

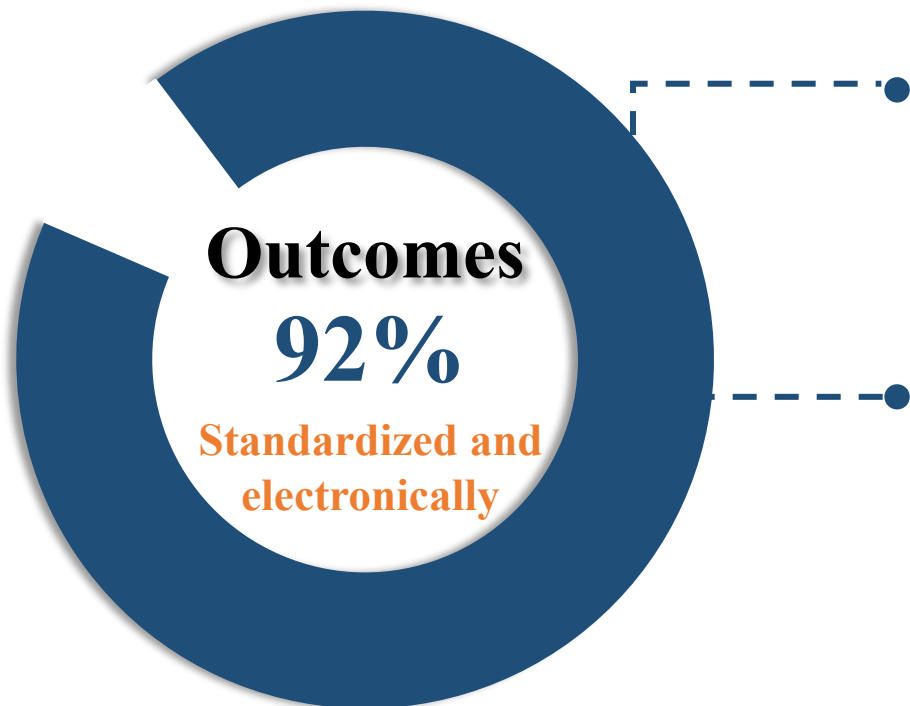
E-Labeling in Taiwan: Implementation Status and Future Directions

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Establish structured electronic drug labeling



All pharmaceutical companies are required to complete the adoption of **standardized and electronically structured** package inserts by December 31, 2026.



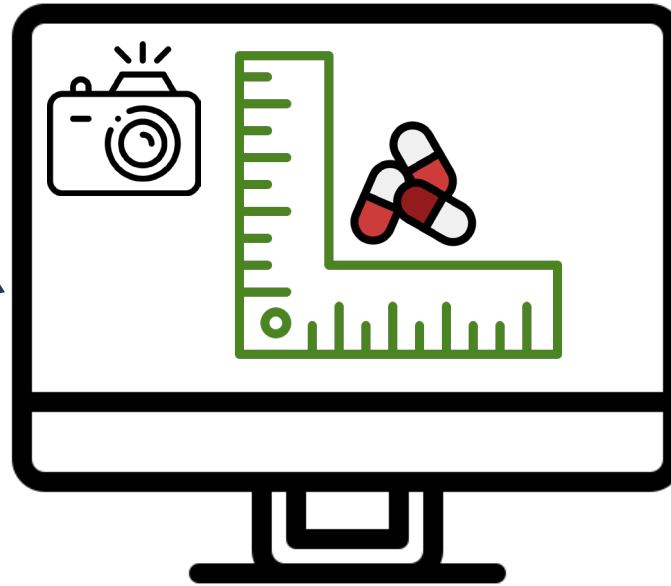
Approximately **11,500 (92%)** drug labels have **completed** Standardized and electronically structured .

Oral Drug Appearance Database and Applications

In July 2023, pharmaceutical companies were requested to register the appearance of oral drugs on the E-labeling Search System.

Purpose

1. Support decision-making for the public and healthcare professionals.
2. Ensure consistency through standardized photography and data entry.
3. Enable future AI-based drug appearance recognition.



Outcomes

The current completion rate of oral drug appearance registration is 94.5%.

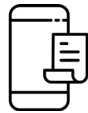
Implementation Outcomes- paperless

92%

Standardized and electronically structured



Aligned with the July 31, 2025 policy on fully electronic structured drug labeling, products with electronically structured package inserts are **eligible for voluntary paperless implementation.**



Among these , **324 (2.57%) products** have adopted **paperless package inserts.**



Notify medical institutions and pharmacies that have purchased the product.



Add a QR-code on the outer package with a statement indicating paperless labeling.



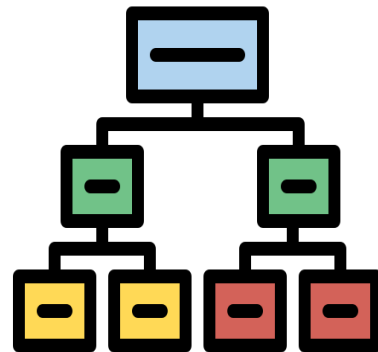
Select the "Paperless" status in the Drug Labeling Information Platform.

Importance and Purpose of Drug Package Inserts

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

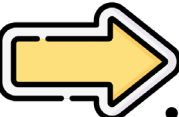


Easy to Read



Advanced Applications

Strategies of promoting electronic package inserts

- 
- 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.

Digitization



Standardization



Structured & Computerized



Paperless



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

- 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
- 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



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)



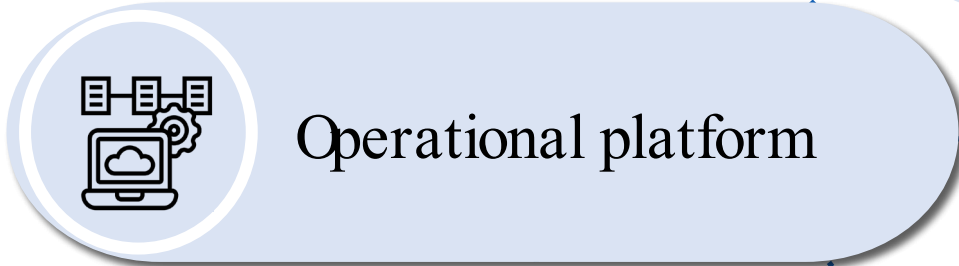
E-labeling Search System



Interface for pharmaceutical companies to create structured package inserts



Require pharmaceutical companies to establish structured package inserts since 2022



Operational platform



About 11,500 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

- Compared EU FHIR ePI; discussed with industry on standards, ePI types, and data elements.
- Challenges: descriptive package inserts → **hard to fit structured format**; need dosage, packaging, ingredients.
- Ensure **consistency, interoperability, and meet healthcare needs.**

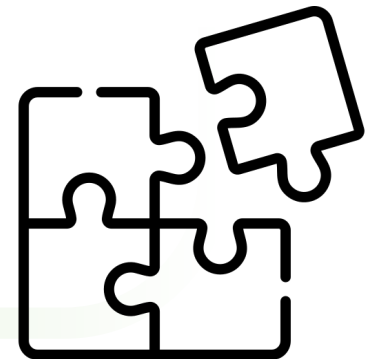


Developing FHIR format standard for ePI (2)



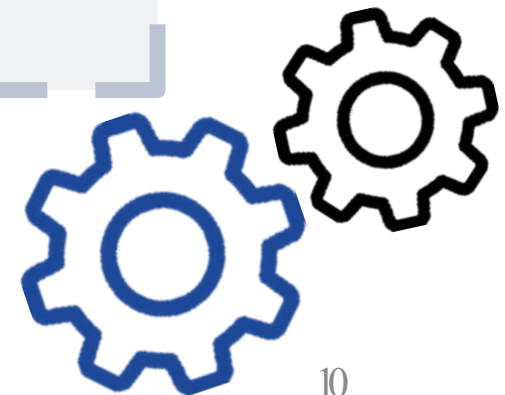
Progress This Year & Future Plans

- **Define overall structure & detailed data elements for Taiwan FHIR ePI.**
- **Develop Taiwan-specific FHIR Implementation Guide (IG).**
- **Pilot program planned before 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



THANK YOU
FOR
YOUR LISTENING

