

sanofi

ePi
e-product information



Preparing for the World of E-labeling

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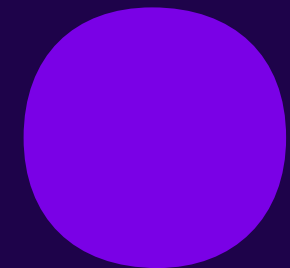
20-Feb-2025

Preparing for the World of E-Labeling (ePI)

- 1 What is ePI?
- 2 Benefits of ePI
- 3 Current Status of ePI in Major Markets
- 4 Moving ePI forward
- 5 Questions



1 What is ePI?

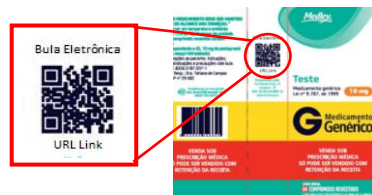


What is ePI?

The ePI is an electronic version of the approved product information:

- *Intended for the healthcare provider or the patient*
- *adapted for handling in electronic format and dissemination via the web, e-platforms and in print*
- *It can be accessed by scanning, a two-dimensional barcode (QR Code or DM Code) on the packaging.*
- *The ePI also allows access to additional information, such as videos, audios, and other instructions that help in the proper use of the medication.*

Add to the label

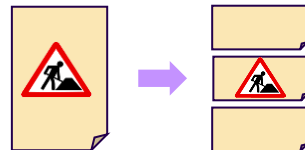


- Statutory information via eLabeling (ePI)
- Non-statutory information (video...)

Video de instrução de aplicação (sistema de segurança Eris)



Structured content



System & process update for modular PU updates



Auto-format and auto-upload product information

Skip Paper Leaflet



- Paper leaflet removal



Why ePI?

Paper leaflets, are difficult to read, potentially out of date and not accessible to all.

ePI is fully responsive and compliant with web content accessibility guidelines.

Global approach - (By product or by Region)

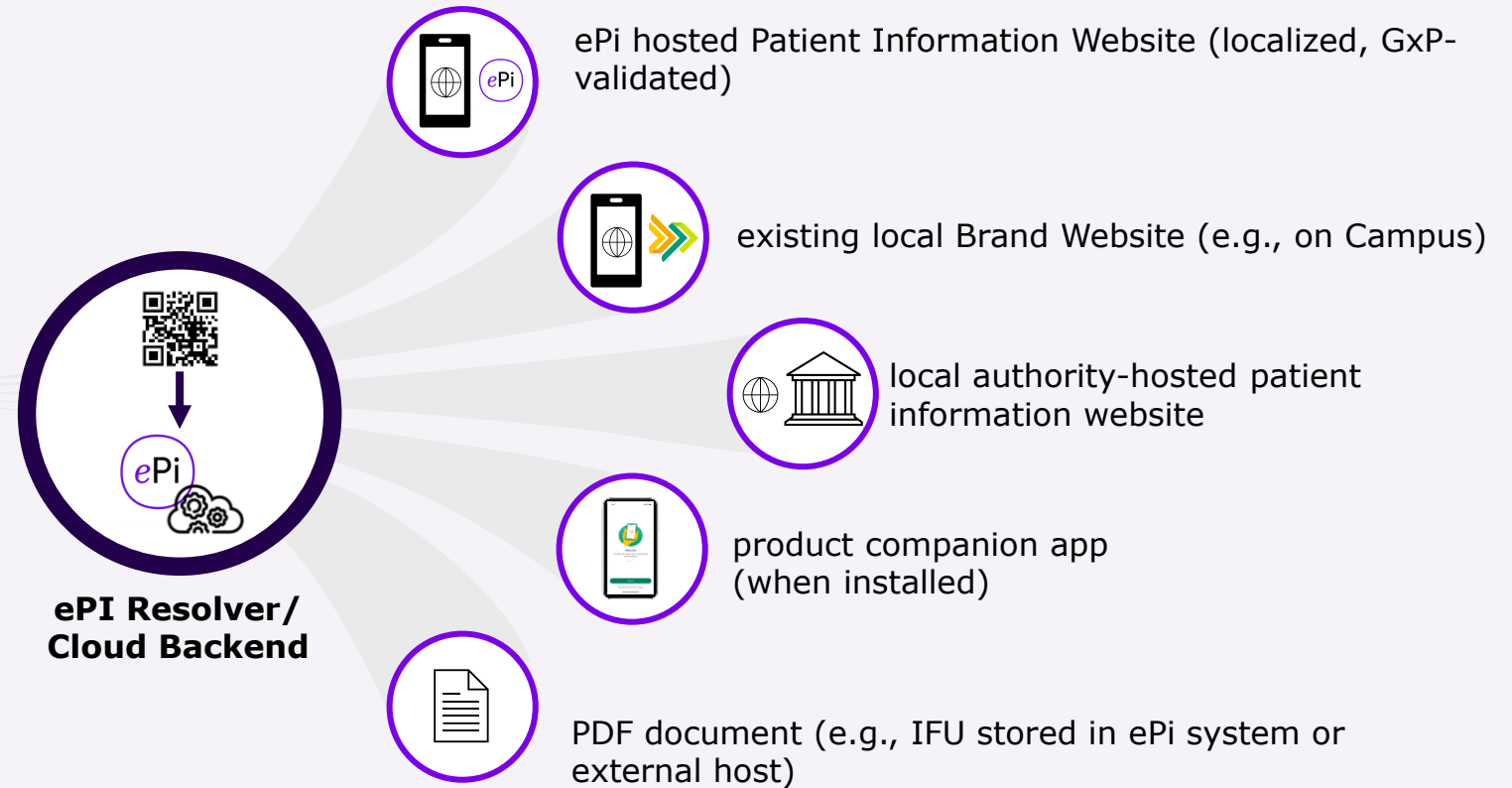
- Provides a connection between Sponsors, manufacturing, Health Authorities, Databases, HCPs and patients
- Need to understand and respect local regulations
- Leverage Learnings between Markets

Leveraging an ePi Digital Platform

... to support large panel of specific action for product/country combinations...



Highly Flexible Core Model



**e-Product Information
existing Website**



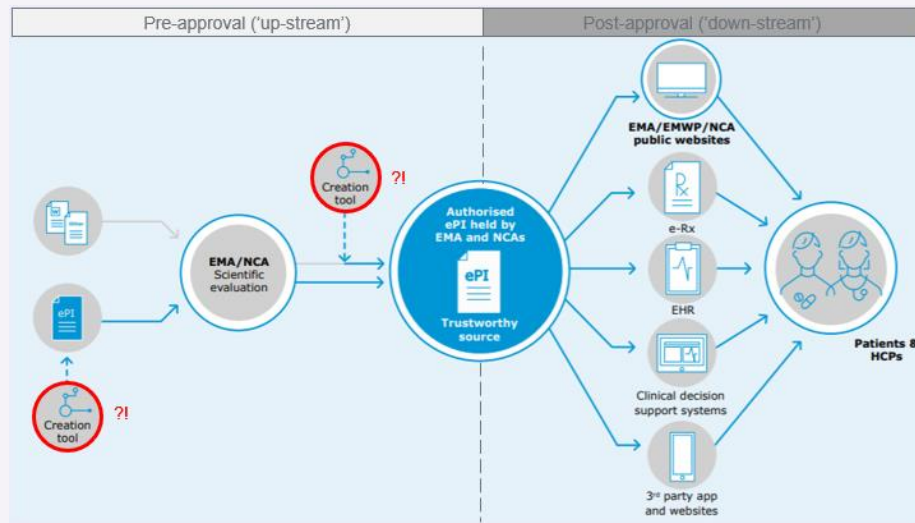
Dissemination of approved product information in a **digital format** via a **common structured format** using global standards



Introduction of ePI in structured format

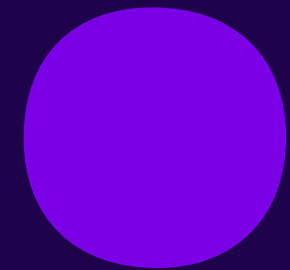
- ❖ **Definition** of ePI in Structured format:
Health Authority approved product information (i.e. USPI, PPI, SmPC, PIL or local leaflet and labeling) in semi-structured format using a common electronic standard
- ❖ **Process:**
Implementation in stepwise approach
(goal: submission of ePI in structured format)

EU Example:



Key principles on ePI published in January 2020 (<https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles>)

2 Benefits of ePI



Key Benefits of ePI



Add to the label – Patient benefits



Improved accessibility

- Text to speech
- Zoom in
- Dynamic Personalized info
- Mutli-lingual



Direct channel to customer

- Better education = higher adherence
- Potential to link to future eSystems



Trusted source of up-to-date product information



Minimize risk related to recalls, alerts



Structured content



Readiness for future regulatory evolution



Faster sharing of new information / compliance



Interoperability between systems & stakeholders



Skip Paper Leaflet



CO2 reduction



Cost reduction Paper cost savings

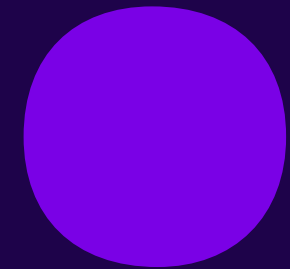


Reducing Lead time to launch new products



Reducing risk of product destruction due to recalls or product information major updates

3 Current Status of ePI in Major Markets



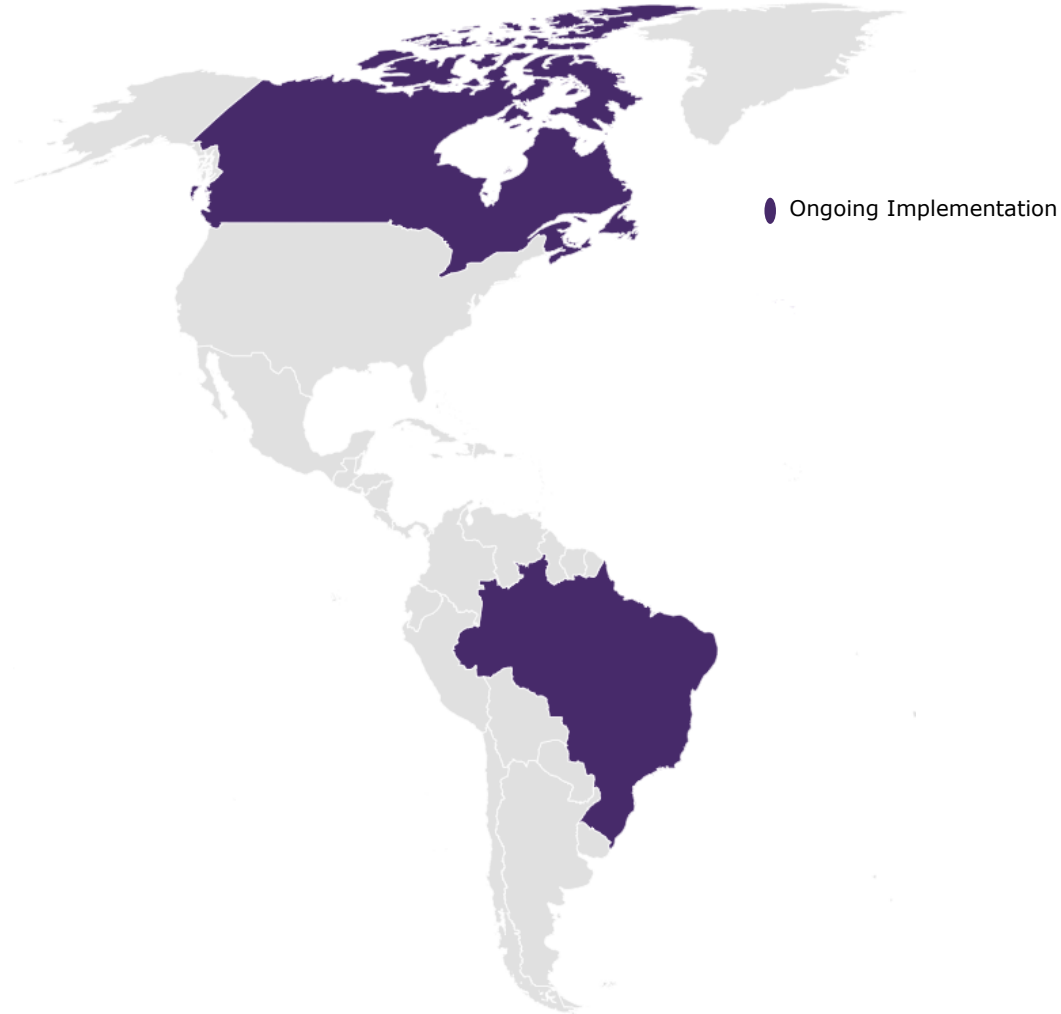
ePI developments in the United States

USA

Characteristics

- FDA requires electronically delivery of product information
- ePI Platform - <https://dailymed.nlm.nih.gov/dailymed>
- Ability to introduce QR codes
- There are hurdles in Congress in moving the ePI with paper leaflet removal initiative forward
- FDA appears to support use of e-labeling with the removal of paper leaflet based on the previously proposed rule*

ePI developments in Americas



Canada

Characteristics

- Printed Paper Leaflet not technically required per regulations but Health Canada still requires it
- All Products
- Ability for Introduction of QR code
- ePI Platform - Third Party

First e-labelling projects focus on products that are sold in bulk/repacked at pharmacy level or drugs administered by HCPs.

Brazil

Characteristics

- Inclusion of QR Code
- Pilot for Removal of Paper Leaflet
- Healthcare Facilities (Hospital Products, Clinics)
- ePI Platform - Third Party

New Legislation was endorsed in 2024 allowing pilots for removal of paper leaflet for all free samples and medicines intended exclusively for use in hospitals, clinics, outpatient clinics and home care services.



Revision of EU Pharma Legislation



EUROPEAN
COMMISSION



Current legal framework:

The paper version of the PIL still needs to be in the package unless exemption is given for a specific product for a specific time.

Review of the Pharmaceutical Legislation as opportunity to get paper package leaflets replaced by electronic versions

- European Commission published its proposals on ePI on 26 April 2023 followed by negotiations with European Parliament and Council/27 Member States

ePI developments in Europe

Ongoing Pilots

Belgium, Luxembourg – since 2018

Iceland – since 2021

Spain, Baltics – since 2022

Netherlands – since 2024

France – since 2024

Characteristics

- Removal of Paper Leaflet
- Hospital Products
- No QR code added

Regulation is shifting as countries decide to experiment paper removal associated to an e-distribution of product information.

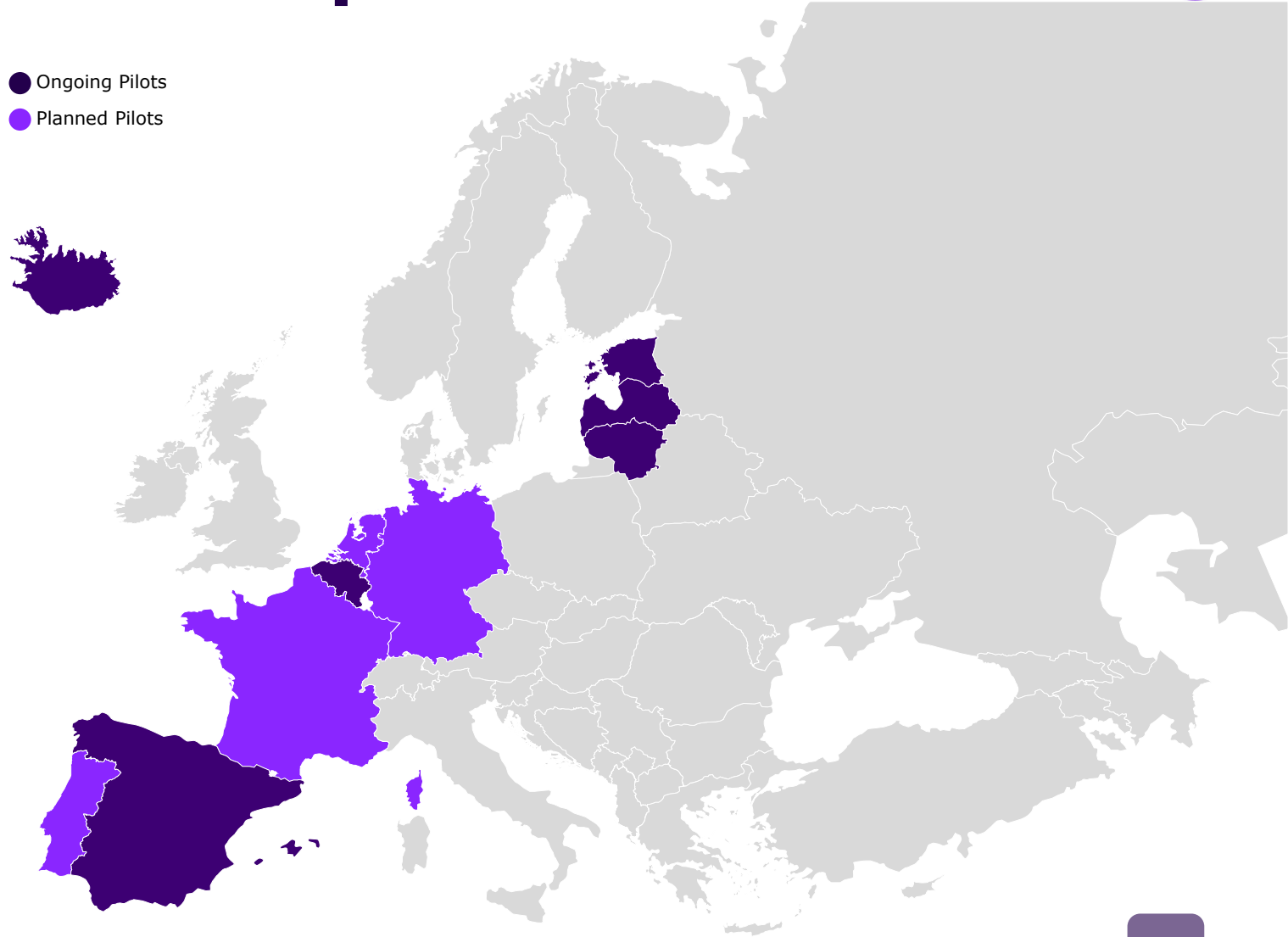
Planned Pilots

Portugal, Germany

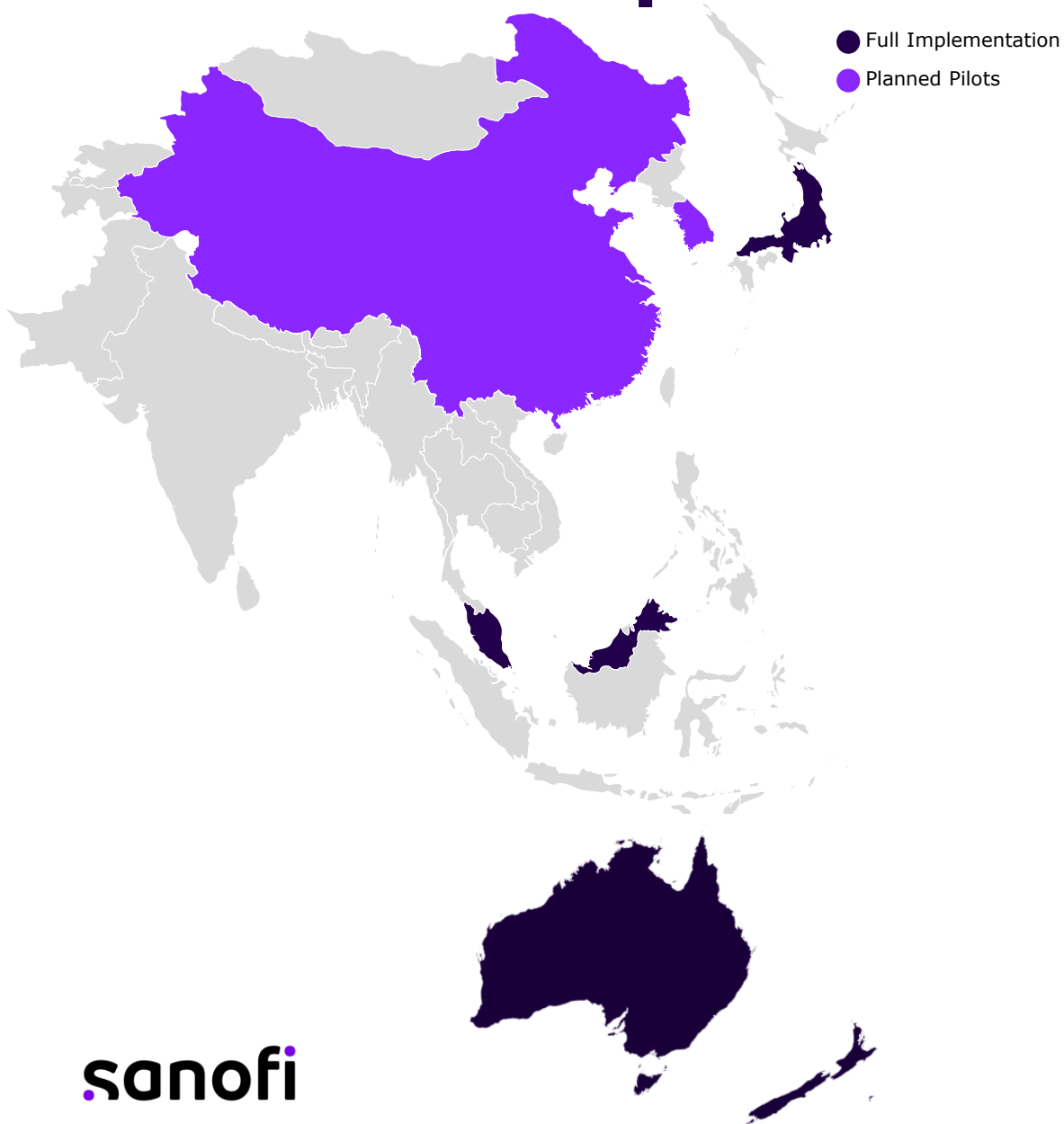
Characteristics

- Removal of Paper Leaflet
- Hospital Products - No QR code added
- Retail Pharmacy (France, as a Phase 2)

- Ongoing Pilots
- Planned Pilots



ePI developments in Asia-Pacific



Fully Implemented

Japan, Australia, New Zealand, Singapore, Malaysia

Characteristics

- No paper leaflet
- All Products
- ePI Platform:
 - Health Authority website – Japan
 - Sanofi website – Singapore
 - Third Party – Australia

Legislation is implemented and allows e-distribution of information as an alternative to printed leaflet.

Planned Pilots

South Korea – to start in 2025

Characteristics

- Removal of Paper Leaflet
- Vaccines, Injectables
- Addition of QR Code
- ePI Platform: Sanofi

China – to start in 2025

Characteristics

- Simplification of Paper Leaflet
- Addition of QR code
- ePI Platform: Third Party

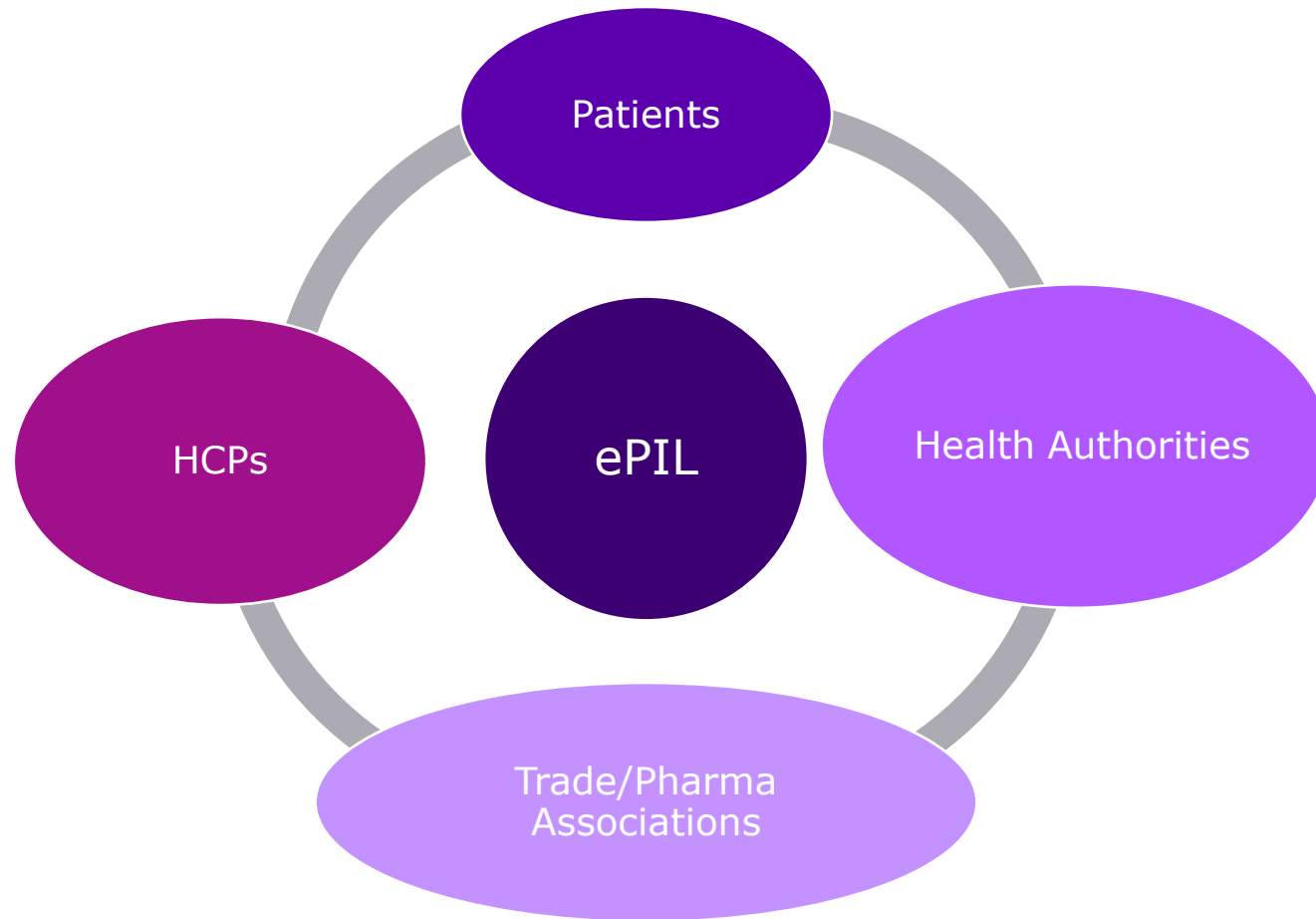


4 Moving ePI Forward



External Stakeholder engagement

Need for strong stakeholder engagement at EU/US level and nationally to drive paperless ePI implementation



External Stakeholder engagement

Patients

Stress benefits:

Most up-to-date user-friendly format providing tailored information

Address asks:

Accessibility to ePIL leaving no one behind

HCPs
(pharmacists/
physicians)

Stress role:

Important role leveraging digitalisation in healthcare system

Address asks:

Providing print-out on request, funding

Authorities/
Trade
Associations

Partnering/collaboration to pave the way for ePI implementation including initiation of ePIL pilots (for hospitals sector and beyond)



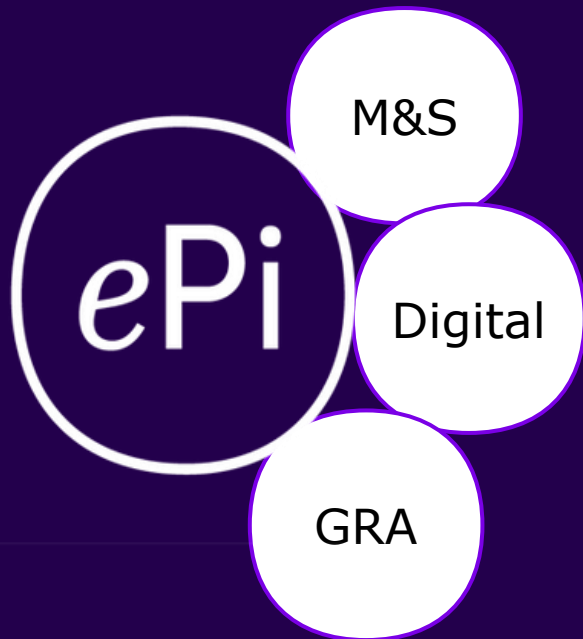
We operate in
90
countries

91,000
There are
Sanofi's
worldwide

We work in
59
manufacturing
sites

We have
20
R&D sites

Internal Stakeholder Engagement



Moving ePI Forward

Foundation Building

Structure
Communication

Understanding Regulatory Landscape

Regulations
Opportunities

Evaluate opportunities in portfolio

Volume
Cost savings

Intentional Approach to Pilots

Outreach
HA interactions



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