EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-HMA-EC ePI initiative: piloting and next steps

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Disclaimer

The views expressed in this presentation are the personal views of the presenter and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

PI Digitalisation in the European Regulatory Medicines Network

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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 prosp
para usted.

- Conserve este
- Si tiene algun
- Este medicam
que usted, ya

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.

Was in dieser Packungsbeilage steht

1. Was ist Lyrica und wofür wird es angewendet?
2. Was sollten Sie vor der Einnahme von Lyrica beachten?

h?

mationen

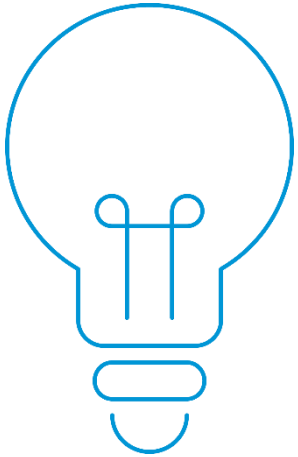
Abschnitt vorlesen lassen

es angewendet?

itteln, die bei Erwachsenen zur Behandlung von

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.



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

Benefits for patients and healthcare professionals

Case 1

List of patient medicines ePI in phone app

Link to authorised video

Receives alert when ePI updated e.g. new safety information

Patient receives information in their preferred format

Case 2

Rapid ePI updates for vaccines and therapeutics in pandemic

Use code to link to national language ePI

Timely access to up-to-date information in patient's language at point of vaccination

Case 3

Pregnancy planning / Lactose intolerance

Targeted ePI search

Treatment decision

Case 4

Print impairment

Large font, read aloud, ask digital assistant

Accessible information

Benefits for regulators, national authorities, companies

Case 1

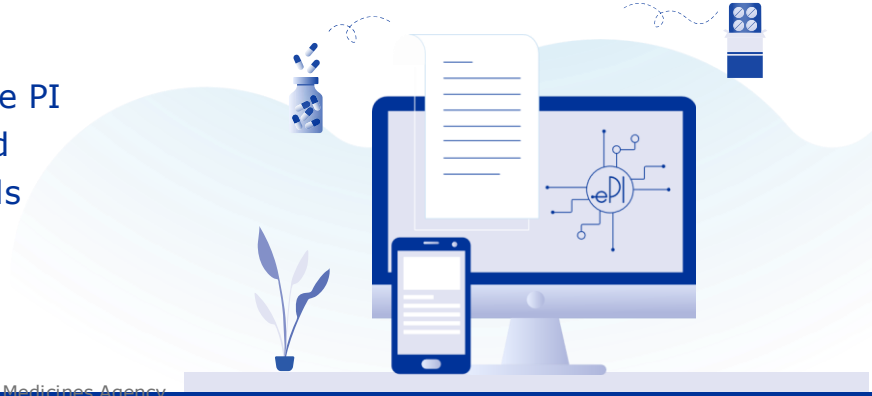
- Medicine shortage anticipated in country A
- Import medicine from country B, link to ePI in language A
- Shortage mitigated

Case 2

- Change that affects multiple PI
- Following variation change is simultaneously implemented in all affected PI annexes
- Harmonised, up-to-date PI available to patient and healthcare professionals

Case 3

- Signal detected
- Facilitate search of existing side effects listed in all relevant PI
- Optimised signal validation



Towards a common standard for electronic product information

Agreement of a common standard will avoid a situation where multiple different standards are developed and used in different parts of the EU, which would generate unnecessary complexity, impede access to information and require multiple interfaces between standards, restricting flow of data.

EU ePI common standard based on FHIR to support a harmonised ePI across the EU 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

Developed with funding by the European Union

ePI creation minimum viable product developed

The MVP is a ready-to-use, first release of a product to be used in regulatory procedures for creation and management of ePI. The MVP enables creation of ePI for application and update following positive opinion.

ePI authoring portal

enables ePI creation, preview, update, upload (in FHIR) and download (in FHIR, Word)

User: Companies

Rich text editing functionality

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

User: Companies

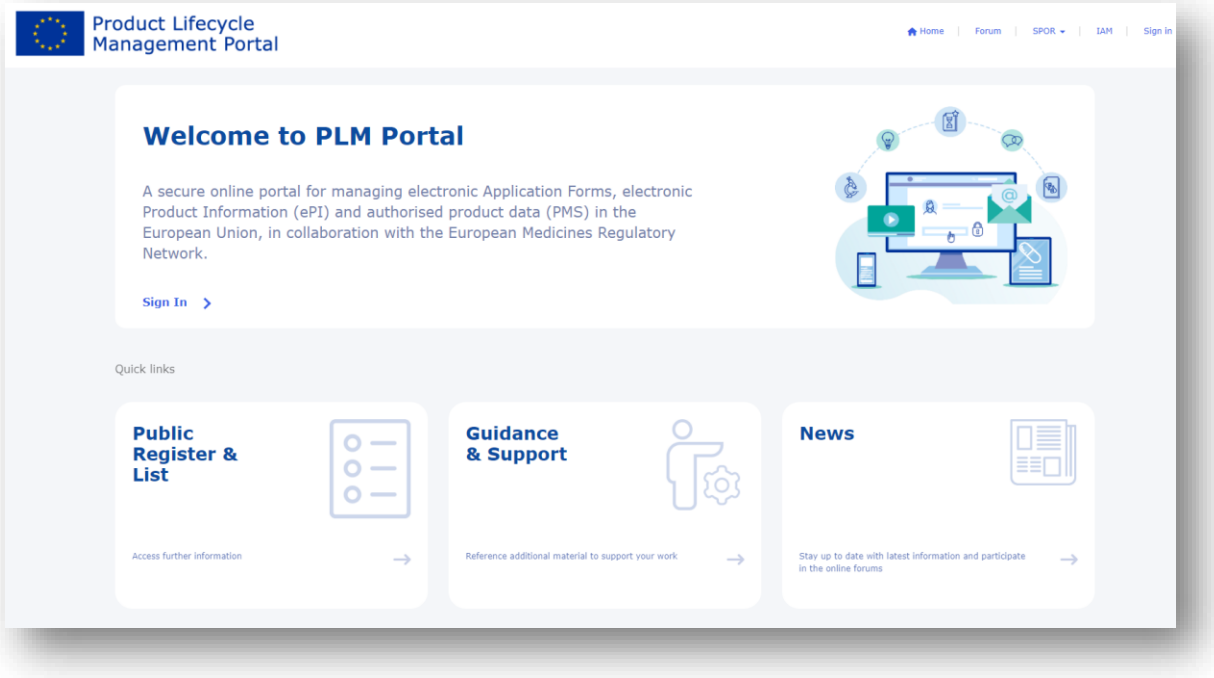
Repository and API

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

Users:
Companies
Regulators
eHealth developers

ePI @ PLM portal

- MVP at https://plm-portal.ema.europa.eu/



ePI pilot

- Pilot of ePI created using MVP has begun
- EMA, MEB, AEMPS, DKMA, MPA
- Centralised (EN only) and national procedures (Article 61(3), Type I A/IB, Type II, Renewal)
- First ePIs published in coming weeks
- ePIs available in publicly accessible PLM webpages and via API

Roadmap

2021	2022	2023-2024	2024-
• EU ePI Common Standard developed & adopted by EMRN	• MVP development • ePI team includes NCA product owner and NCA and pharma SMEs onboarded	• MVP completed • Pilot begins	• Pilot outcomes inform implementation strategy • Feature development

Product Lifecycle Management – Connecting the Value Stream

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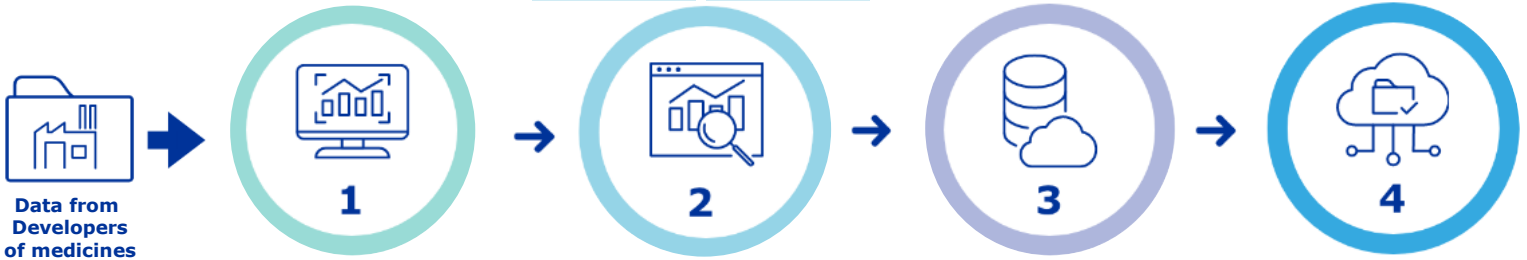
A smoother and more coherent user journey

1. Capture data for regulatory processes		2. Validate, assess and analyse data		3. Store data using agreed standards		4. Share data & information across the lifecycle for customer value	
eAF Web Forms	ePI Authoring Portal	Regulatory Procedure Mgmt (IRIS)	Expert Panels for Medical Devices	PMS (SPOR)	eCTD v4.0	European Medicines Web Portal	UPD
Product Data Enrichment/ Correction UI	UPD	Electronic Submission and Review Tools	Common Repository	ISO IDMP	ePI	APIs / FHIR (SPOR/ePI)	ePI



SPOR Master Data Management & FHIR Data Exchange

Legend

API: Application Programming Interface
eAF: Electronic Application Form
eCTD: Common Technical Document in electronic format
ePI: Electronic Product Information
FHIR: Fast Healthcare Interoperability Resources
ISO IDMP: International Standards Organization Identification of Medicinal Products
PMS: Product Management Service
SPOR: Substance, Product, Organisation and Referential
UPD: Union Product Database

Thank you for your attention

For latest updates, join our system demos

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