Updates on E-labelling Initiatives in Malaysia
23 April 2024

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PRESENTATION OUTLINE

1 **BACKGROUND**
- E-Labelling Milestones in Malaysia
- Survey on Industry Readiness: Main findings

2 **E-LABELLING REQUIREMENTS IN MALAYSIA**

1) Definition
2) Guideline
3) Product Scope
4) Implementation date
5) Data Format
6) Hosting Site

3 **UPCOMING RESEARCH : Impact of E-labelling Implementation on Pharmaceuticals on the Public, Healthcare Professionals, and Industries**

4 **WISHLIST**

Asia Partnership Conference
of Pharmaceutical Associations

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2019

Joint Industry Task Force proposed e-labelling implementation in Malaysia

2022

- Issuance of directives and guidance document for e-labelling by NPRA
- Voluntary e-labelling implementation started on 1st May 2023

2024

▪Sharing of e-labelling initiative during industry dialogue with NPRA
▪Formation of Joint Industry Task Force consist of PhAMA, MOPI and MAPS
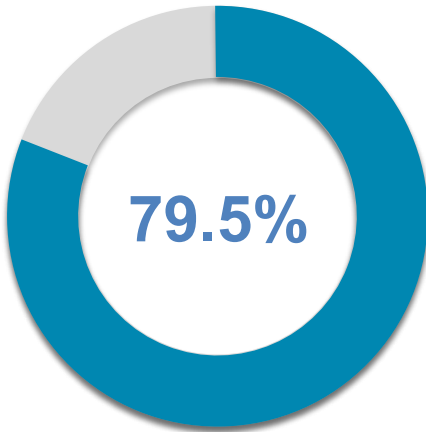
2021

- Formation of e-Labelling Task Force consists of representatives from Ministry of Health and industrial associations
- Survey on the readiness of the industry for the e-labelling implementation is conducted
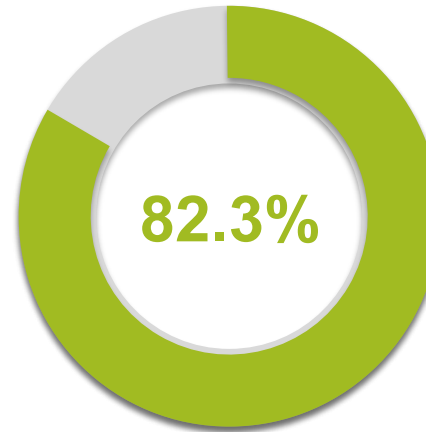
2023

- Ongoing implementation of e-labelling
- Planning for Study on *Impact of E-labelling Implementation on Pharmaceuticals on the Public, Healthcare Professionals, and Industries*

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

MAIN RESULT OF THE SURVEY

79.5%

READINESS ON E-LABELLING IMPLEMENTATION BY Q3 2022

- **20.5% ready**

- **79.5% not ready due to:**
    a) The current product label has been printed in a large amount
    b) Need more time to re-design label to include QR code
    c) Worry about variation approval time
    d) The readiness of the hosting site

82.3%

WHEN DO YOU ANTICIPATE READINESS COULD BE ATTAINED?

- **82.3% ready to implement between 2023 - 2025**

- **17.7% ready to implement by Q32022**

52.6%
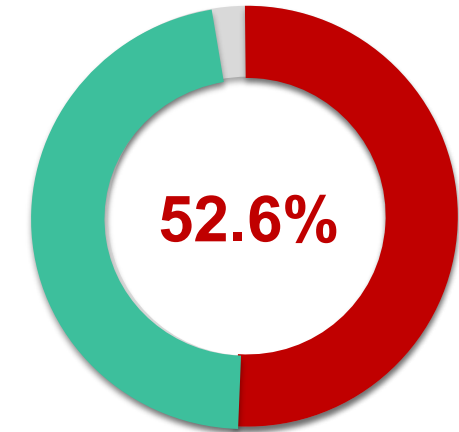
WHAT IS YOUR PREFERRED HOSTING SITE?

- **52.6% preferred NPRA**

- **43.6% preferred company/ 3rd party**

- **3.8% has no preference**

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E-LABELLING REQUIREMENTS IN MALAYSIA

E-LABELLING DEFINITION

The provision of an approved product information that includes the
- Package Insert (PI) and/or
- Consumer Medication Information Leaflet (RiMUP)

electronically via a machine readable QR code on the outer carton/inner label of the product that links to the NPRA QUEST3+ system

VOLUNTARY IMPLEMENTATION
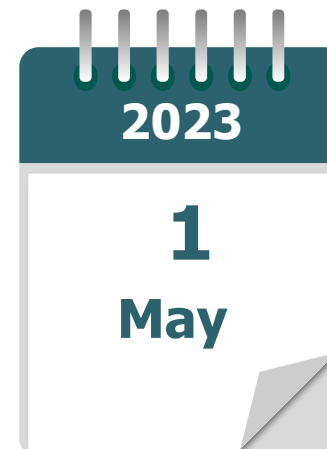
2023
1
May

START

2026
31
December

END

E-LABELLING REQUIREMENTS IN MALAYSIA

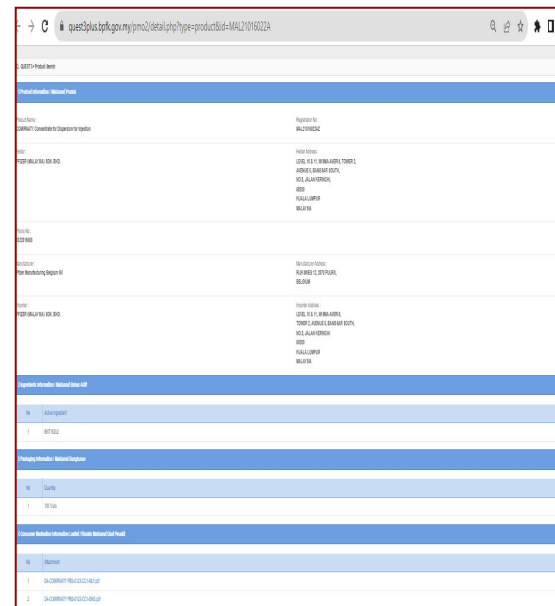| DATA CARRIER: **QR CODE**	DATA FORMAT: **PDF**	HOSTING SITE: **NPRA QUEST SYSTEM**

QR CODE SCAN
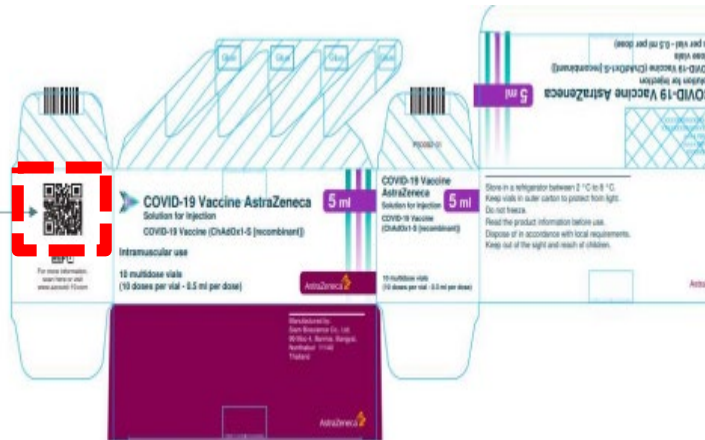
- The QR code may be displayed on the outer carton or inner label
- The QR code may be printed or affixed onto the outer carton/inner label using a stick-on label

NPRA QUEST SYSTEM OF THE PRODUCT:

PRODUCT INFORMATION FROM NPRA QUEST SYSTEM:

- Product Name
- Registration Number
- Holder & Address
- Manufacturer & Address
- Importer & Address
- Ingredient Information
- Packaging Information
- Consumer Medication Information Leaflet (RiMUP)
- Product Label
- Package Insert

E-LABELLING APPLICATIONS (PRODUCTS)

Legend: May-23 · Jun-23 · Jul-23 · Aug-23 · Sep-23 · Oct-23 · Nov-23 · Dec-23 · Jan-24 · Total
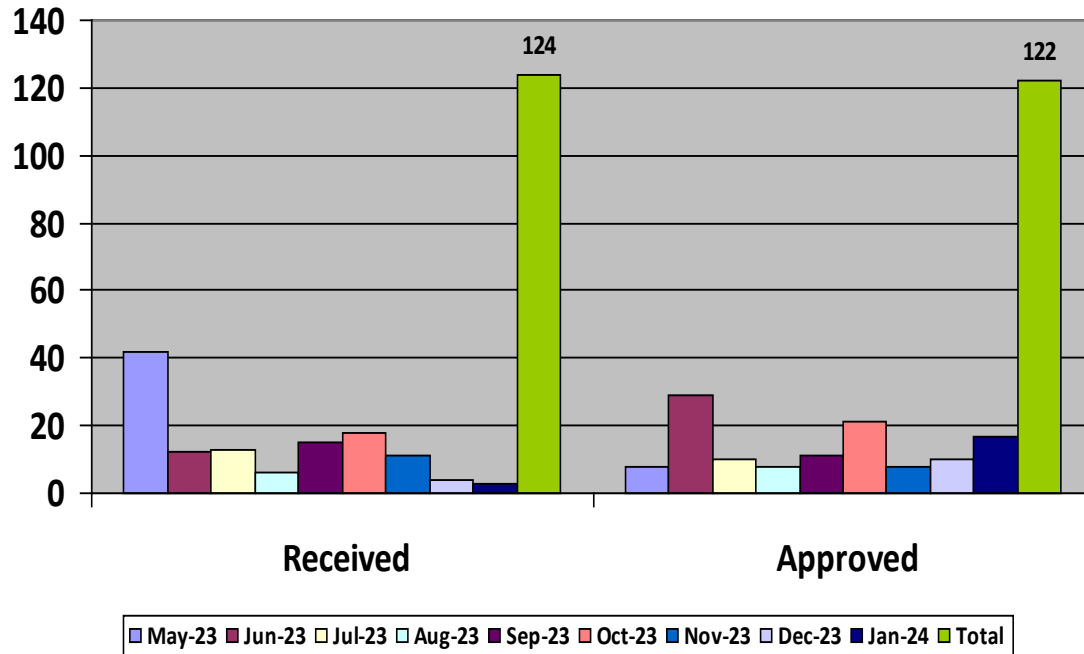
Product category:
- Biologic
- New Drug Product
- Generic Product Containing Scheduled Poison

Voluntary application by phases (PILOT) :
- Phase 1: 1 May – 31 July 2023
- Phase 2: 1 Aug – 31 Oct 2023
- Phase 3: 1 Nov 2023 – 31 Jan 2024

(During PILOT, applicant will send a list of products for e-labeling application. Phase 4 is ongoing)

Procedure:

Minor Variation – Notification (MiV-N) : "Do & Tell"

(If the notification fulfills the requirements as per described, PRH must notify NPRA. NPRA shall acknowledge the valid notification)

- E-labelling PILOT Implementation Mechanism during Voluntary Implementation is decided by e-Labelling Task Force consists of representatives from Ministry of Health and Industrial Associations.
- Issues and problems pertaining to e-labelling will be discussed in the Task Force meeting. The meeting occurs at intervals throughout the year.

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UPCOMING RESEARCH :
Impact of E-labelling Implementation on Pharmaceuticals on the Public, Healthcare Professionals, and Industries

APAC
Asia Partnership Conference
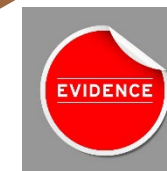of Pharmaceutical Associations

Impact & Benefits
To assess the impact and benefits of e-labelling implementation on the public, healthcare professionals, and pharmaceutical industry

Evidence
EVIDENCE
To gather evidence to support further policy decision making on e-labelling

Potential
To investigate the potential for expanding the scope of e-labelling to cover other groups of products & outcome to continually improve e-labelling implementation

Recommendation
To provide recommendations for the way forward in e-labelling implementation

UPCOMING RESEARCH :
Impact of E-labelling Implementation on Pharmaceuticals on the Public, Healthcare Professionals, and Industries

Analysis of findings:
•**One year after implementation (Interim analysis)**
•**Two years after implementation**

Methodology

Mixed Method

Quantitative

Online Survey

A structured questionnaire will collect quantitative data on the perceptions, experiences, and attitudes of the public, healthcare professionals, and industries towards e-labelling implementation

A combination of a questionnaire survey and semi-structured interviews, which are exploratory, descriptive, or explanatory will be used

Qualitative

Focus Group

These discussions will allow for an in-depth exploration of the participants' experience, perspectives, concerns, and suggestions regarding e-labelling

WISHLIST

Cross-Platform Compatibility: Designing e-labeling solutions that are compatible with a wide range of devices, operating systems, and software applications enhances interoperability

Standardized Formats: Adopting standardized formats for e-labeling data is essential for interoperability. Common formats ensure that information can be easily exchanged and understood by different systems and devices

Medication Management:
- E-labelling integration can enable healthcare providers, consumers and patients to access comprehensive medication information electronically
- This includes details such as dosage instructions, contraindications, and potential drug interactions

ACKNOWLEDGEMENT

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- Director of NPRA

- Malaysian Joint Task Force for e- labelling

- Secretariat of Malaysian Joint Task Force for e-labelling