

E-labeling progression – Thailand

Presented by:

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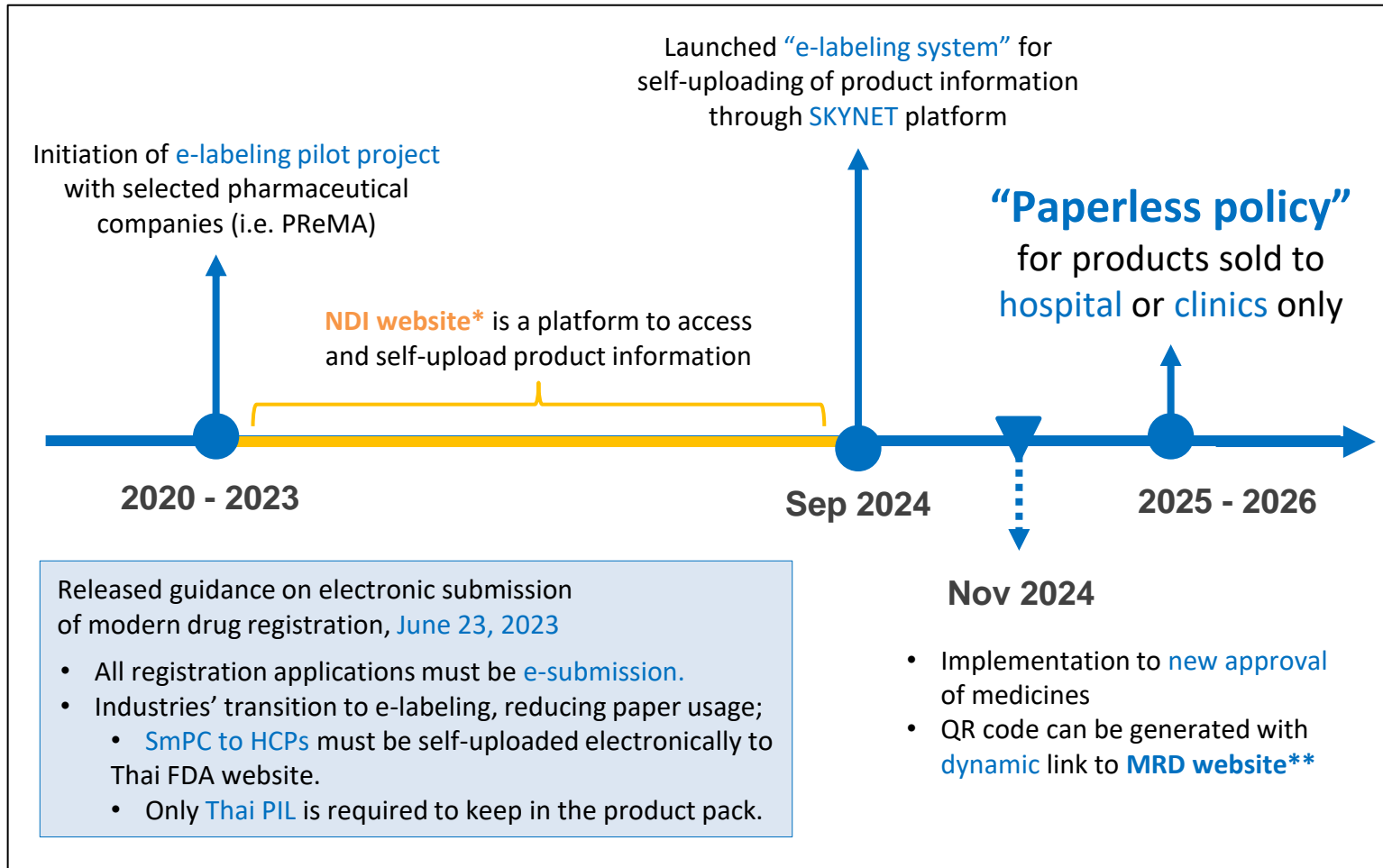
Director of Medicines Regulation Division

Food and Drug Administration

Ministry of Public Health

Thailand

Thailand e-labeling journey



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

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.

Product Information publicly available on Thai FDA website

Link of product information

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




No impact on QR code

dynamic link for e-labeling

NDI

drug link and QR code

DRUGLINK

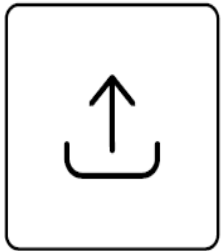


QR Generate

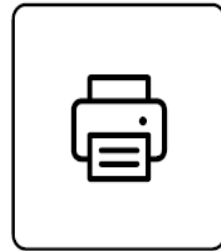
Use **“Dynamic Link”**
to generate QR code
DRUGLINK.FDA.MOPH.GO.TH/u1dr....

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

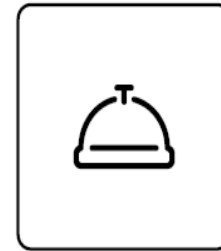
EMPOWERING ENTREPRENEURS WITH SELF-MANAGED E-LABELING FILES



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**.

“One barcode for all information”

Current Product Information
including SmPC and PIL 


Monitoring and verification of
e-labeling **web-based** system



Regulation
& Registration


Real-time
access to HCPs
and Patients

Track and Trace the distribution of Medicines



 ติดตามและตรวจสอบฉลากยาอิเล็กทรอนิกส์


ติดตามและตรวจสอบฉลากยาอิเล็กทรอนิกส์
วันที่: 10 เมษายน 2568


☒ สืบค้นการติดตามการกระจายผลิตภัณฑ์สุขภาพตลอดห่วงโซ่
☐ สืบค้นฉลากและเอกสารกำกับยาอิเล็กทรอนิกส์

สแกนหรือกรอกข้อมูลของผลิตภัณฑ์ที่ต้องการค้นหาข้อมูล


Q กรอก GTIN

Q กรอก Lot No.





Q กรอก S/N

 ค้นหา

หรือ

 สแกนที่นี่

ตัวอย่างของรหัสบาร์โค้ดและ QR Code ที่รองรับ

 Data Matrix	 (01) 1 0012345 67890 2 (10) 123ABC GS1-128	 819010721002478 EAN-13	 QR Code
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Thank you