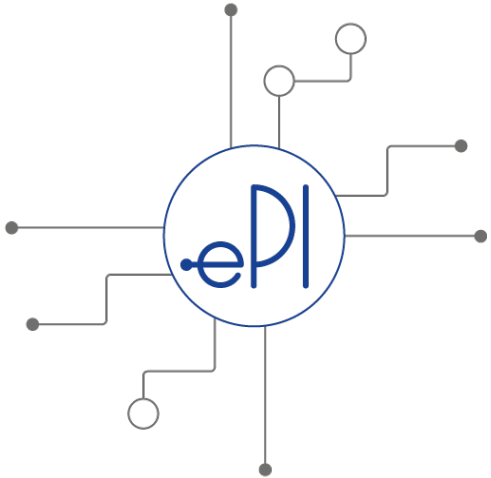
Background of ePI initiative

Information Workshop on electronic Product Information (ePI)



Juan García Burgos
Head of Public and Stakeholder Engagement Department, EMA

EMA action plan on product information based on European Commission's recommendations

- Amendments of Guidelines and QRD templates to enhance readability of PL
- Improving patient input in developing and testing of PLs
- Promotion and exchanges of best practice
- Electronic SmPC/ PL formats
- Potential introduction of key information section in the SmPC and PL

Given initial priority
work started on landscaping and stakeholder engagement

Why ePI?

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

Definitions

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

A **common EU electronic standard** for ePI refers to the **technical features** (including mark-up language, controlled vocabularies and interoperability specifications) agreed by regulators and stakeholders. The common standard will be used to generate ePI.

Landscape

>500,000
Human Medicines

24
Official EU languages, Icelandic and Norwegian

Centrally authorised (through EMA) and **nationally authorised** (through Member State authorities)

National authorities in EU countries provide PI as pdfs or electronically (e.g., Spain), many ongoing initiatives

Companies/pharmaceutical industry organisations provide ePI, some collaborate with national authorities

Patient and healthcare professional initiatives for friendly accessible PI

Need for harmonisation and trustworthy source

Key principles

Principles to guide ePI implementation

Stakeholder workshop to draft key principles

Public consultation →

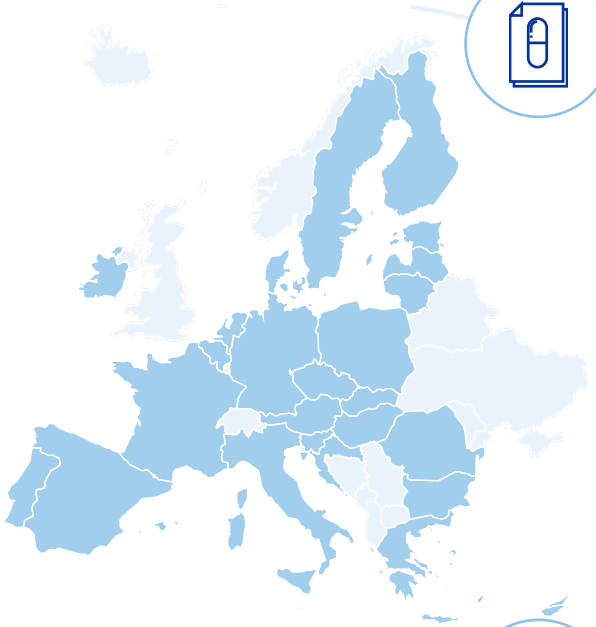
71 submissions

>500 comments

Diverse stakeholders

High interest and support

EU context



- Complementing paper leaflet
- Multilingual
- Open access
- Flexible implementation
- Interoperability with ongoing EU eHealth initiatives

Benefits for patients and healthcare professionals

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 QR 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

Benefits for regulators and national authorities

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

Set-up project: deliverables

Deliverable #1

Create an **EU common standard** based on FHIR for ePI in the EU to support harmonised ePI across the EU and collaboration across the network

Deliverable #2

Provide a **proof-of-concept prototype** using the common standard. The prototype will be used for a design and technical feasibility study to generate some example FHIR-based documents associated with products in SPOR to publish on a website. This is not a business-ready solution

Deliverable #3

Provide a realistic medium-term **vision and road map** to achieve the benefits for stakeholders, HMA, EC, EMA MB, as outlined in the **Key principles for ePI in the EU**

Set-up project: milestones

Thank you for listening

Further information

ePI@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**