

# FHIR ePI 101:

A beginners guide to electronic labeling



## What is e-Labeling?



Global term for “electronic labeling”



Can refer to anything digital (PDFs, web pages, XML)



A digital alternative to printed leaflets and paper labels

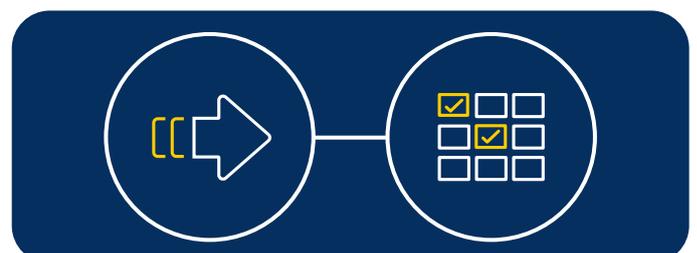
**THINK: PRODUCT INFORMATION AVAILABLE ONLINE, NOT IN A BOX.**

## Glossary of terms:

- **e-Labeling** – Any form of digital labeling (PDF or XML)
- **ePI** – Electronic Product Information (always structured, XML-based)
- **FHIR®** – Fast Healthcare Interoperability Resources
  - A global standard for structuring and exchanging health data (including ePI)
  - Uses XML and/or JSON
  - Developed by **Health Level 7 (HL7)**
  - Built for easy integration into digital health systems, apps, and platforms

## XML e-Labeling Formats in Use

- **HL7 FHIR**
- **PharmaLedger™ ePI (PLA)**
- **GS1 XML**
- **DITA XML**



## How do these initiatives work together?

- **e-Labeling** is the **umbrella term**.
- **ePI** is a type of structured eLabeling.
- **FHIR** is a **data format standard** used for ePI.



## Structured vs. Unstructured e-Labeling

Challenge	Unstructured e-Labeling	Structured e-Labeling
Definition	✗ Label content is presented as traditional documents (e.g., PDFs, Word files) without underlying data structure.	✓ Label content is encoded in a standardized, machine-readable format (e.g., XML, HL7 SPL).
Purpose	✗ Mainly intended for human reading, not easily usable by machines or automated systems.	✓ Enables systems (like regulatory portals) to automatically search, validate, and reuse information.
Benefits or Drawbacks	✗ Difficult to extract data for reuse, prone to manual errors, and harder to update consistently across systems.	✓ Supports multilingual updates, improves patient safety, and reduces errors in submissions and product data management.

## Side-by-Side Feature Comparison: Structured vs. Unstructured

	PDF eLabeling (Unstructured)	XML eLabeling (Structured)
Searchable	✗ Hard to search	✓ Instantly Searchable
Updatable	✗ Manual Updates	✓ Updates in Real Time
Translatable	✗ Not Machine-Friendly	✓ Supports Auto-Translation
Interoperable	✗ Low Interoperability	✓ Built for Digital Systems

## Why e-Labeling is Becoming the Standard



**Accessibility** for patients & professionals



**Updatability** in real time



**Adaptability** across regions & languages

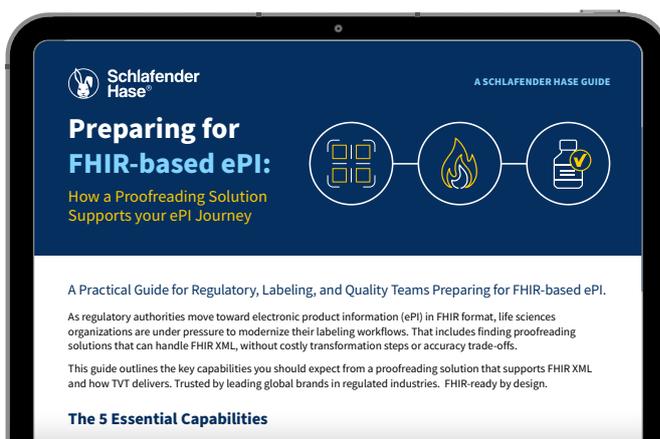


**Environmental impact** reduces paper waste

## The Future of Product Information: Global FHIR ePI Adoption Snapshot

Authority	Country/ Region	Status
EMA	EU	Pilot/ Implementation
MHRA	UK	Exploratory
HSA	Singapore	Pilot
TGA	Australia	Planning
FDA	USA	Exploratory
Health Canada	Canada	Early Evaluation

**Start Your FHIR ePI Prep Today**



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### Contact us

#### SCHLAFENDER HASE GMBH

St Martin Tower,  
Franklinstr. 61-63,  
60486 Frankfurt am Main,  
Germany

**Phone:** +49 69 244 481 0

**Email:** [TVT@sh-p.com](mailto:TVT@sh-p.com)

#### SCHLAFENDER HASE INC.

245 First Street Suite 1800 – 103,  
Cambridge, MA 02142-1292,  
USA

**Phone:** +1 617 607 4900

**Email:** [us@sh-p.com](mailto:us@sh-p.com)