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

Huang, Mei-Chen

Senior Technical Specialist

Division of Medicinal Products, Taiwan FDA

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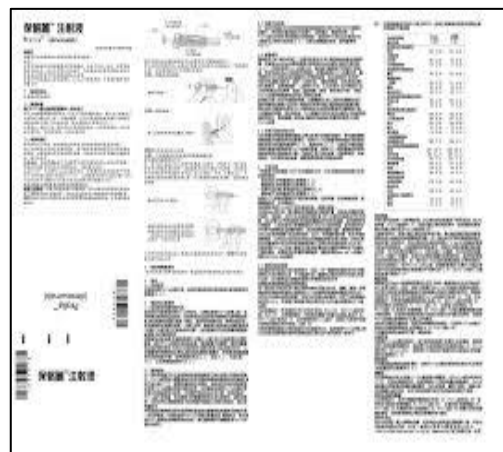
Importance of Drug Package Insert

Content

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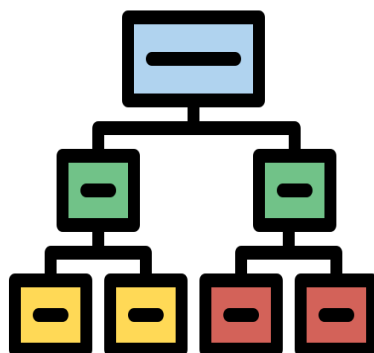- Others

Tool

- Risk communication
- Risk management

Package Insert

Rx

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

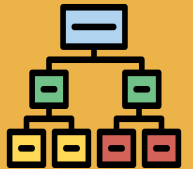# Strategies of promoting electronic package inserts

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.

of Pharmaceutical Associations

Structured and Computerized E-labeling (1)

The New E-labeling Search System since 2021

Structured package inserts appears in a Tree view

Subscription for the package inserts

User friendly interface

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

Responsive Web Design

Open data files of structured package inserts

Structured and Computerized E-labeling (2)

E-labeling Search System

Operational platform

Interface for pharmaceutical companies to create structured package inserts

Require pharmaceutical companies to establish structured package inserts since 2022
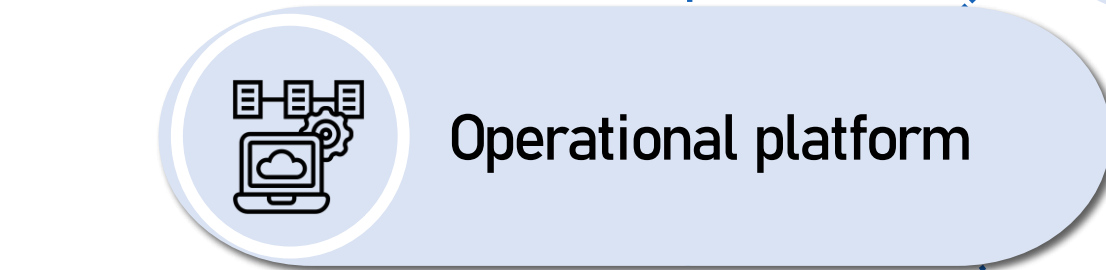
About 7300 drugs have structured package inserts

Publish the XML format standard in 2023

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

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)

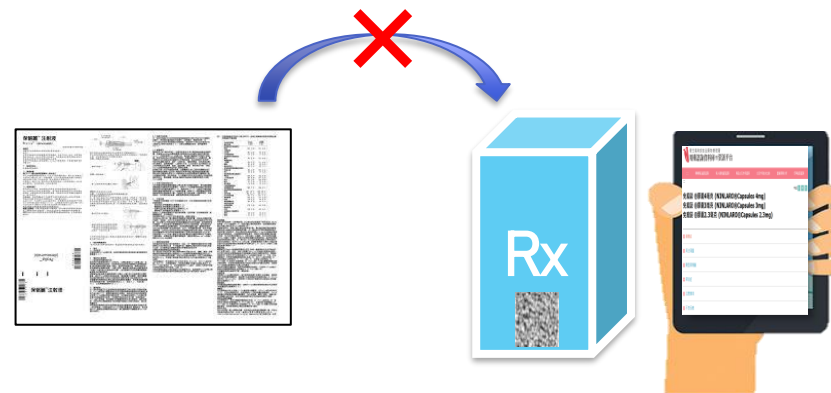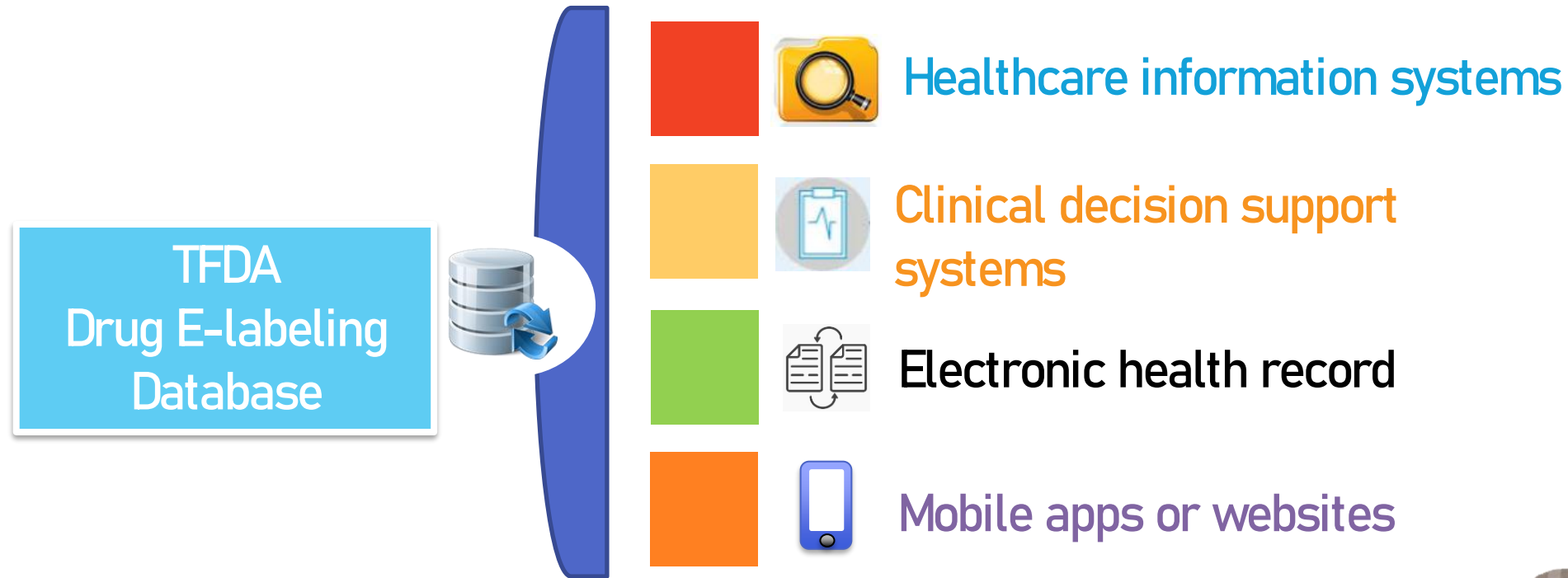## Progress this year and future plans

- ➢ 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
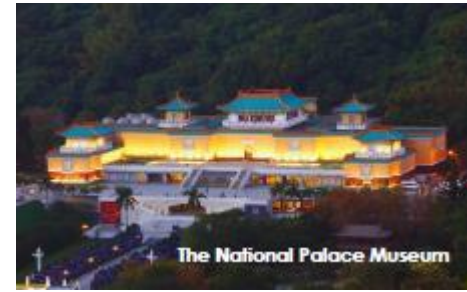
Future Work

- 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

TFDA Drug E-labeling Database

- Healthcare information systems
- Clinical decision support systems
- Electronic health record
- Mobile apps or websites

Rx

Thank You
For Your Listening!