

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 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



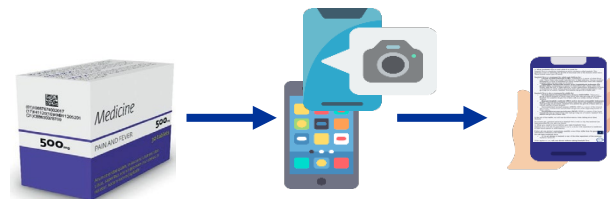
PLM Portal

Creation and management by companies & regulators at PLM portal



Reflection

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





23

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

5

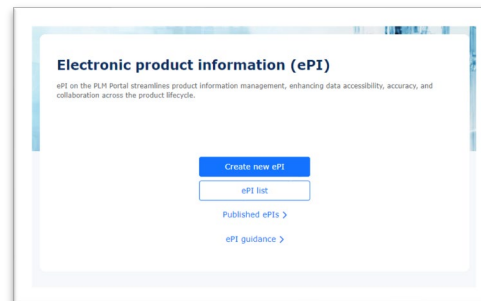
CAP ePIs published

18

NAP/MRP/DCP ePIs published

1

Report in preparation on pilot outcomes



SmPC 100 mg, 400 mg hard capsules	
SUMMARY OF PRODUCT CHARACTERISTICS	
1. NAME OF THE MEDICINAL PRODUCT	
Imatinib Teva 100 mg hard capsules	
Imatinib Teva 400 mg hard capsules	
2. QUALITATIVE AND QUANTITATIVE COMPOSITION	
<u>Imatinib Teva 100 mg hard capsules</u>	
Each hard capsule contains 100 mg of imatinib (as mesilate).	
<u>Imatinib Teva 400 mg hard capsules</u>	
Each hard capsule contains 400 mg of imatinib (as mesilate).	
For the full list of excipients, see section 6.1.	
3. PHARMACEUTICAL FORM	
Hard capsule.	
<u>Imatinib Teva 100 mg hard capsules</u>	
Non transparent orange capsules with black marking 7629 on capsule body and black marking TEVA on capsule cap. The content of the capsule is white to light yellow granulated powder.	
The length of the capsule is from 19.1 mm to 19.7 mm and the width is 6.91 mm.	
<u>Imatinib Teva 400 mg hard capsules</u>	
Non transparent orange capsules with black marking 7630 on capsule body and black marking TEVA on capsule cap. The content of the capsule is white to light yellow granulated powder.	
The length of the capsule is from 23.0 mm to 23.6 mm and the width is 8.53 mm.	
4. CLINICAL PARTICULARS	
4.1 Therapeutic indications	



Developed with funding by the
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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

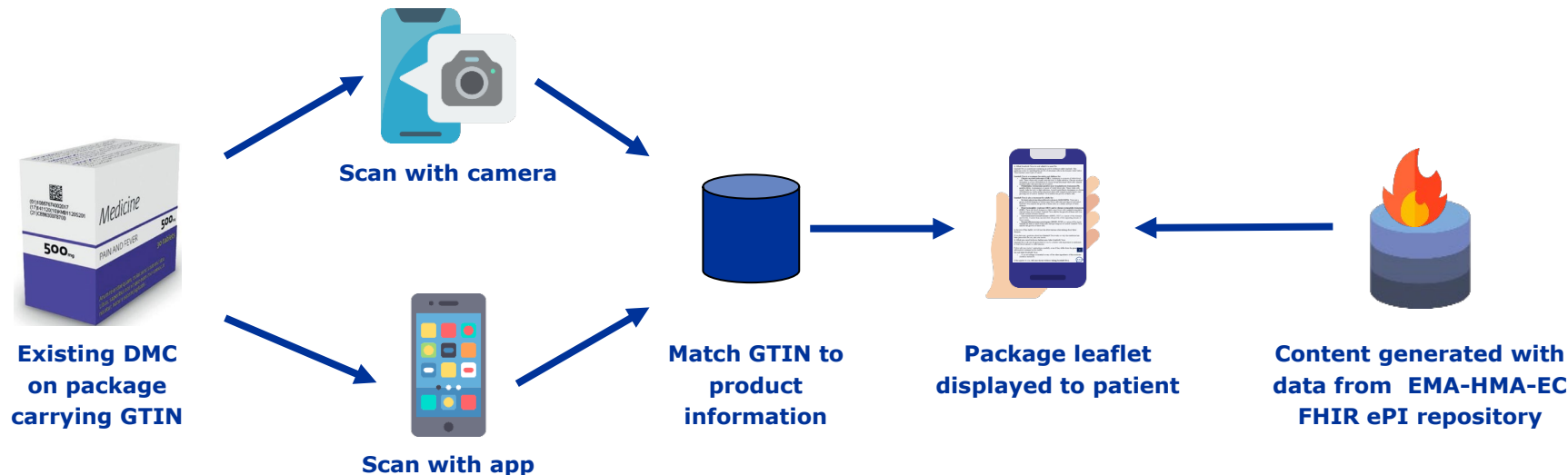


Next steps prioritisation of essential development, phased implementation starting with CAPs

- 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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