ePI Pilots readout, learnings and next steps

13th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines, 22 November 2024

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ePI ecosystem

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ePI definition

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: ePI Key principles

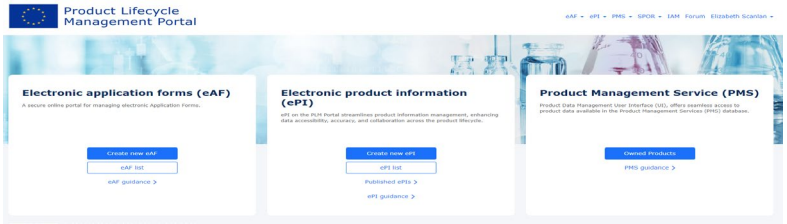
Standard

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

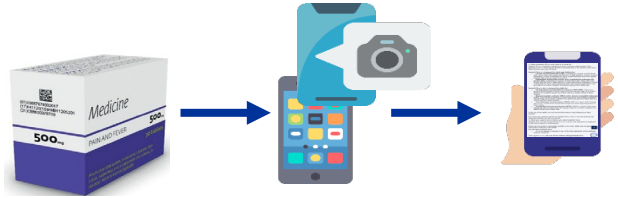
PLM Portal

Creation and management by companies & regulators at PLM portal



Reflection

Access by patients via GTIN/NTIN in DMC on medicine package



Pilot outcomes

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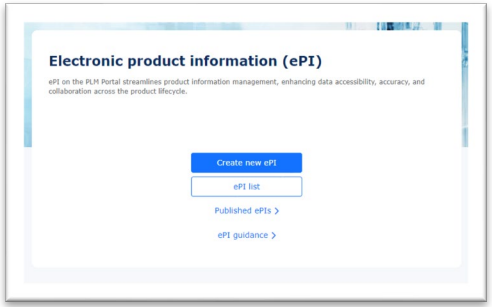
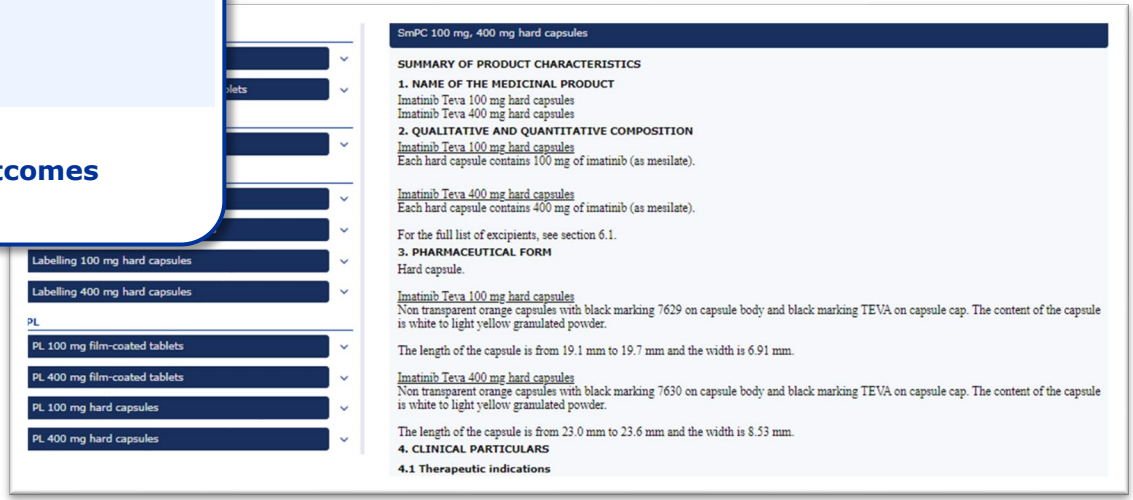
23 Total Number of **ePIs published** in the pilot

5 **CAP ePIs published**

18 **NAP/MRP/DCP ePIs published**

1 **Report in preparation on pilot outcomes**





Developed with funding by the European Union

Pilot report

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Key performance indicators targets for ePI creation time, creation and publication, portal usability, guidance, processes, editor

Learnings and recommendations for guidance, business process and PLM portal functionality

Next steps prioritisation of essential development, phased implementation starting with CAPs

ePI data will enable patient-friendly access

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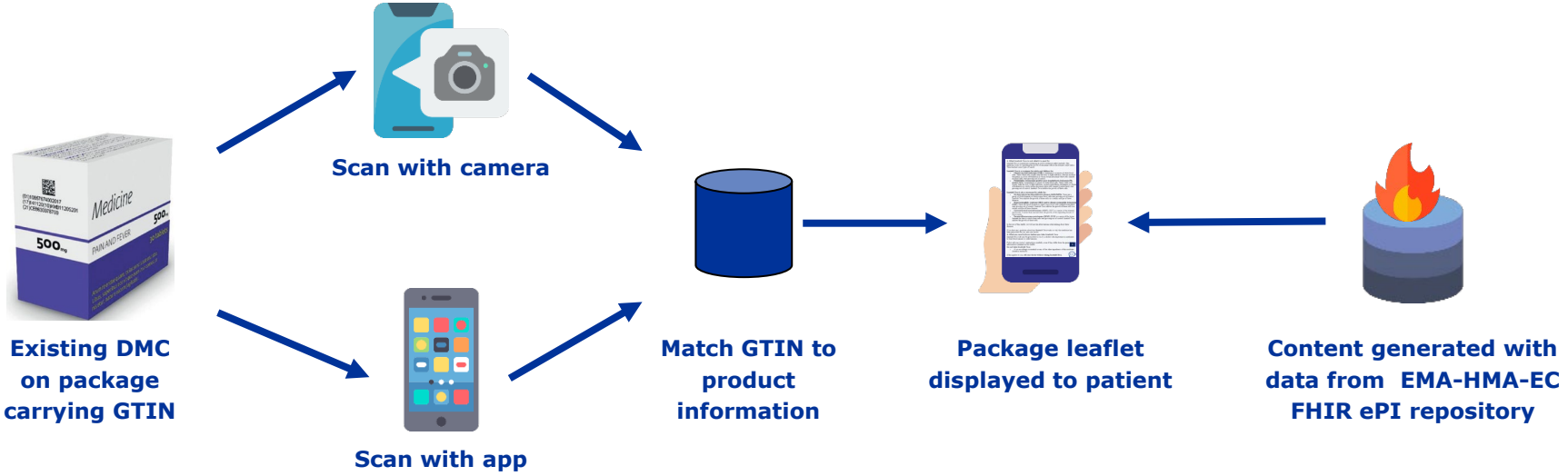
- Solution/app for EU-wide access to ePI for all EU medicines
- Patients should not need multiple apps to access their medicines information
- Existing DMC on package should be leveraged for positive user experience

Role of EMA-HMA-EC ePI initiative:

- ❖ Providing functionality for ePI annotated with associated GTINs/data carrier
- ❖ providing access to previous ePI versions (archived ePIs)



Thank you for your attention

Further information

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