Gravitate-Health:
putting ePI to work in the patient journey to drive better use of medicines

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ADVANCING HEALTH PRIORITIES

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EUROPEAN MEDICINES AGENCY

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Electronic Product Information (ePI) towards harmonised implementation in the European Union

#S0802-H: Gravitate-Health: Putting ePI (Electronic Product Information) to Work in the Patient Journey to Drive Better Use of Medicines

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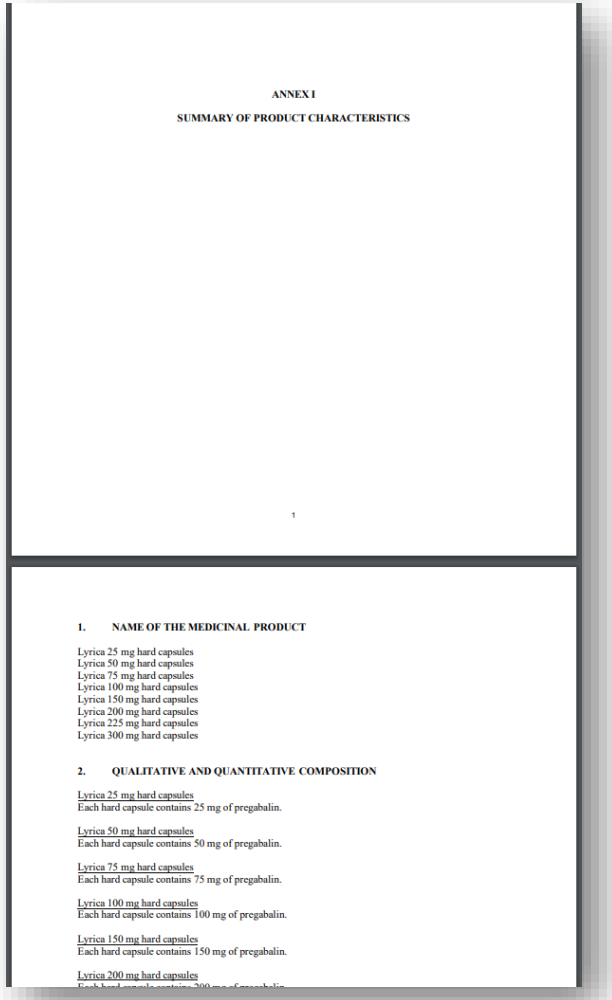
Disclaimer

The presenter does not have any conflict of interests.

Towards electronic solutions for product information



ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1

1. NAME OF THE MEDICINAL PRODUCT

Lyrica 25 mg hard capsules
Lyrica 50 mg hard capsules
Lyrica 75 mg hard capsules
Lyrica 100 mg hard capsules
Lyrica 150 mg hard capsules
Lyrica 200 mg hard capsules
Lyrica 225 mg hard capsules
Lyrica 300 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyrica 25 mg hard capsules
Each hard capsule contains 25 mg of pregabalin.

Lyrica 50 mg hard capsules
Each hard capsule contains 50 mg of pregabalin.

Lyrica 75 mg hard capsules
Each hard capsule contains 75 mg of pregabalin.

Lyrica 100 mg hard capsules
Each hard capsule contains 100 mg of pregabalin.

Lyrica 150 mg hard capsules
Each hard capsule contains 150 mg of pregabalin.

Lyrica 200 mg hard capsules

agencia española de medicamentos y productos sanitarios cima

PROSPECTO LYRICA 25 MG CAPSULAS DURAS

Introducción

1. Qué es Lyrica y para qué se utiliza
2. Qué necesita saber antes de empezar a tomar Lyrica
3. Cómo tomar Lyrica
4. Posibles efectos adversos
5. Conservación de Lyrica
6. Contenido del envase e información adicional

Introducción

Lea todo el prospecto detenidar

Abschnitt vorlesen lassen

Gebrauchsinformation: Information für Anwender

Lyrica® 20 mg / ml Lösung zum Einnehmen
Pregabalin
Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen, denn sie enthält wichtige Informationen.

- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben. Geben Sie es nicht an Dritte weiter. Es kann anderen Menschen schaden, auch wenn diese die gleichen Beschwerden haben wie Sie.
- Wenn Sie Nebenwirkungen bemerken, wenden Sie sich an Ihren Arzt oder Apotheker. Dies gilt auch für Nebenwirkungen, die nicht in dieser Packungsbeilage angegeben sind. Siehe Abschnitt 4.

s in dieser Packungsbeilage steht

1. Was ist Lyrica und wofür wird es angewendet?
2. Was sollten Sie vor der Einnahme von Lyrica beachten?
3. Wie ist Lyrica einzunehmen?
4. Welche Nebenwirkungen sind möglich?
5. Wie ist Lyrica aufzubewahren?
6. Inhalt der Packung und weitere Informationen

Abschnitt vorlesen lassen

Was ist Lyrica und wofür wird es angewendet?

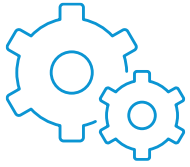
ca gehört zu einer Gruppe von Arzneimitteln, die bei Erwachsenen zur Behandlung von

ePI towards harmonised implementation in the EU

Problem statement

Need to expand public access and dissemination of unbiased, up-to-date, regulator-approved PI for all medicines in the EU

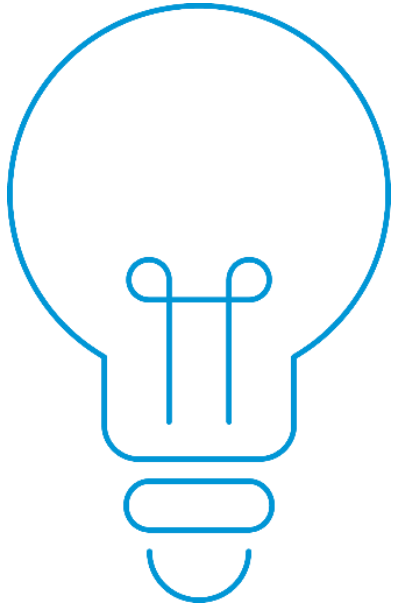
Need to facilitate access to PI data across different regulatory procedures



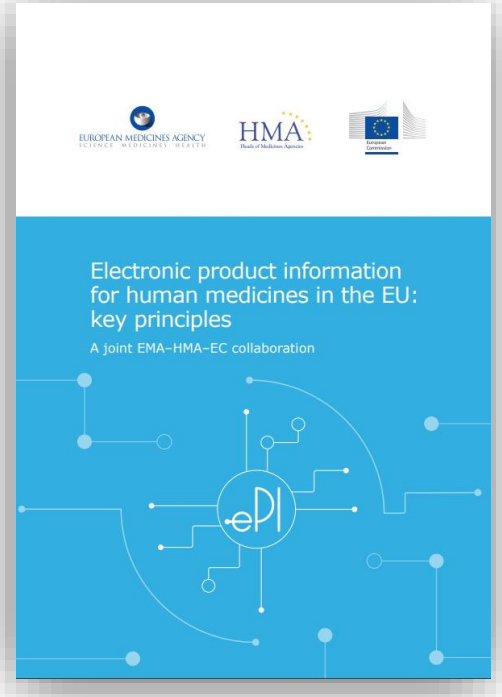
Growing administrative burden of maintaining and updating Word/PDF files

ePI Key Principles

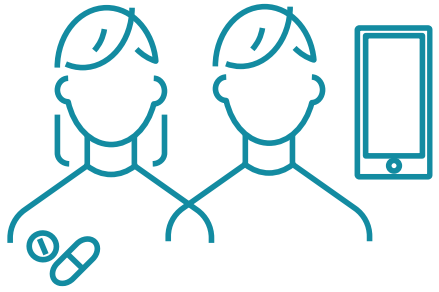
ePI is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using a **common EU electronic standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms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



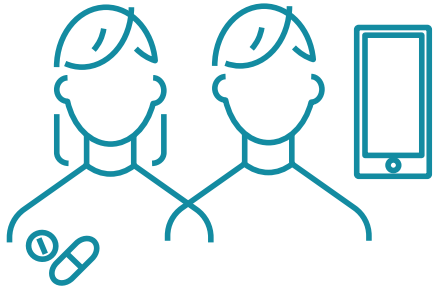
Key principles: adopted by HMA and EMA, published January 2020



ePI facilitates dissemination to patients and healthcare professionals



Access medicine ePI on phone/tablet → Seek reminder of how to take medicine → **Go to 'How to take your medicine' Option to watch video**



Support rapid roll out of COVID-19 vaccines and therapeutics → Use QR code to link to national language PL → **Delivery of vaccine to all EU countries**

ePI achievements in 2021

#1

Created an **EU ePI Common Standard** based on FHIR to support harmonisation across the EU and collaboration across the network

#2

Demonstrated a **proof-of-concept prototype** using the EU ePI Common Standard by generating example FHIR-based documents associated with product data to publish on a website.

#3

Developed a realistic medium-term **vision and road map** towards achieving the benefits for stakeholders, HMA, EC, EMA as outlined in the Key Principles for ePI in the EU

ePI deliverable #1 EU ePI Common Standard

EU ePI common standard based on FHIR for electronic product information (ePI) in the EU to support a harmonised ePI across the EU to support collaboration across the network

Fast

Healthcare

Interoperability

Resources

FHIR is: a set of XML (and/or JSON) health data resources, plus a REST API for accessing them

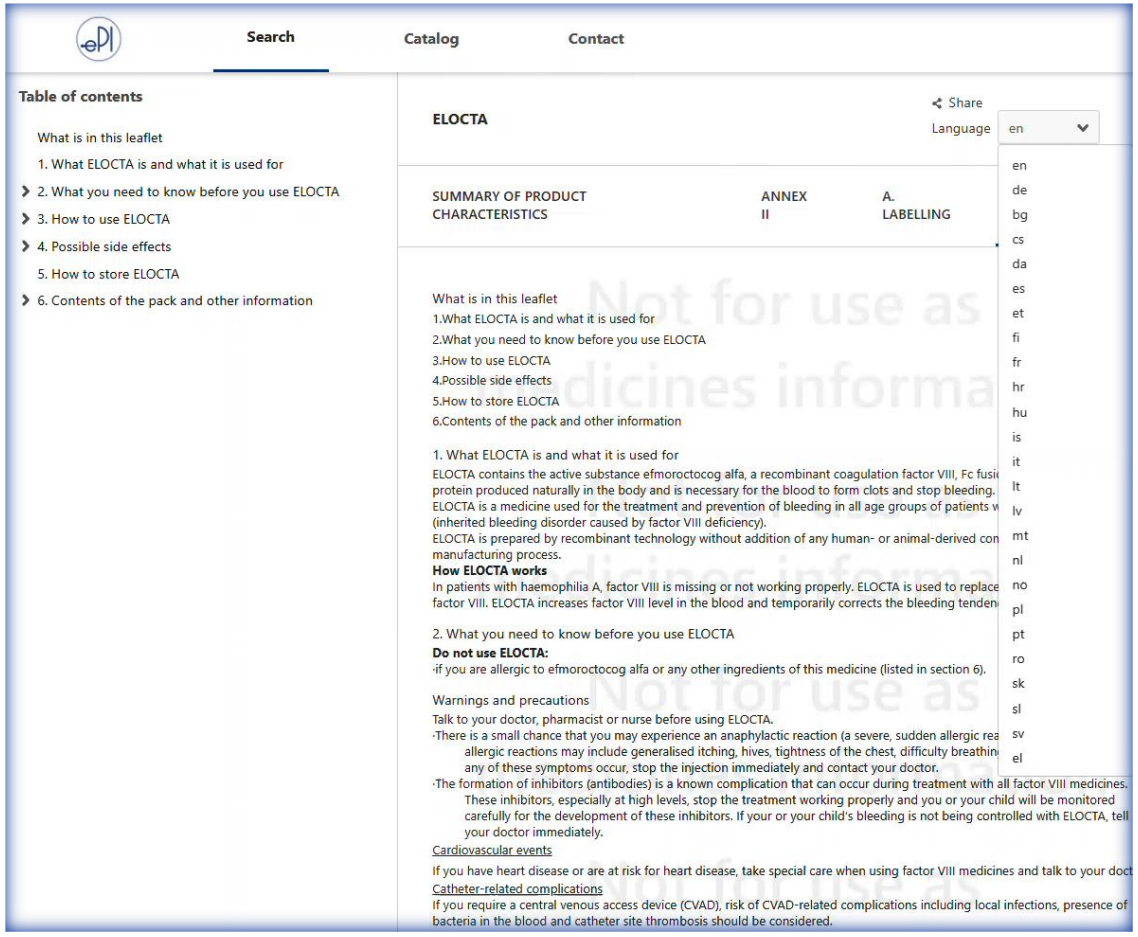
Adopted EU Common Standard for ePI published on GitHub: https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard Consisting of:

1. ePI **API Specification** (PDF) and the associated ePI API service list (Excel);
2. A **FHIR XML template** based on the Quality Review of Documents (QRD) template for human medicines;
3. An **instance** of an ePI sample message provided in XML and HTML, along with a sample XSL transformation.

ePI deliverable #2 Proof-of-concept

Demonstrated at 5 July Information Workshop

(https://youtu.be/s0_md3zQpJE around 53 min)



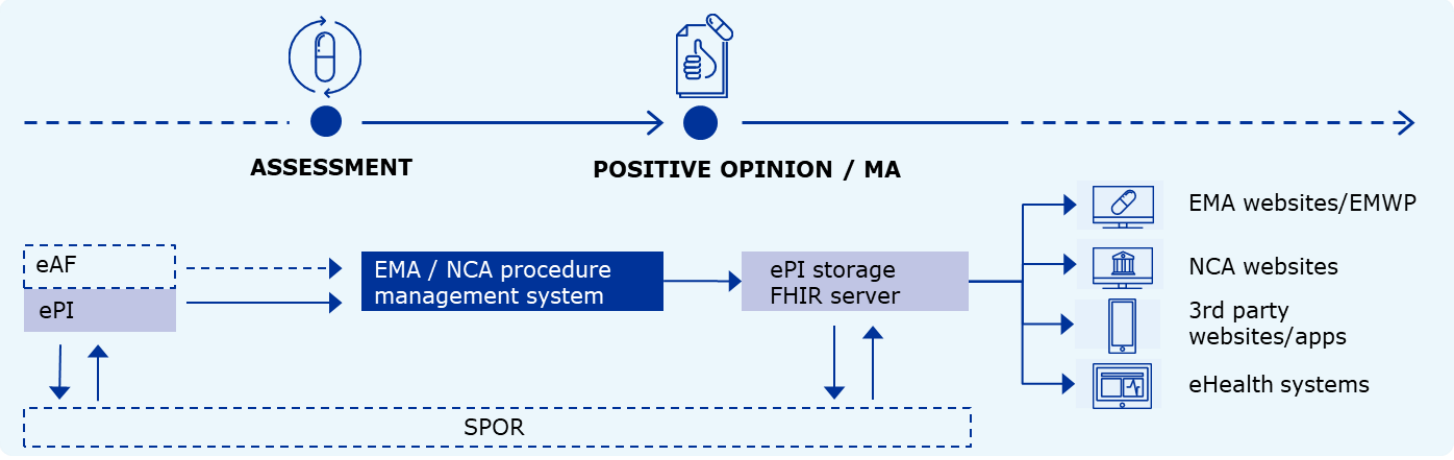
- ePI based on the draft EU common standard is:
  - Multilingual
  - Accessible
  - User-friendly
  - Interoperable with SPOR master data providing benefits of structured data

ePI deliverable #3 Roadmap

2021	2022	2023-2024	Future
• EU ePI Common Standard developed; • Public consultation; • EU ePI Common Standard adopted.	• Creation tool for ePI based on adopted EU ePI Common Standard developed; • Guidance material created for new products and legacy data.	• Pilot begins; • Results of pilot feed back to tooling and guidance.	• CAP implementation; • Phased implementation NAPs; • EU ePI Common Standard evolves; • Controlled up-versioning.

Minimum Viable Product

- The MVP enables an early version of ePI with limited features that can be used by early adopters. The MVP is a ready-to-use, first release of a product to be used in the business process, and not a prototype.
- For CAPs, MVP will be piloted; for NAPs, some NCAs may also pilot use of ePI in procedure management system.
- The MVP enables creation of ePI at point of application and update following positive opinion.



ePI towards harmonised implementation in the EU

MVP tooling to be developed

ePI authoring portal

enables ePI creation, update, submission and download in various formats (HTML, XML, Word), utilising synergies with DADI

User: Companies

Functionality for the authoring portal to enter images/ tables/ formulae/ styling

supports creation and editing of ePI with all styling aspects needed for PI documents

User: Companies

Repository and API

ePI to be stored in FHIR server and made available to websites and machines via the ePI API

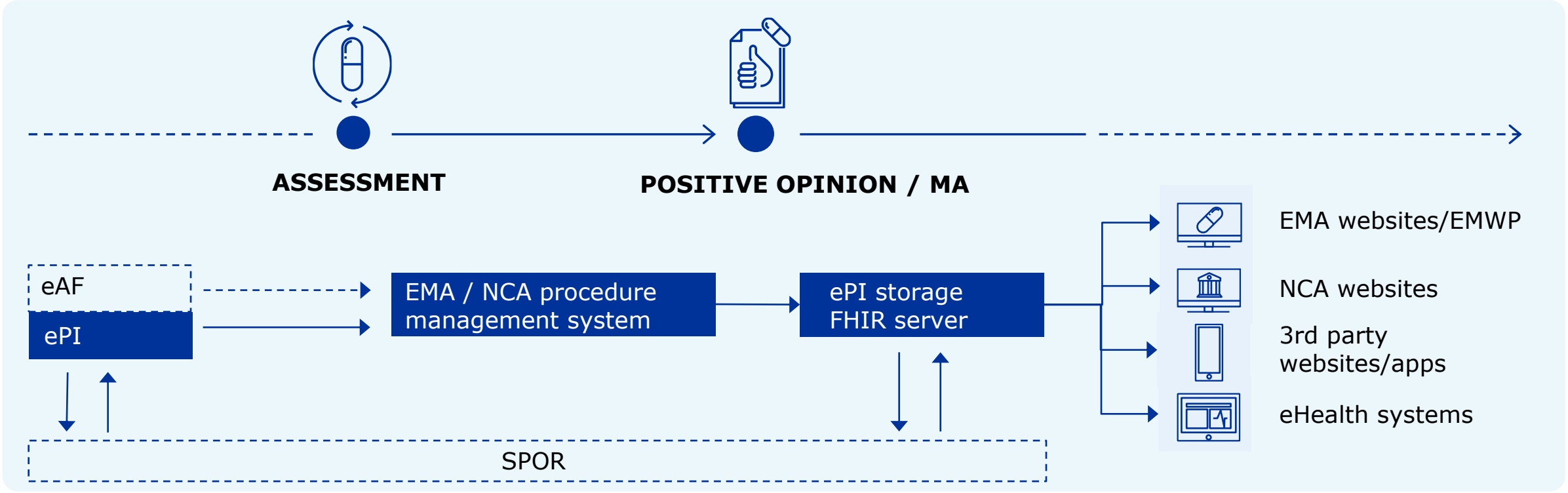
Users:

Companies

Regulators

Future vision for ePI in regulatory procedures

ePI will be seamlessly integrated with all EMA/NCA systems supporting medicines assessment.



Thank you for your attention

I am available at the EMA booth (RH3) at the virtual exhibition to answer questions on 30 March at 11:00

Further information

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