

Advancing E-Labeling in Taiwan: Implementation Journey and Future Plans

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Importance of Drug Package Insert

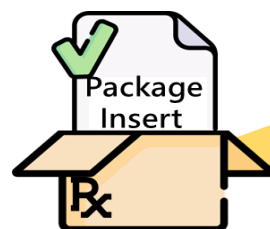
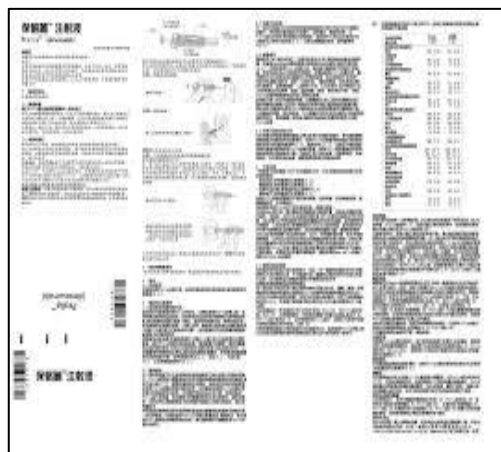
Content

- Indication
- Contraindication
- Warning and Precaution
- Adverse reaction
- Drug interaction
- Others



Tool

- Risk communication
- Risk management



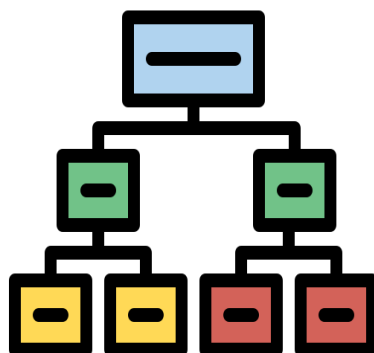
Purpose of promoting electronic package insert



Limitation of paper package insert

- The content may not be the latest
- Not easy to read and apply

Information Technology



Electronic package insert



Easily Accessible



Easy to Read



Advanced Applications

Strategies of promoting electronic package inserts

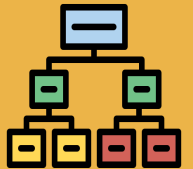
Digitization

- TFDA established the **Drug License Online Search System** in **2006**.
- The public can search for approved drug information.
- The public can download drug package inserts in PDF format.



Standardization

- A **standardized template** for drug package inserts was introduced to promote the implementation of e-labeling.
- Since **2016**, **OTC drug** inserts have adopted a standardized format.
- In **2021**, the template for **prescription drugs** was also standardized.



Structured & Computerized

- The **new Drug Package Inserts (E-labeling) Search System** was launched in **2021** with **structured** and computerized format.



Paperless

- The **e-Labeling (paperless) principle** and program has launched in **2022**.
- **Prescription drugs** that fall **within the announced scope** are eligible to apply for replacing paper package inserts with electronic ones.



Structured and Computerized E-labeling (1)

The New E-labeling Search System since 2021

Structured package
inserts appears
in a Tree view



Subscribe

Subscription for the
package inserts



User friendly interface



Responsive Web
Design



Open data files of
structured
package inserts



<https://mcp.fda.gov.tw/>

Structured and Computerized E-labeling (2)

Interface for pharmaceutical companies to create structured package inserts

Require pharmaceutical companies to establish structured package inserts since 2022

About 7300 drugs have structured package inserts

Publish the XML format standard in 2023

Start research and discussions on developing the FHIR format standard since 2024



E-labeling Search System



Require pharmaceutical companies to establish structured package inserts since 2022



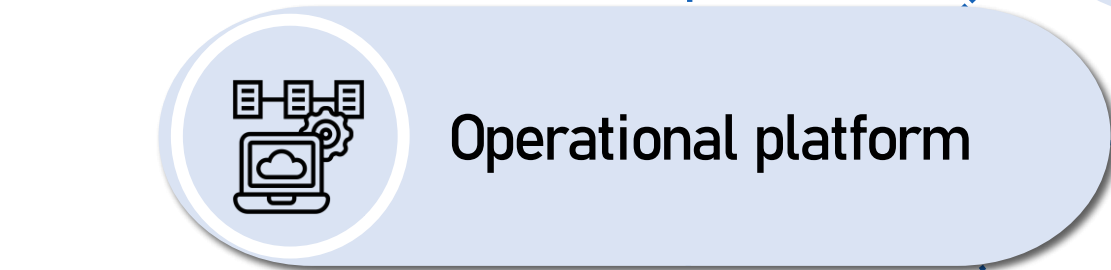
About 7300 drugs have structured package inserts



Publish the XML format standard in 2023



Start research and discussions on developing the FHIR format standard since 2024



Developing FHIR format standard for ePI (1)



Current Progress and Challenges

- A comparison has been made with the EU version of FHIR ePI to help developing Taiwan's version
- Discuss with industry association regularly to gather suggestions
- Challenges:
 - package insert is descriptive in nature
 - consistency and interoperability with international formats and meeting the needs of healthcare institutions
 - need technical supports

Developing FHIR format standard for ePI (2)



Progress this year and future plans

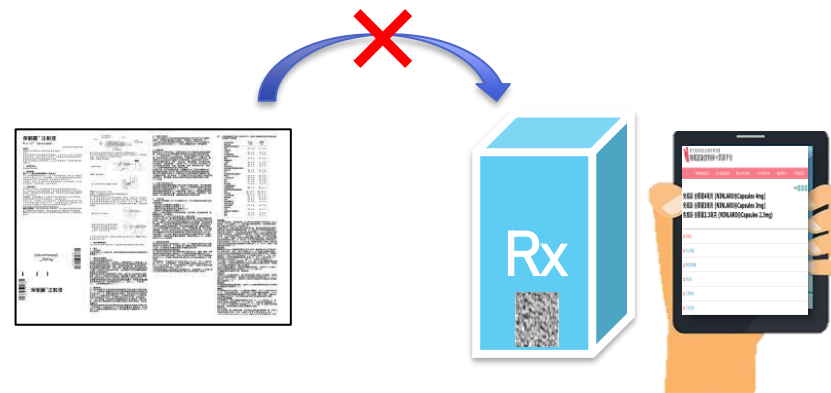
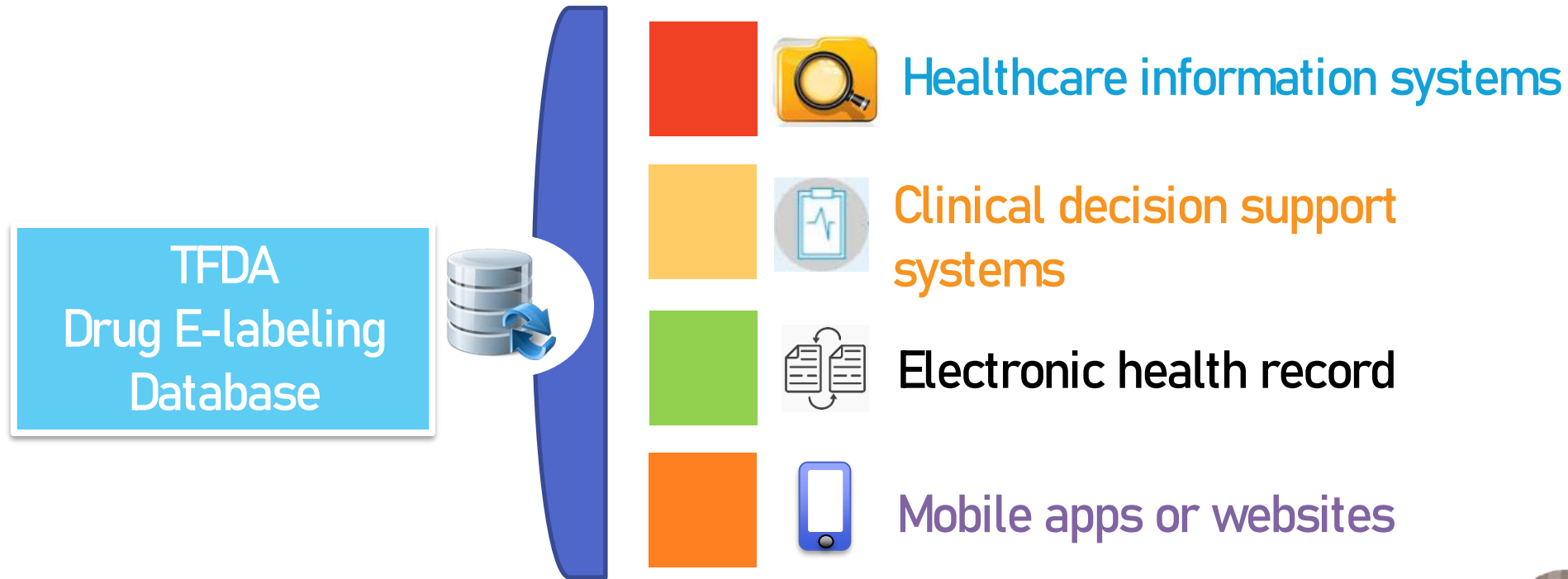
- Define the overall structure and detailed data elements of the FHIR ePI standard
- Develop an FHIR Implementation Guide (IG) tailored for Taiwan ePI
- In the future, a pilot program will be implemented first to facilitate the official launch

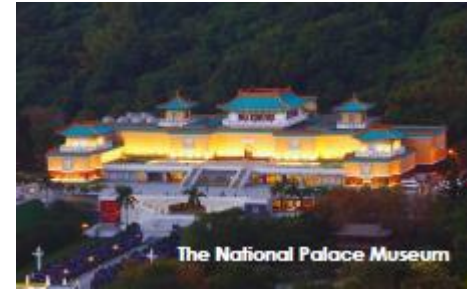
Future Work

- Facilitate the completion of structured package inserts for all medicinal products
- Improve functions of the E-labeling Search System
- Develop the FHIR format standard and Implementation Guide for ePI and promote the applications of ePI
- Expand the scope of e-labeling (paperless) program



Prospects for the application of E-labeling





**Thank You
For Your Listening!**

