EMA
EUROPEAN MEDICINES AGENCY

Update on ePI

12th Industry Standing group (ISG) meeting

Presented by Elizabeth Scanlan on 28 March 2025

ePI product owner

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

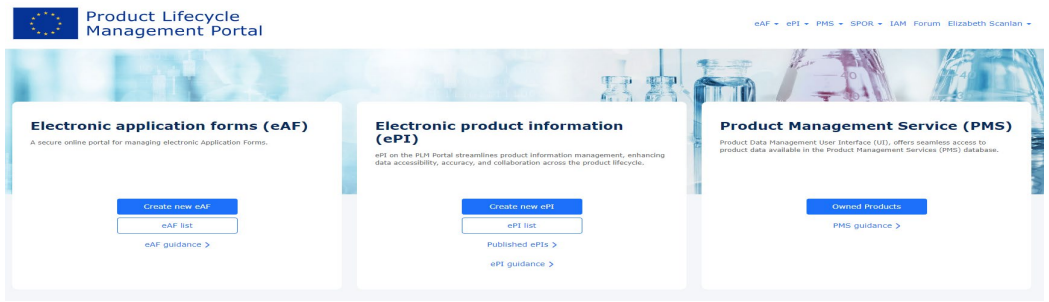
EU ePI Common Standard

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 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 to be implemented by ePI team and NCA SMEs, including

- Guidance to be created
- Business processes to be elaborated
- Development at PLM portal

User Acceptance Testing with Industry stakeholders

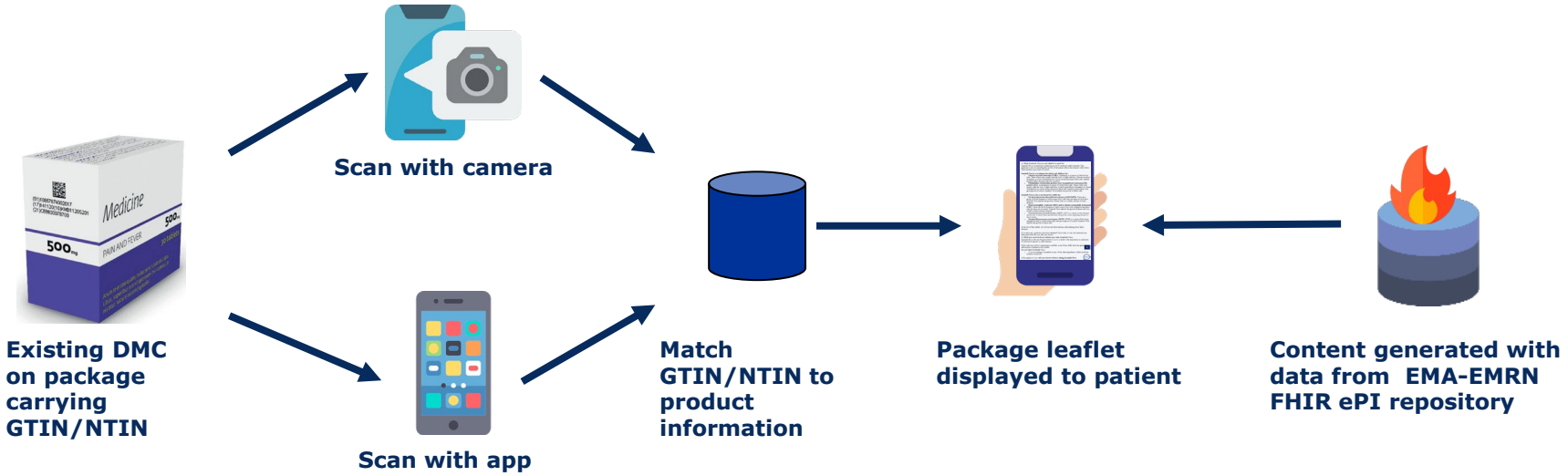
ePI access from medicine package: public consultation on **Reflection paper** (Q2 2025)

Road map for **phased implementation** – working towards CAP go live first, assess NCA readiness

Phased implementation ahead of **new pharmaceutical legislation**

Industry is also expected to start considering how to manage ePI technical requirements and how to make ePIs easily accessible to patients.

Digital format easily accessible to all patients



Reflection Paper in preparation to guide towards harmonisation >Public consultation planned in Q2

- ❑ Data matrix code (already on the box and used for FMD) preferred to adding additional QR code
- ❑ Availability of EU wide app is desirable in cross-industry collaboration

Strategic decisions & preparedness for industry

Company level

- How will your company create ePI?
- Is your company preparing to incorporate ePI into business processes?

Cross-industry level

- How will EU consumers access ePI?
- How can industry work together on optimal experience for EU patients?
- Will industry be ready to provide ‘easily accessible’ ePI in time for NPL?

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Thank you

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