



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Piloting creation of electronic product information (ePI) for EU medicines

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PCWP/HCPWP joint meeting

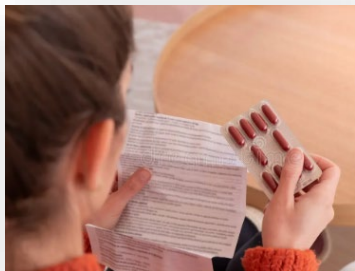
Presented by Elizabeth Scanlan on 28 June 2023  
Stakeholders and Communication Division EMA

An agency of the European Union





# 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.

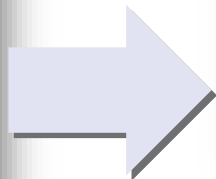
**Lyrica 100 mg hard capsules**  
 Each hard capsule contains 100 mg of pregabalin.

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

**Lyrica 200 mg hard capsules**  
 Each hard capsule contains 200 mg of pregabalin.

**Lyrica 225 mg hard capsules**  
 Each hard capsule contains 225 mg of pregabalin.

**Lyrica 300 mg hard capsules**  
 Each hard capsule contains 300 mg of pregabalin.



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**

[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?

**Lea todo el prosp. para usted.**

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



1 Piloting creation of electronic product information (ePI) for EU r...

# 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

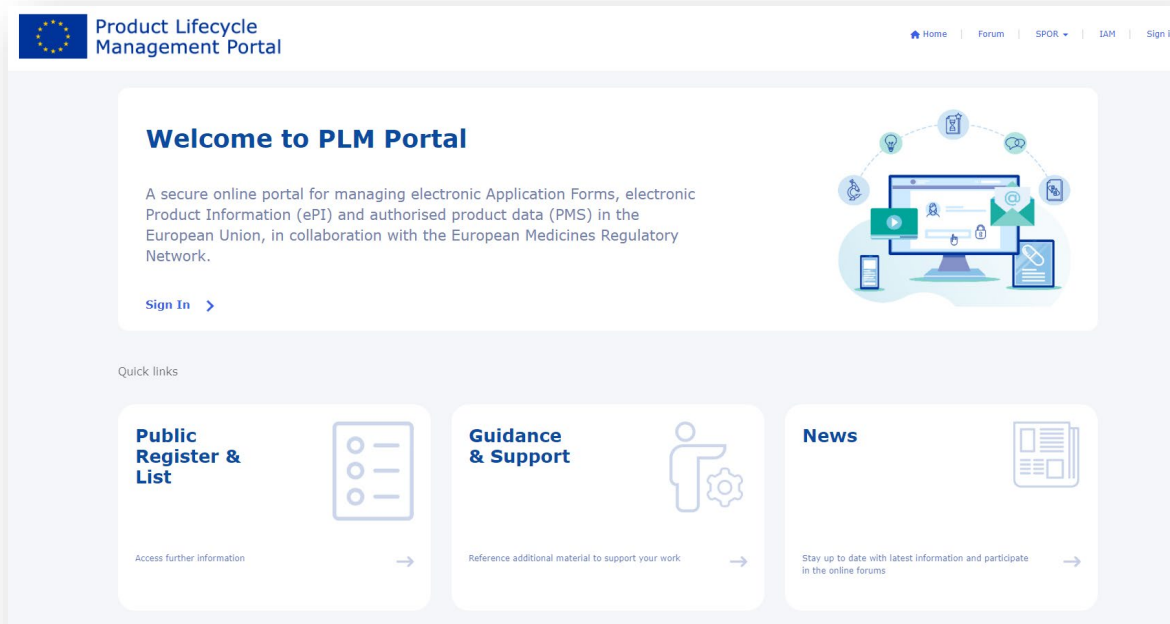


Adopted EU Common Standard for ePI published on GitHub:

<https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>

## ePI initiative

- Pilot of ePI created using EU ePI Common Standard starting in H2
- EMA, MEB, AEMPS, DKMA, MPA
- Companies will create ePI using authoring tool
- Centralised and national procedures
- ePI available in a publicly accessible repository via API
- Inform future implementation



The screenshot shows the homepage of the Product Lifecycle Management Portal. At the top left is the European Union flag and the text 'Product Lifecycle Management Portal'. On the top right are navigation links: Home, Forum, SPOR, IAM, and Sign in. The main content area features a 'Welcome to PLM Portal' heading, followed by a paragraph describing it as a secure online portal for managing electronic Application Forms, ePI, and PMS. Below this is a 'Sign In' link. To the right is an illustration of a computer monitor with various icons around it. Underneath is a 'Quick links' section with three cards: 'Public Register & List' (with a list icon and 'Access further information' link), 'Guidance & Support' (with a person and gear icon and 'Reference additional material to support your work' link), and 'News' (with a document icon and 'Stay up to date with latest information and participate in the online forums' link).





# ePI supporting health literacy

## Find ~~~~~ Understand ~~~~~ Use health-related information

### Case 1

List of patient medicines  
ePI in phone app

Does not remember  
how to take asthma  
medicine

Goes to 'How to take  
your medicine' to  
downloadable video

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

### Case 2

Rapid ePI updates for  
COVID-19 vaccines and  
therapeutics

Use 2D 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 A

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

## Case B

- 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 C

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





# Any questions?

## Further information

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Elizabeth.Scanlan@ema.europa.eu; ePI@ema.europa.eu

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

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