E-LABELLING UPDATES IN MALAYSIA

The 12th Asia Partnership Conference of Pharmaceutical Associations
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PRESENTATION OUTLINES

01

E-LABELLING MILESTONES IN MALAYSIA

a) Formation of e-labelling task force
b) Survey on industry readiness
c) Results of the survey

02

E-LABELLING REQUIREMENTS IN MALAYSIA

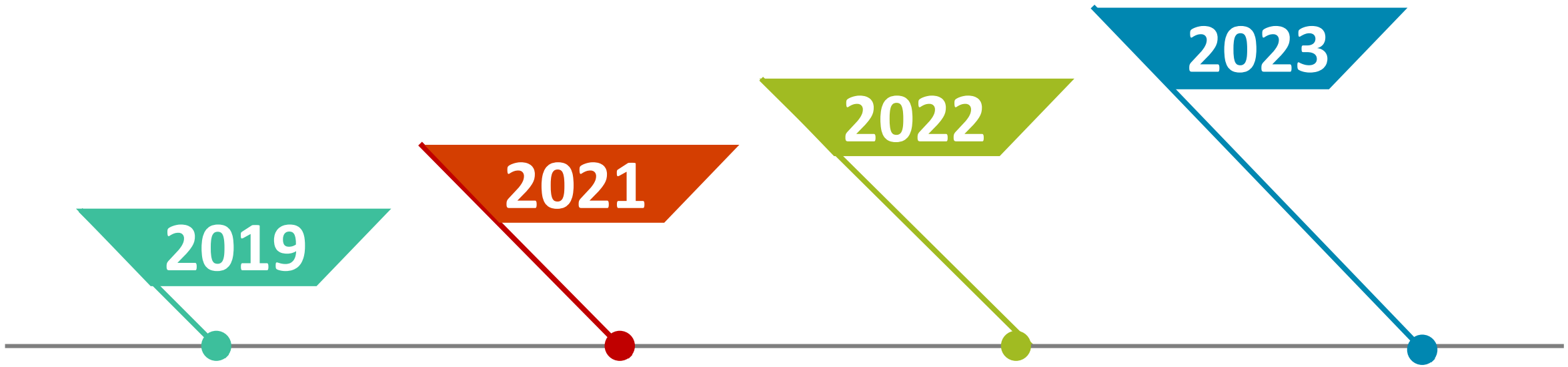
03

RESPONSIBILITIES OF PRODUCT REGISTRATION HOLDERS

04

VOLUNTARY PHASE: TO CONDUCT E-LABELLING ASSESSMENT

E-LABELLING MILESTONES IN MALAYSIA



2019

Formation of Joint Industry Task Force consists of the industry associations: PhAMA, MOPI and MAPS

2021

Joint Industry Task Force proposed e-labelling implementation

2022

Formation of e-Labelling Task Force consists of representatives from Ministry of Health and industrial associations

2023

- Proposal to implement e-labelling was approved by the Malaysian Drug Control Authority
- Voluntary e-labelling will be implemented starting 1 May 2023

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

(1) FORMATION OF E-LABELLING TASK FORCE

3 Identify the potential issues and find the solutions

Conduct survey on the industry readiness for the implementation 2

4 Develop the policy and requirements of e-labelling

Share the knowledge to facilitate the implementation 1

5 Plan the implementation

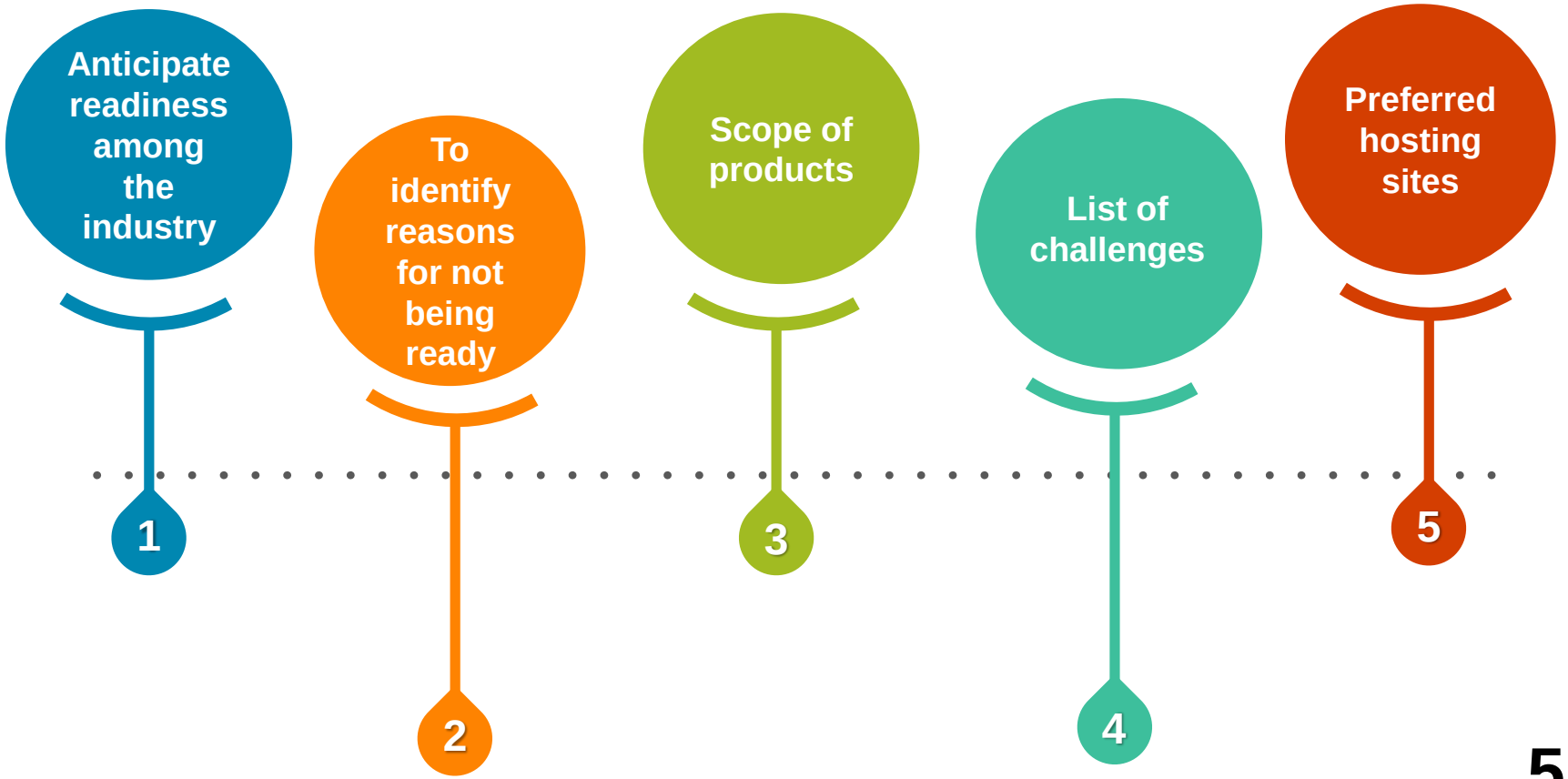
PhAMA 'Innovative Medicines for Malaysia' mapi

MAPS MALAYSIAN ASSOCIATION of PHARMACEUTICAL SUPPLIERS

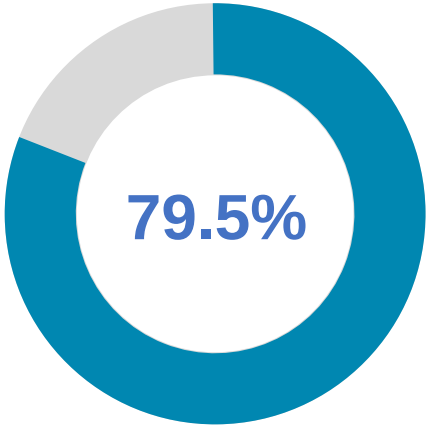
(2) SURVEY ON INDUSTRY READINESS

- Conducted in March – April 2022
- Participated by 78 members of PhAMA, MOPI and MAPS

OBJECTIVES OF THE SURVEY:

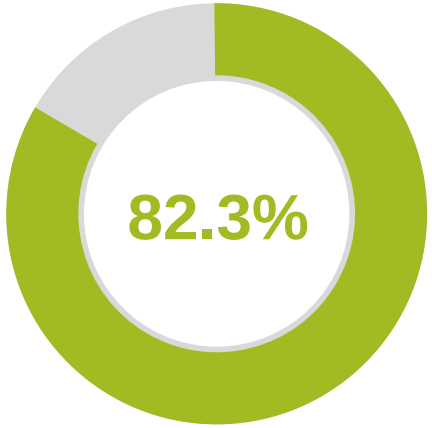


(3) RESULTS OF THE SURVEY



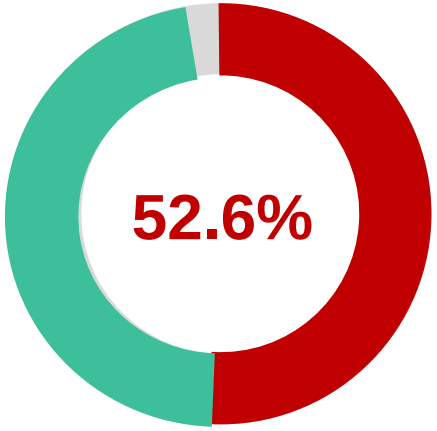
READINESS ON E-LABELLING IMPLEMENTATION BY Q3 2022

- 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 Q3 2022



WHAT IS YOUR PREFERRED HOSTING SITE?

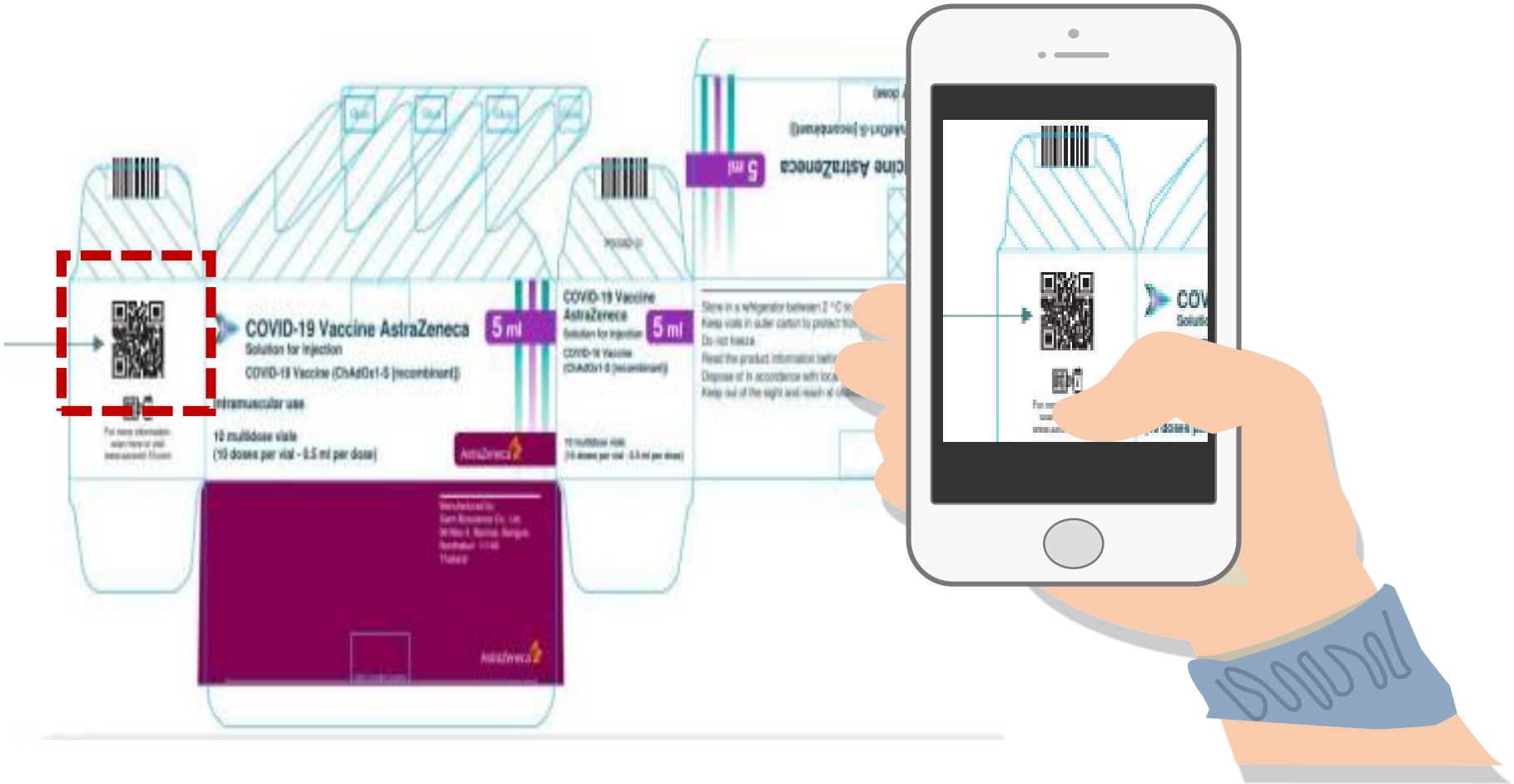
- 52.6% preferred NPRA
- 43.6% preferred company/ 3rd party
- 3.8% has no preference

(3) RESULTS OF THE SURVEY

LIST OF CHALLENGES IDENTIFIED:

1. The need to conduct assessment before implementation
2. To identify hosting platform that is viable in terms of resources, technical maintenance, accessibility, reliability and compliance
3. Limited accessibility in rural areas. Alternative measure is to provide a paper copy should it be required
4. Changes in URL and QR code will incur cost to the product label
5. To create awareness among the users on the implementation

E-LABELLING REQUIREMENTS IN MALAYSIA



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

E-LABELLING FORMAT

Shall be presented in a QR code that is translated to NPRA QUEST3+ system which displays the same product information in pdf format.

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

E-LABELLING REQUIREMENTS IN MALAYSIA

IMPLEMENTATION DATE

Voluntary starting
1 May 2023 – 31 December 2026

IMPLEMENTATION SCOPE

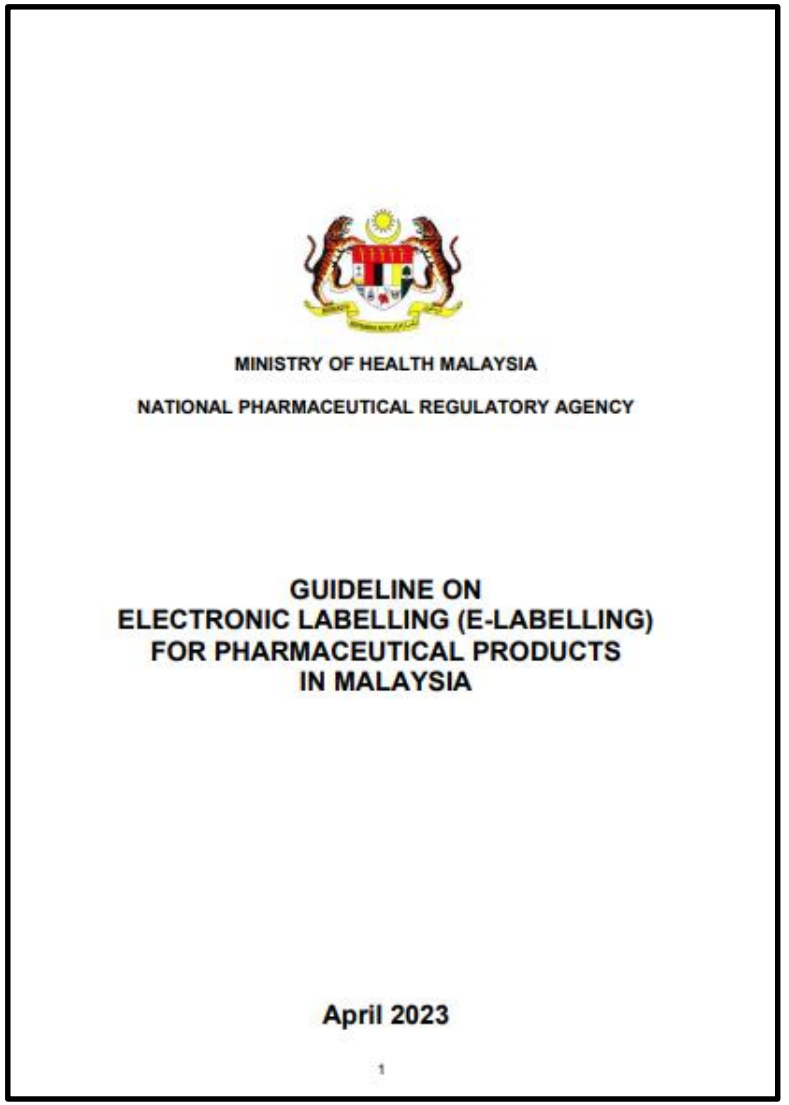
Pharmaceutical product for human use

IMPLEMENTATION METHOD

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

GUIDELINE

Guideline on Electronic Labelling (e-Labelling) for Pharmaceutical Product in Malaysia



MINISTRY OF HEALTH MALAYSIA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

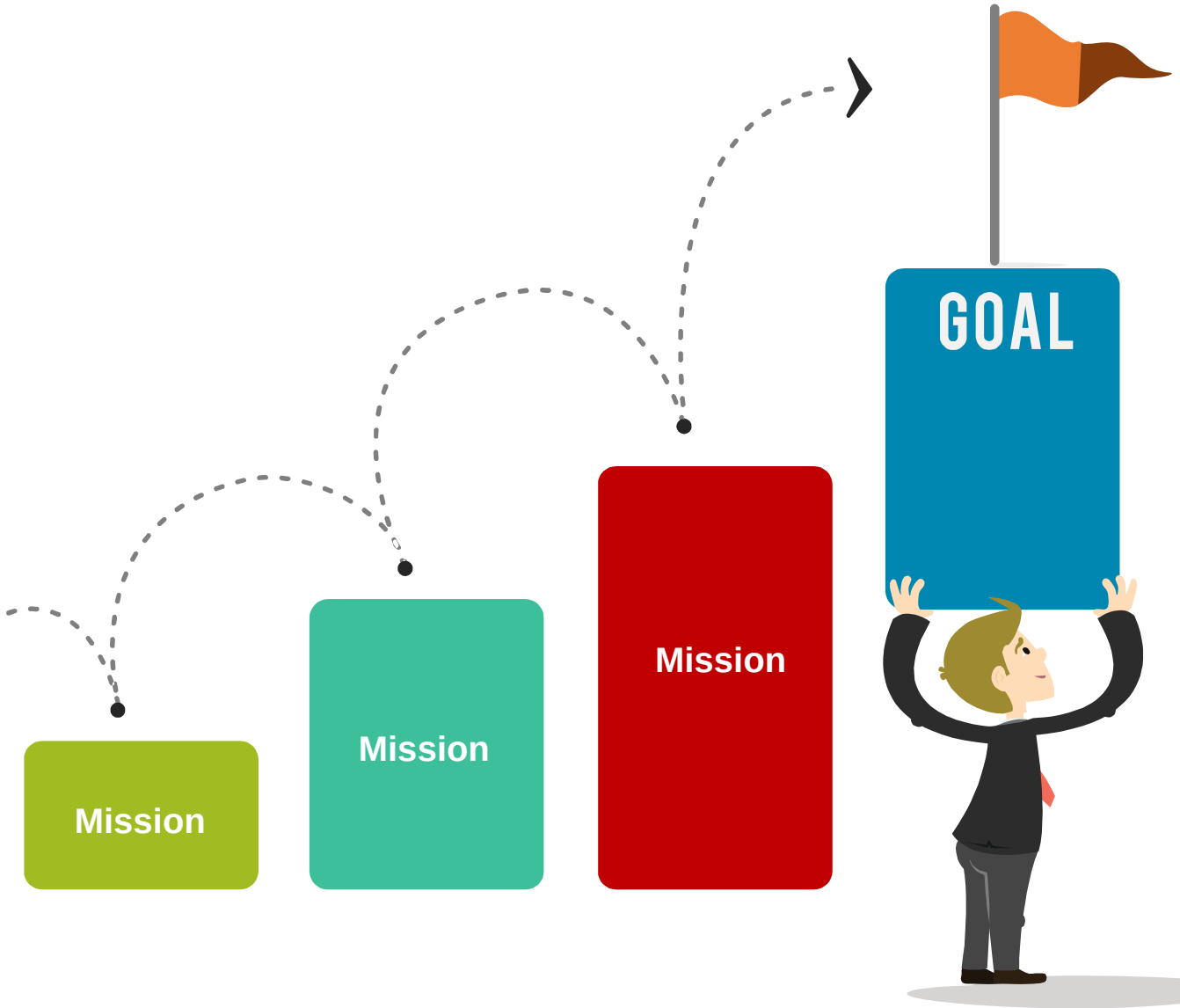
GUIDELINE ON
ELECTRONIC LABELLING (E-LABELLING)
FOR PHARMACEUTICAL PRODUCTS
IN MALAYSIA

April 2023

1

RESPONSIBILITIES OF PRODUCT REGISTRATION HOLDER (PRH)

1. Submit variation to change the product label in stages
2. Issue DHCP Letter to healthcare professionals (HCP) together with hardcopy package insert (PI) and/or consumer medication information leaflet (RiMUP)
3. Provide hardcopy PI and/or RiMUP when required
4. Monitor complaints, feedback and request for hardcopy PI and/or RiMUP from HCP



VOLUNTARY PHASE :
TO CONDUCT E-LABELLING ASSESSMENT

1. To analyse complaints and feedback received from stakeholders

2. To be conducted:
   a) One year after implementation (Interim analysis)
   b) Two years after implementation

3. Identified stakeholders:
   a) Malaysian Medical Association
   b) Malaysian Pharmacist Society
   c) Malaysian Nurses Association
   d) Pharmacy Practice and Development Division

THANK YOU
FOR YOUR ATTENTION

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