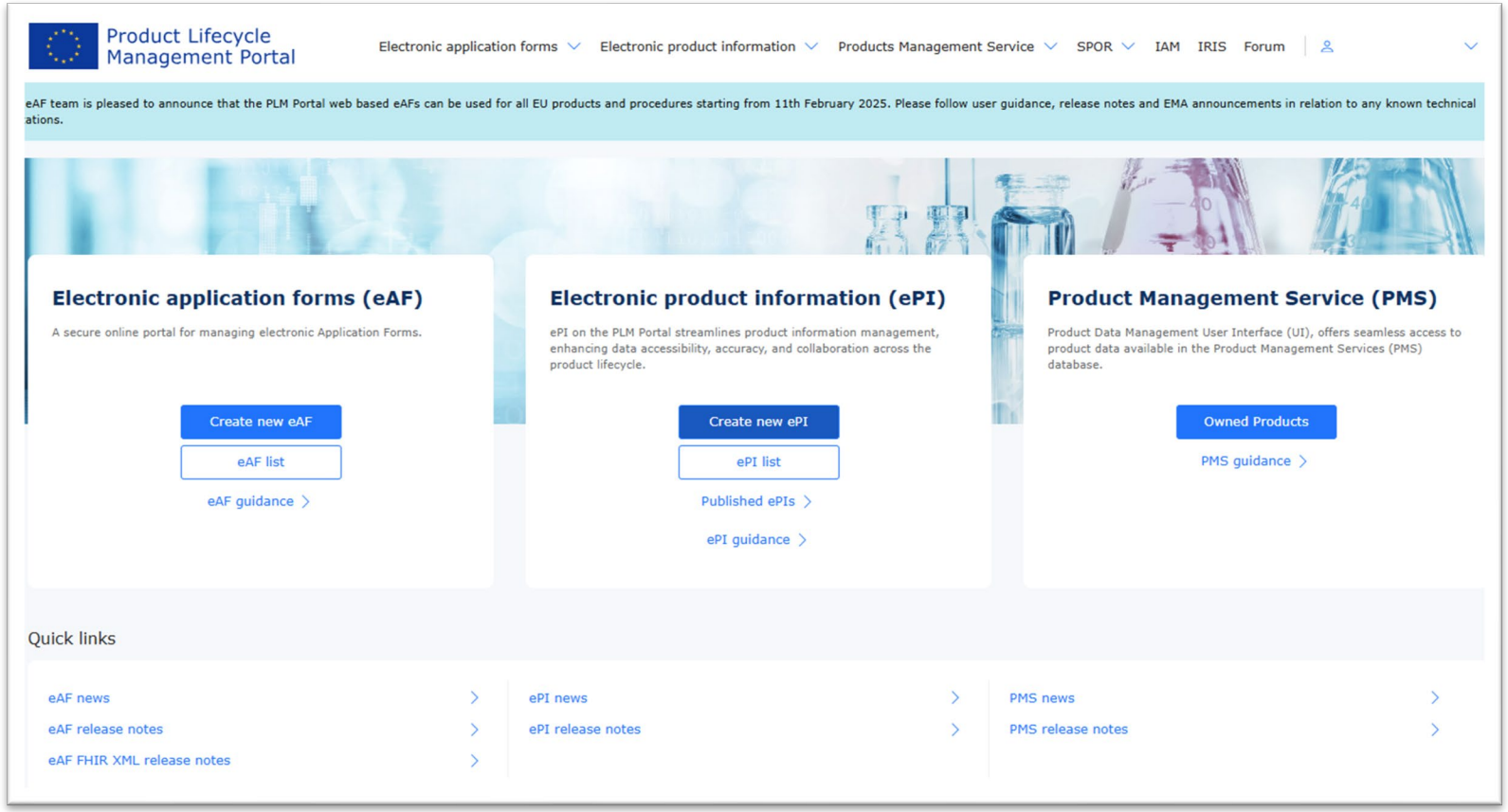


Pilot

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

Developed with funding by the European Union

ePI at the Product Lifecycle Management portal



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

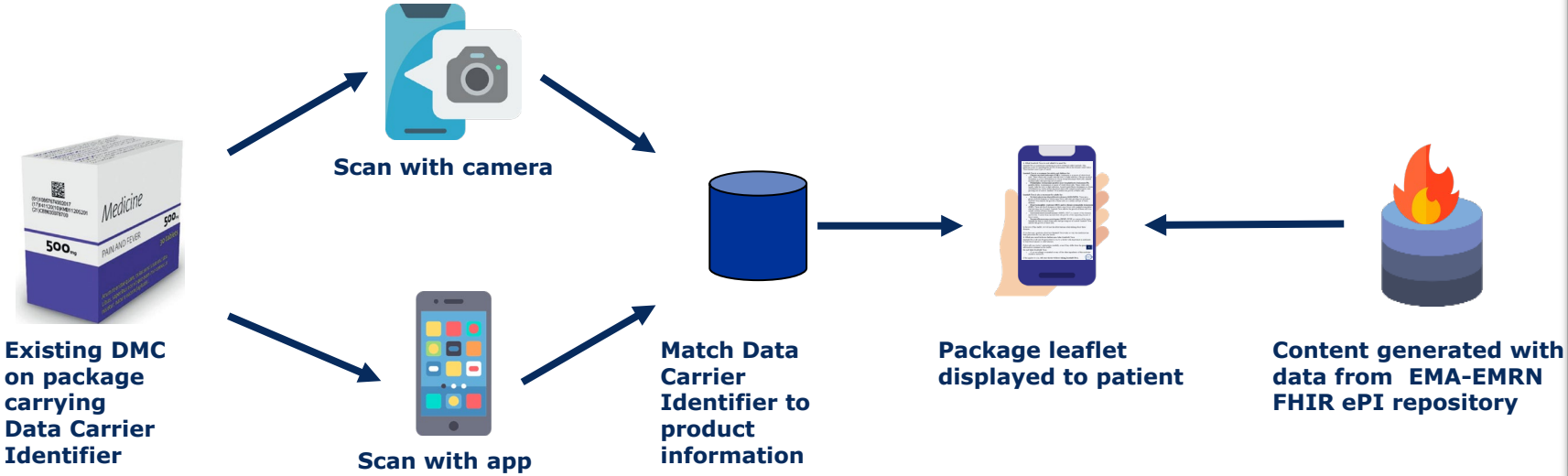
- Guidance to be created
- Business processes to be elaborated
- PLM portal features to be developed

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?



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

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

- ❑ 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

ePI@ema.europa.eu

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