

# **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

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# 2019



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

Joint Industry Task Force proposed e-labelling implementation in Malaysia

# 2022



# 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

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

# 2023

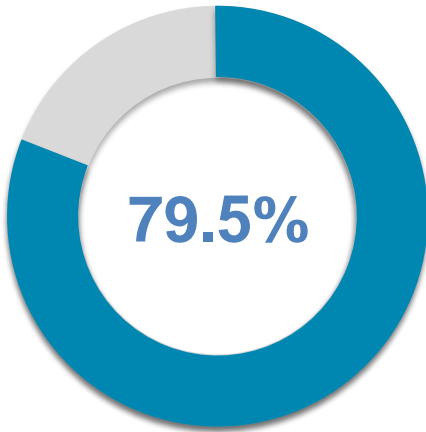


# 2024



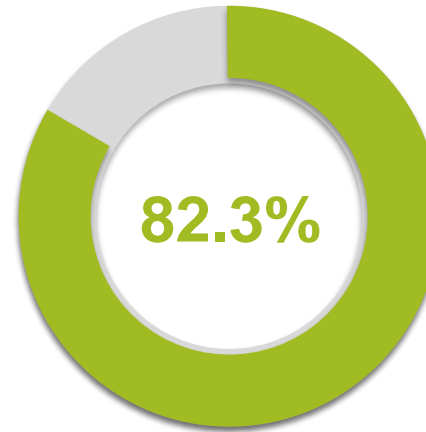
- Ongoing implementation of e-labelling
- Planning for Study on *Impact of E-labelling Implementation on Pharmaceuticals on the Public, Healthcare Professionals, and Industries*

## MAIN RESULT OF THE SURVEY



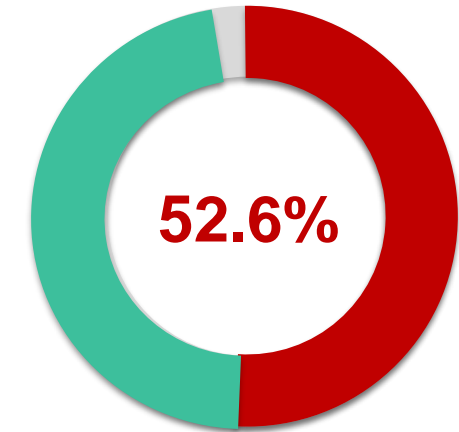
### READINESS ON E-LABELLING IMPLEMENTATION BY Q3 2022

- 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



### WHEN DO YOU ANTICIPATE READINESS COULD BE ATTAINED?

- 82.3% ready to implement between 2023 - 2025
- 17.7% ready to implement by Q32022



### WHAT IS YOUR PREFERRED HOSTING SITE?

- 52.6% preferred NPRA
- 43.6% preferred company/ 3<sup>rd</sup> party
- 3.8% has no preference

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# E-LABELLING REQUIREMENTS IN MALAYSIA

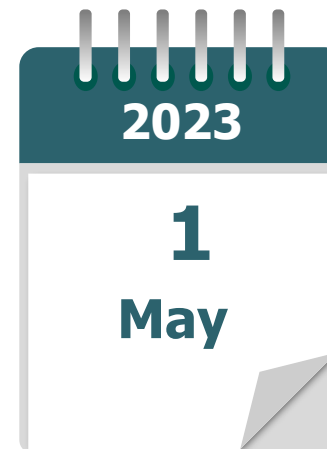
## E-LABELLING DEFINITION

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



**START**



**END**

# E-LABELLING REQUIREMENTS IN MALAYSIA

## IMPLEMENTATION DATE

Directive of implementation: 11 April 2023  
Voluntary starting :  
1 May 2023 – 31 December 2026

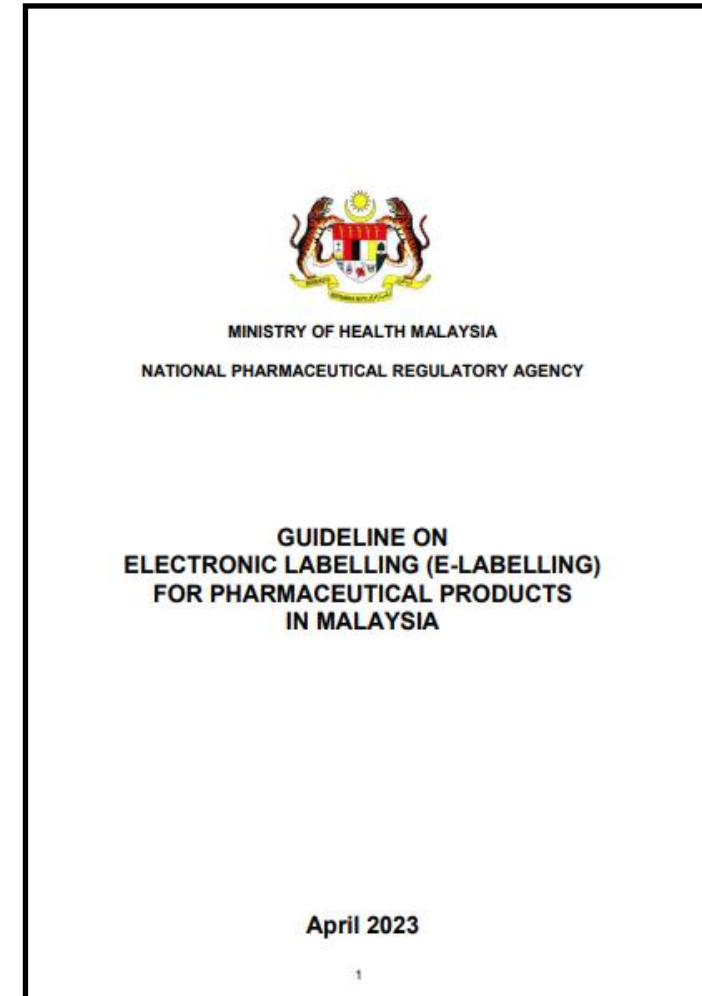
## IMPLEMENTATION SCOPE

**Product Scope:**  
Biologic, New Drug Product & Generic Product  
Containing Scheduled Poison

## IMPLEMENTATION METHOD

- New product: As part of product dossier
- Existing product: Minor Variation Notification

## GUIDELINE





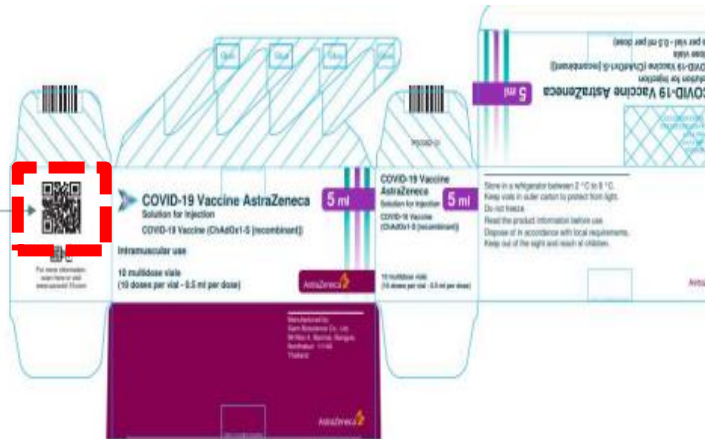
# E-LABELLING REQUIREMENTS IN MALAYSIA

**DATA CARRIER:**  
**QR CODE**

**DATA FORMAT:**  
**PDF**

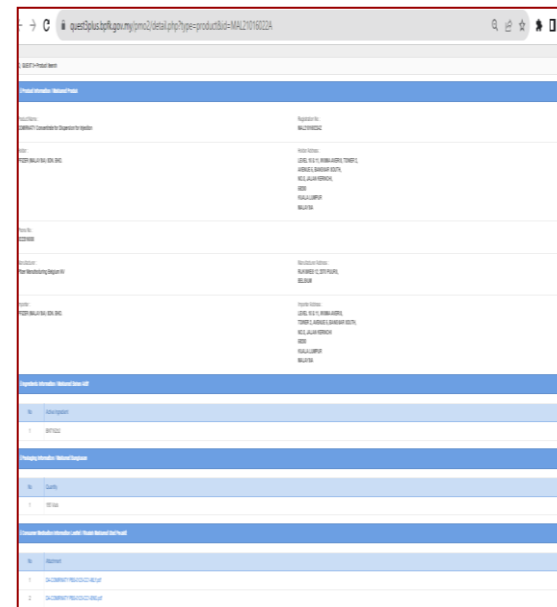
**HOSTING SITE:**  
**NPRA QUEST SYSTEM**

## 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

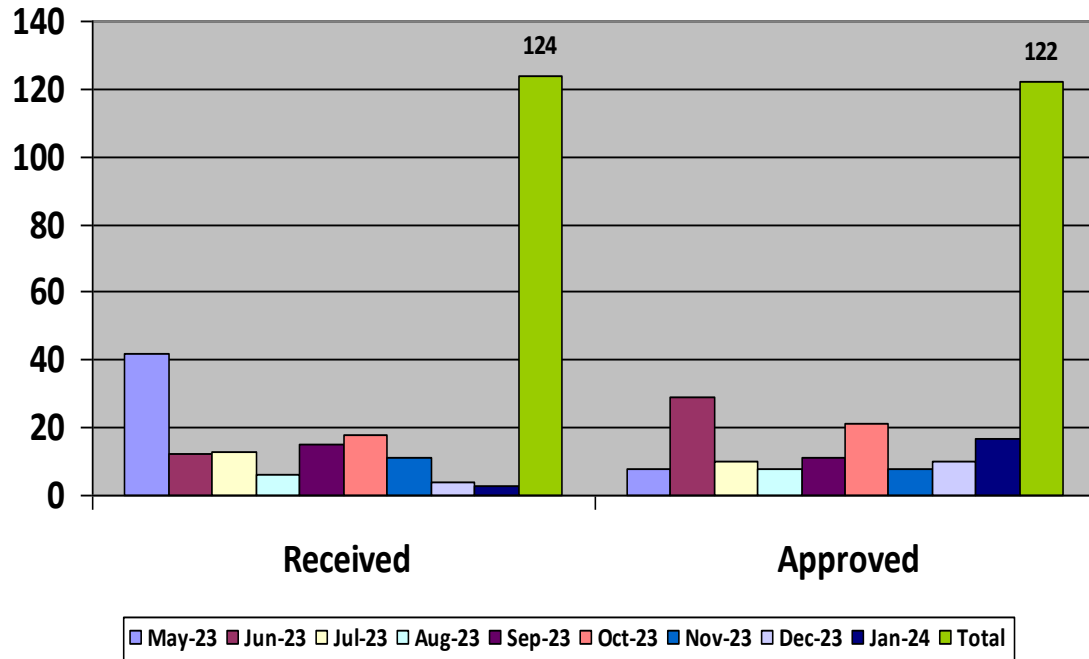
## NPRA QUEST SYSTEM OF THE PRODUCT:



## 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) RECEIVED



### 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-Labeling 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



### Impact & Benefits

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



### 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



### Evidence

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



### 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

#### 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

#### Mixed Method

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

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# WISHLIST

## Cross-Platform Compatibility:

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



VectorStock.com 79202892

## 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

Special thanks & gratitude to :

- Director of NPRA
- Malaysian Joint Task Force for e- labelling
- Secretariat of Malaysian Joint Task Force for e-labelling



ありがとう  
Arigatō