E-labeling progression – Thailand

Presented by:
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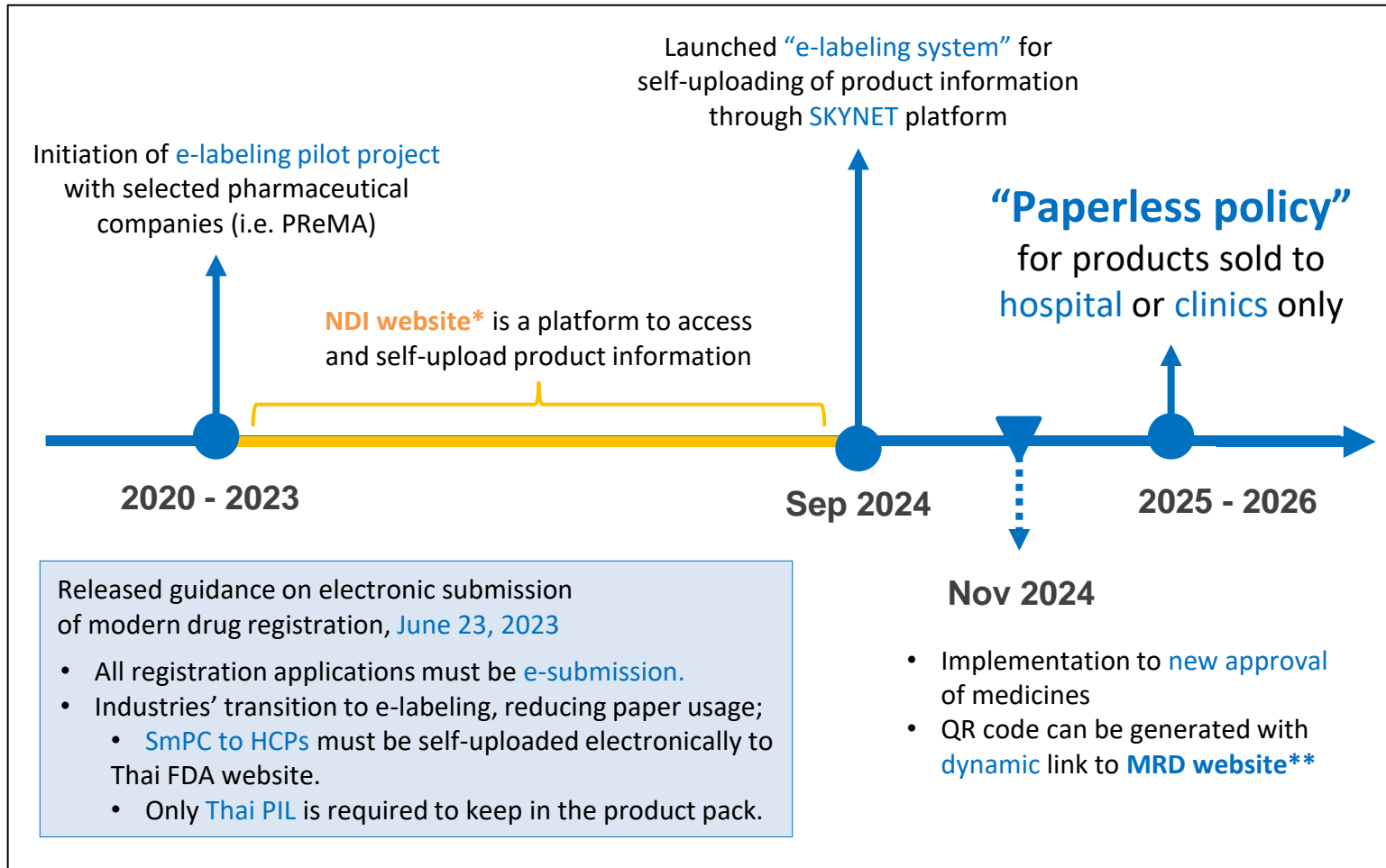**Director of Medicines Regulation Division**
Food and Drug Administration
Ministry of Public Health
Thailand

Thailand e-labeling journey

![APAC - Asia Partnership Conference of Pharmaceutical Associations]

Launched "e-labeling system" for
self-uploading of product information
through SKYNET platform

Initiation of e-labeling pilot project
with selected pharmaceutical
companies (i.e. PReMA)

NDI website* is a platform to access
and self-upload product information

"Paperless policy"
for products sold to
hospital or clinics only

2020 - 2023

Sep 2024

2025 - 2026

Nov 2024

- Implementation to new approval
of medicines
- QR code can be generated with
dynamic link to **MRD website**

Released guidance on electronic submission
of modern drug registration, June 23, 2023
- All registration applications must be e-submission.
- Industries' transition to e-labeling, reducing paper usage;
  - SmPC to HCPs must be self-uploaded electronically to
Thai FDA website.
  - Only Thai PIL is required to keep in the product pack.

- **Implementation in 2025**
  - "Paperless policy" is applicable for
products sold to hospital or clinics only.
    - Exception for
      - Vaccines
      - Self-care injectable medicines
      - Veterinary injectable medicines
for animals intended for
consumption.
  - Roll-out of the e-labeling system to
all pharmaceutical companies.
  - Continuous monitoring and optimization
of the e-labeling system based on user
feedback.

*NDI = National Drug Information
**MRD = Medicines Regulation Division

Product Information publicly available on Thai FDA website

APAC
Asia Partnership Conference
of Pharmaceutical Associations

Link of product information

- ✓ PERTENTO.FDA.MOPH.GO.TH/fda_information_drug/... (MRD website, default)
- ✓ NDI/FDA.MOPH.GO.TH/... (NDI website, optional)

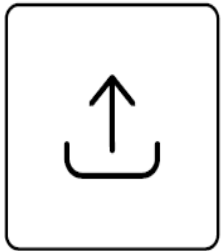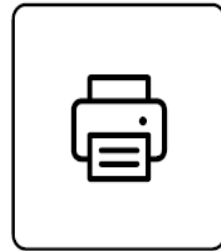dynamic link for e-labeling

NDI

drug link and QR code

DRUGLINK   https://druglink.fda.moph.go.th/U1DR1A1012620000111C

QR Generate

Use "Dynamic Link" to generate QR code
DRUGLINK.FDA.MOPH.GO.TH/u1dr....

No impact on QR code and link.
No need for new label submission.

No impact on QR code

EMPOWERING ENTREPRENEURS WITH SELF-MANAGED E-LABELING FILES

pdf Files Upload Procedure

Required Link and QR Generation
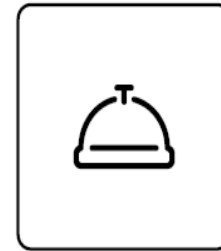
Precautions

The license holder shall maintain the dissemination of e-labeling, product images, and risk minimization of educational materials, under current regulatory approvals.

This E-labeling system enables public access to current approve of product information, thereby enhancing consumer protection through utilization of digital platforms.

If any discrepancies are identified, such matters shall be promptly reported to the license holder for immediate rectification in compliance with approved regulatory content.

Drug Images

Tablet and Capsule

Primary and secondary package

E-labeling Initiative

- ## Digital Labeling Initiative:
  - Digital labels must be accessible to all users via digital devices (such as smart phone)
  - **Paperless** for products exclusively sold to hospital and clinic, used solely by HCPs.
    Exception for Vaccines, Self-care Injectable medicines and veterinary injectable medicines for animals intended for consumption.
  - **Carton Label Requirements**: Include a URL, QR code, or barcode to access the Product Information (PI).
  - **PI Requirements**: Include a URL or QR code that directly links to Thai FDA website.

- ## Track and Trace System Initiative with e-Labeling FHIR
  - Implement serialization for **"Tracking and Tracing"** the distribution of medicines.
  - Roadmap: Implemented by 2025 (pilot phase) in high-risk drug for abuse or addiction.

Thank you