



NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)  
MINISTRY OF HEALTH MALAYSIA



# THE *QUEST* FOR INTEROPERABILITY: MALAYSIA'S STRATEGIC ROADMAP FROM PDF TO FHIR-READY XML

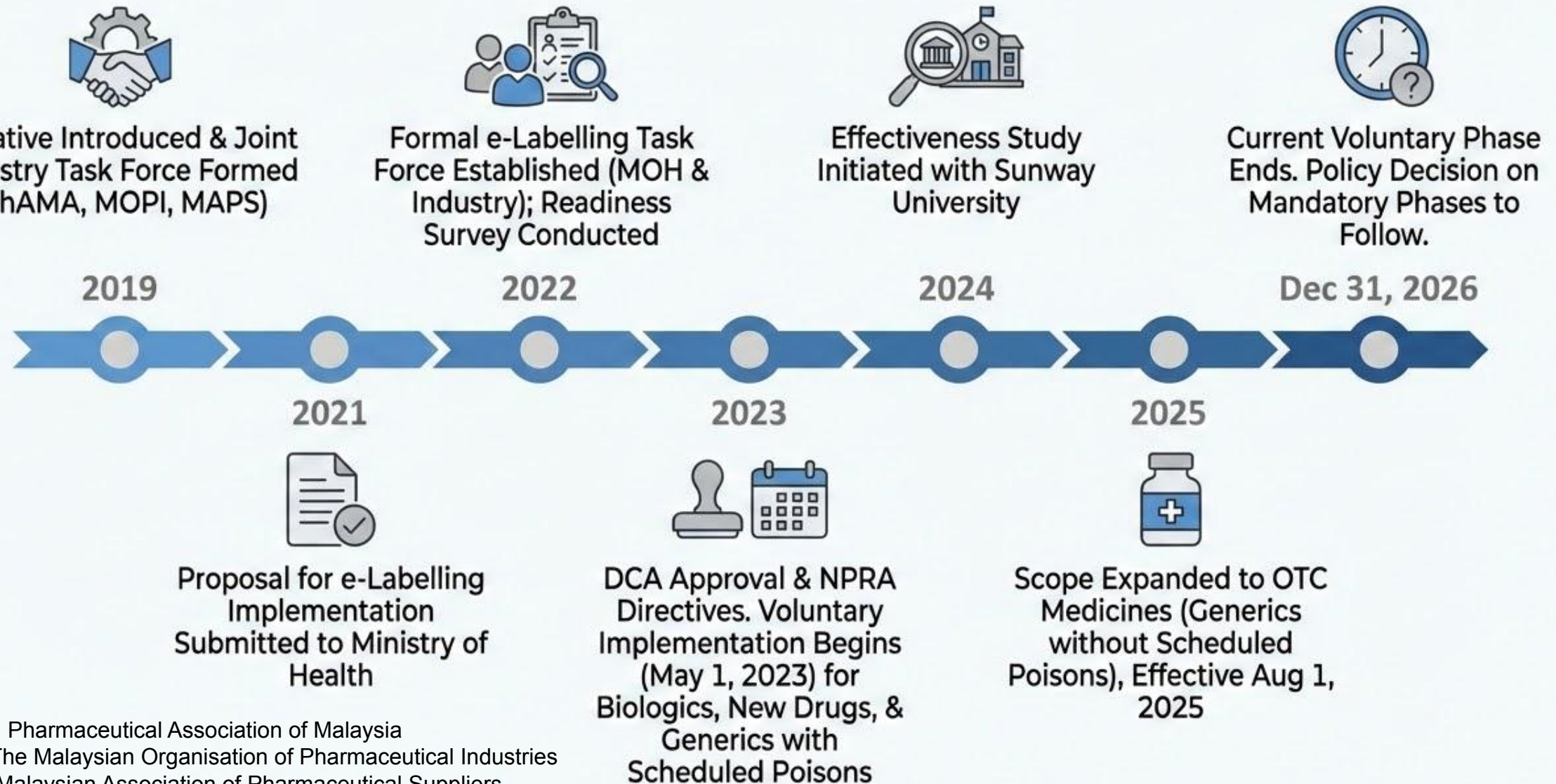
THE 15TH APAC  
21 APRIL 2026 | TUESDAY | TOKYO, JAPAN

KOBU THIRUVANACKAN



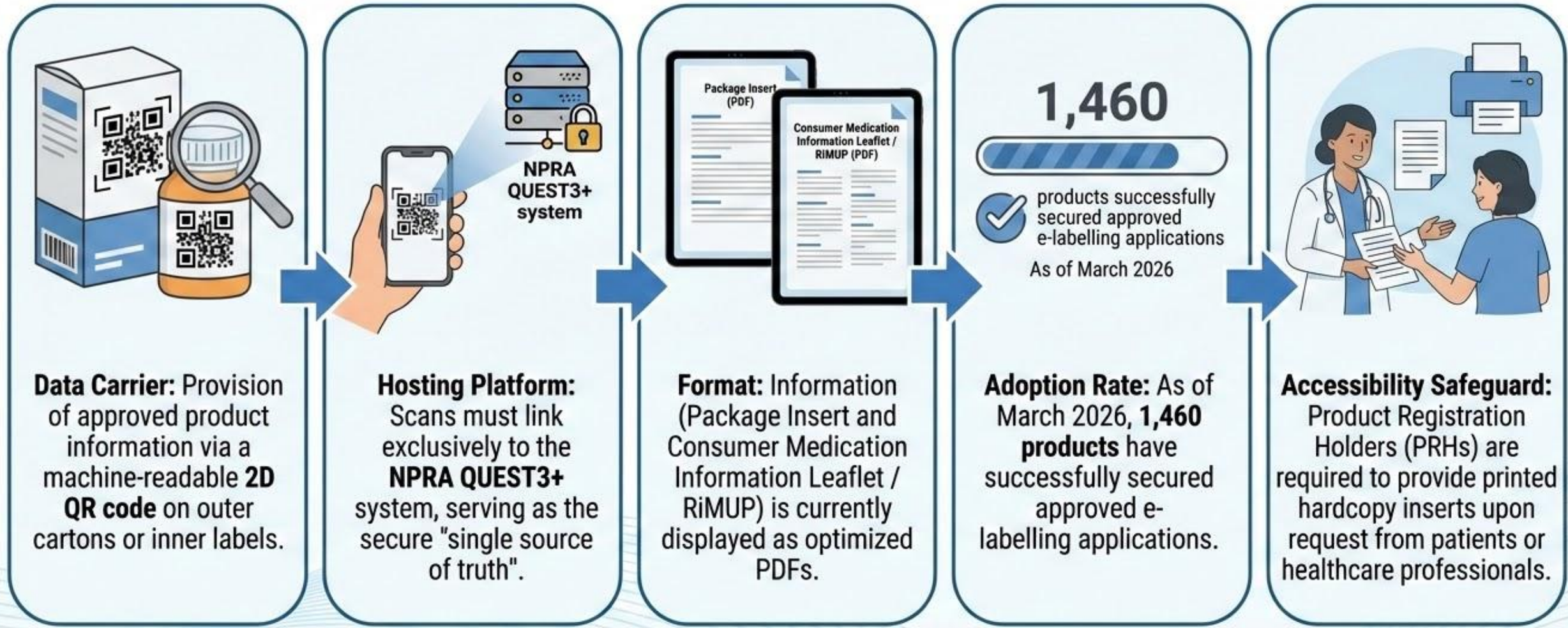
-  • Malaysia's E-Labeling Initiatives: Key Milestones (2019-2026)
-  • Current Implementation Mechanism
-  • Overview Of Multi-Stakeholder Studies (Public & HCPs)
-  • Overview Of Multi-Stakeholder Studies (Industry & Regulators)
-  • Key Implementation Challenges
-  • Way Forward - Upgrading The Digital Ecosystem
-  • Way Forward - Policy, Training, & Regional Harmonisation

# MALAYSIA'S E-LABELLING INITIATIVES: KEY MILESTONES (2019-2026)



PhAMA: Pharmaceutical Association of Malaysia  
MOPI: The Malaysian Organisation of Pharmaceutical Industries  
MAPS: Malaysian Association of Pharmaceutical Suppliers

# CURRENT IMPLEMENTATION MECHANISM





## STUDY DESIGN

Comprehensive assessment evaluating readiness across 435 public respondents and 309 Healthcare Professionals (HCPs).



## PUBLIC PERCEPTION

- 73.1% overall acceptance among patients. Driven by access to updated info, language choices, and environmental benefits.

⚠ Significant age-related digital divide exists—adults aged 50 and above are substantially less likely to adopt.



## HCP READINESS

Over 80% of HCPs are willing to adopt e-labelling. They strongly recognize the benefits.

- Emphasize need for:
  - Operational support
  - Technical training
  - Offline access solutions



## CLINICAL REALITY

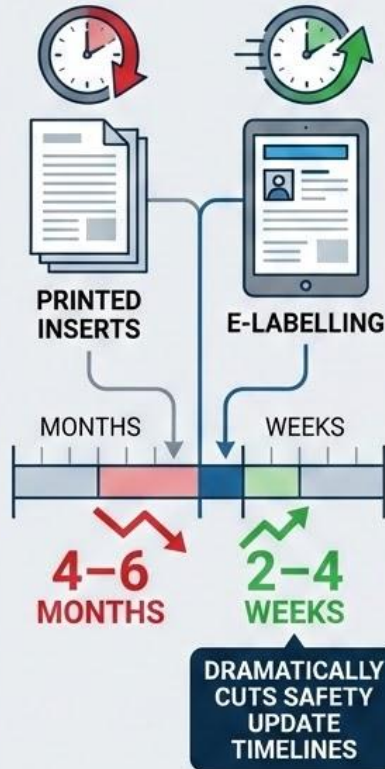
Despite digital availability, over 80% of HCPs still frequently consult package inserts for dosing and contraindications.

**System reliability is critical.**

# OVERVIEW OF MULTI-STAKEHOLDER STUDIES (INDUSTRY & REGULATORS)



## OPERATIONAL AGILITY



Updates that took 4-6 months with printed inserts are now executed in 2-4 weeks.

## COST & SUPPLY CHAIN EFFICIENCY



Industry reports indicate early signals of a 20-30% cost reduction (saving on paper, storage, and manpower) and the elimination of labor-intensive 'redressing'.

## REGULATORY FOCUS (GOVERNANCE & SAFETY)



While the industry focuses on efficiency, regulators prioritize governance, data integrity, and patient safety by mitigating the risk of mismatched or outdated information versions.

## DIGITAL INEQUITY



The digital divide for the elderly and those in rural areas with limited internet connectivity remains the primary risk for universal adoption.

## SYSTEM AND INFRASTRUCTURE RISKS



Current reliance on QUEST3+ creates a potential single point of failure; stakeholders highlight the need for robust system redundancy to handle traffic.

## REGIONAL PACKAGING CONSTRAINTS



ASEAN shared packs present a logistical hurdle, as a single pack cannot currently accommodate multiple country-specific QR codes.

## UNEQUAL INDUSTRY READINESS



Local generic manufacturers face higher infrastructural burdens and transition pressure compared to multinational companies with established digital platforms.

# WAY FORWARD - UPGRADING THE DIGITAL ECOSYSTEM

## TRANSITION TO QUEST 5



SEPT  
2027

### TRANSITION TO QUEST 5

A massive digital transformation to a new cloud-based platform (QUEST 5) is targeted to go live in **September 2027**, bringing enhanced system resilience and mobile-optimized access.

## FROM PDF TO HL7 FHIR (XML)



2027  
MANDATE

### FROM PDF TO HL7 FHIR (XML)

Malaysia plans to mandate a shift from static PDFs to the HL7 FHIR interoperability standard using structured XML format by 2027. This enables dynamic formatting, advanced searchability, and clinical system integration.

## ADVANCED TRACEABILITY



### ADVANCED TRACEABILITY

Exploring integration with the Pharmaceutical Track & Trace System (PTTS) QR codes to provide unique serialization, anti-counterfeit protection, and full supply chain visibility.

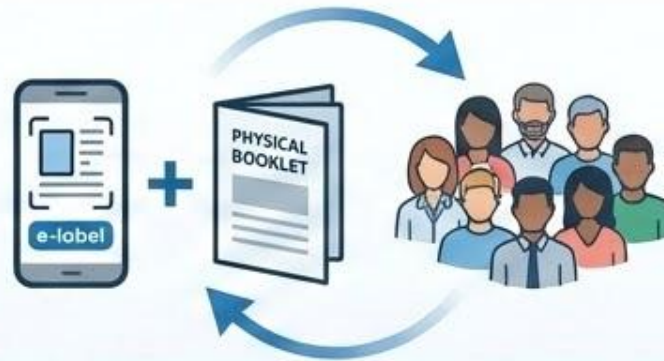
## WORKFORCE TRANSFORMATION



HCPs (especially pharmacists) must receive **targeted capacity building** to transition from “passive dispensers of printed information” to “active digital health navigators”.

*Targeted Capacity Building*

## INCLUSIVE POLICY MANDATE



Future **mandatory implementation** must utilize a **hybrid transition model**, keeping “paper-on-request” mechanisms active.

*Ensuring no patient is left behind due to the digital divide.*

## ASEAN HARMONISATION



Active **engagement** with the **ASEAN Pharmaceutical Product Working Group (PPWG)** is a critical next step.

*Resolve shared-pack constraints & align with regional electronic Product Information (ePI) standards.*

# HOW E-LABELLING WORKS

## SCAN THE QR CODE



## Members of the e-Labelling Task Force

## The local university conducting the study



MOH: Ministry of Health Malaysia including NPRA  
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# THANK YOU FOR YOUR ATTENTION

## ご清聴ありがとうございました



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