



# E-LABELING PILOT PROJECT IN INDONESIA

Dra. Rita Endang, M.Kes., Apt  
Deputy Chairperson of Drug, Narcotics, Psychotropics, Precursors and  
Addictive Substance Control  
**Indonesian Food and Drug Authority**

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# OUTLINE

E-labeling Overview

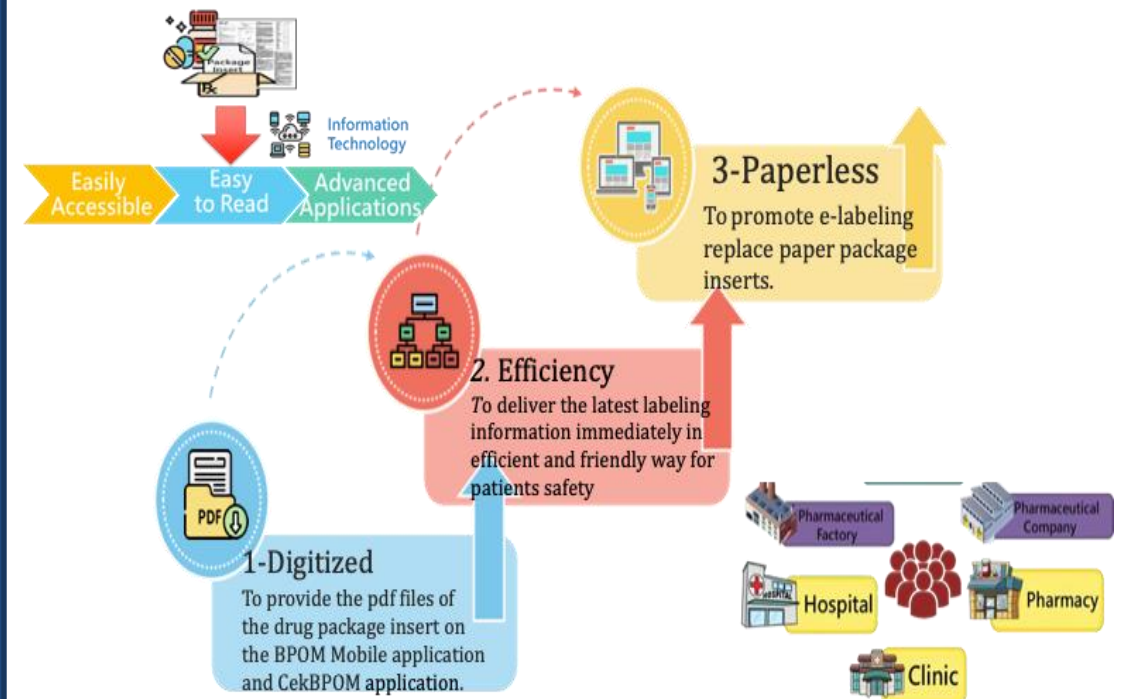
Legal Drafting Process of The Decree of the Indonesian FDA Chairperson No. 317 of 2023

The Implementation of E-Labeling Pilot Project

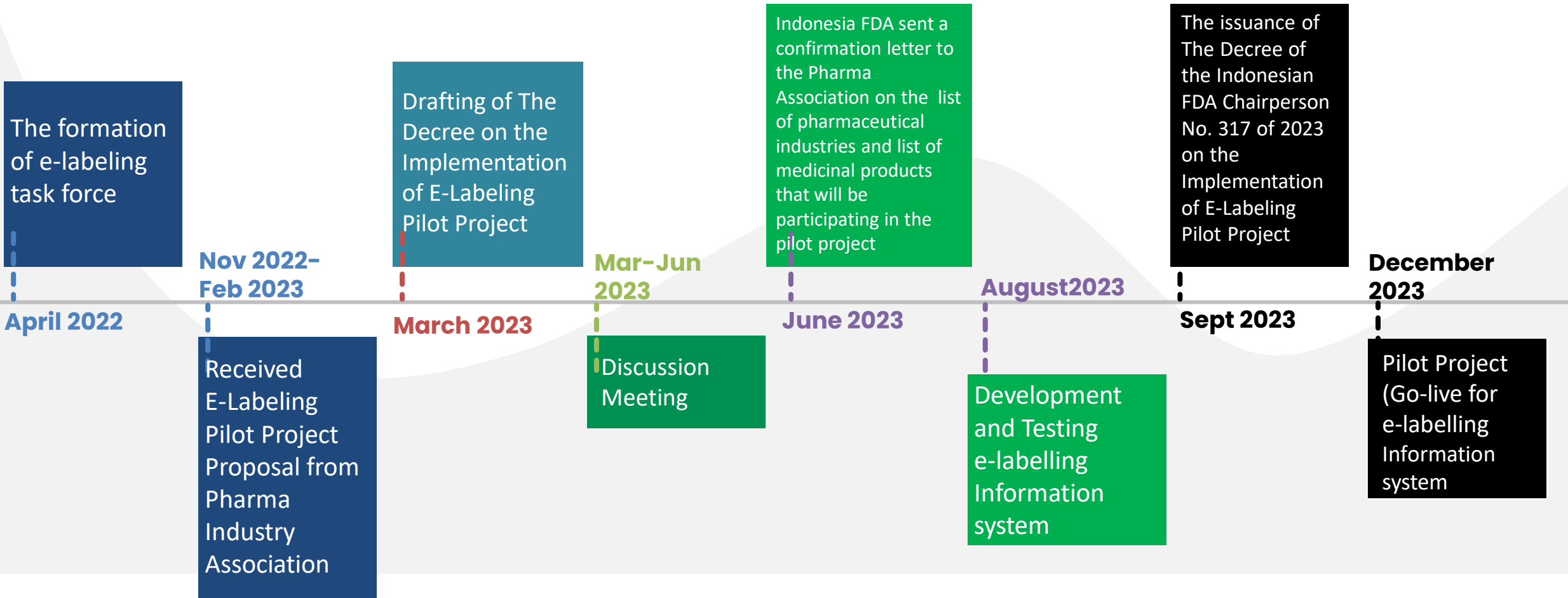
# E-labelling Overview

- 1 E-labeling is an electronic label that contains product information for health workers and patients which can be accessed through reading two-dimensional barcodes (2D Barcodes) in accordance with the Indonesian FDA Regulations concerning the application of 2D Barcodes on medicinal product packaging
- 2 E-labeling aims to expand and accelerate the dissemination of the latest information related to products in a more effective and efficient way.
- 3 During Covid-19 Pandemic, Indonesia has implemented an e-labeling for Covid-19 vaccine. To extend the implementation of e-labeling, Indonesia FDA has initiated the pilot project which is legalized through The Decree of the Indonesian FDA No. 317 of 2023 on The Implementation of E-labeling Pilot Project (promulgated on 1 September 2023).

## PROMOTE ELECTRONIC DRUG PACKAGE INSERT E-LABELING



# Legal Drafting Process of The Decree of the Indonesian FDA Chairperson No. 317 of 2023



# THE IMPLEMENTATION SCHEDULE OF E-LABELING IN INDONESIA



The implementation of the Pilot Project E-Labeling is carried out for 2 (two) years starting from December 2023 to November 2025, and conducted in 3 stages as follows

Stage 1			Stage 2			Stage 3							
2023	2024		2024			2024			2025				
Dec	Jan	Feb	Mar	Apr	May	June	Sept	Dec	Jan	Mar	June	Sept	Nov

**(Dec 2023-Feb 2024)**

- Vaccine and injection
- 24 product
- Started in December 2023

**(Mar-May 2024)**

- Prescription drug included vaccine and injection
- 54 product (total product 78)
- Started in March 2024

**(June 2024- Nov 2025)**

- Product Prescription drug included vaccine and injection and OTC
- 35 product (total product 113)
- Started in June 2024

**Paper Label**

Paper or electronic label access code on package

Full-scale operation of the e-labelling application

**All Safety Information available on BPOM Mobile**

## Indonesian FDA Task

Indonesian FDA provides:

1. A place to upload product information on the track and trace application
2. Product information display for health workers and patients on “the BPOM mobile application” and “Cek BPOM application”.
3. Evaluating the implementation of the pilot project e-labeling that has been reported by Pharmaceutical Industries

## Pharmaceutical Industries Task

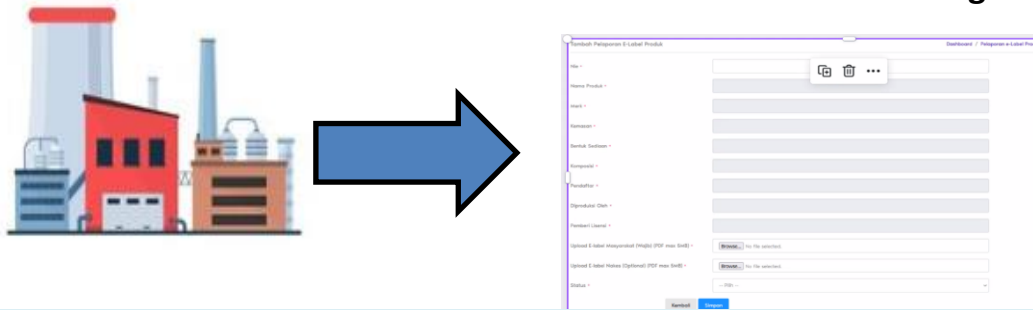
1. Provide education to health workers and consumers regarding the use of e-labeling
2. Carry out monthly monitoring and evaluation of the implementation of the e-labeling pilot project
3. Ensure risks and risk mitigation are carried out correctly
4. Report the results of monitoring, evaluation and risk mitigation to the Indonesian FDA

# Indonesian FDA and Pharmaceutical Industries Task During e-labeling Pilot Project

# Process Flow of E-labeling Pilot Project

Track and Trace Application ([ttac.pom.go.id](http://ttac.pom.go.id)) hosted by the Indonesian FDA

## Module E-Labeling



The pharmaceutical industry uploads the latest product information that has been approved by the Indonesian FDA (PDF format) through track and trace application ([ttac.pom.go.id](http://ttac.pom.go.id)). Product information will be contained as one of the entities in the two-dimensional barcodes (2D Barcodes).

## 2D Barcode Authentication

### 2D Barcode



### 2D BARCODE BPOM



E-labeling can be accessed through reading 2D Barcodes printed on medicinal product packaging using “the BPOM Mobile Application”.

## Identification



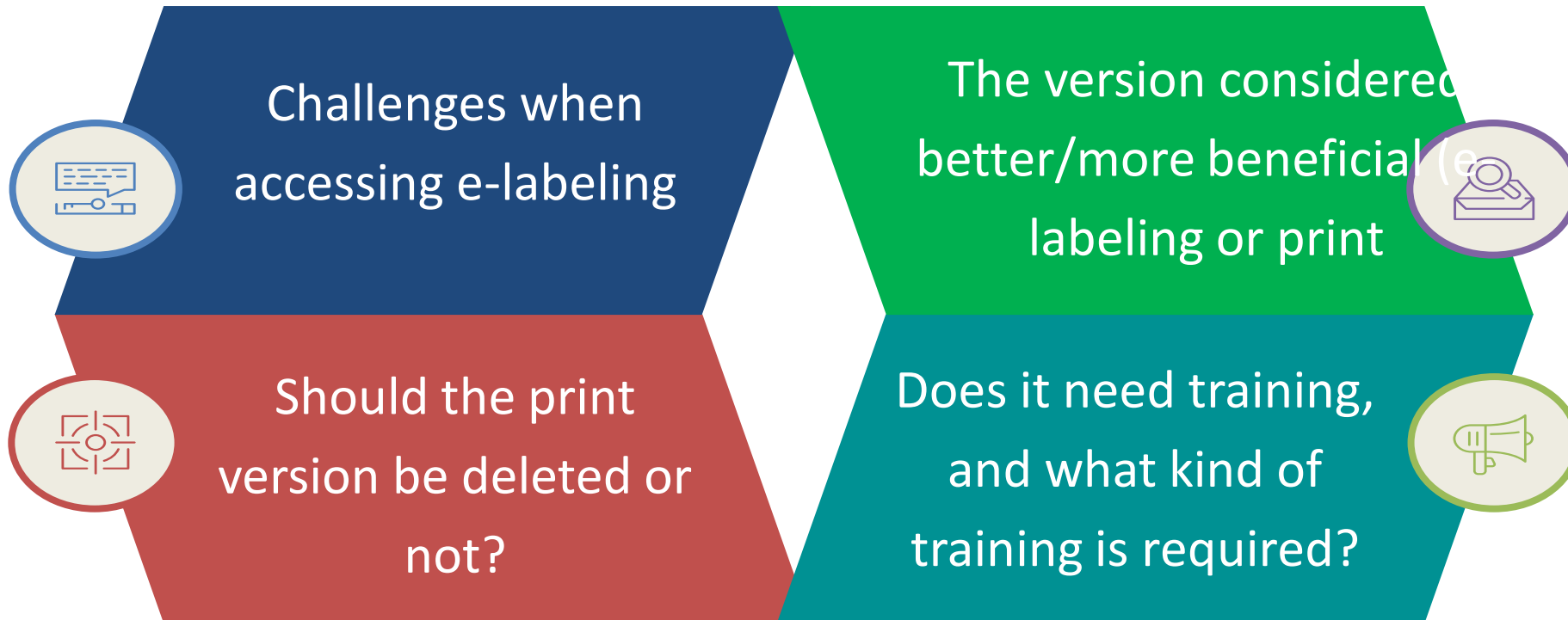
For medicinal products that have not implemented the 2D Barcode authentication method, e-labeling can be read by searching for the marketing authorization number of the medicinal product through “the Cek BPOM application”

After scanning the 2D Barcode, e-labeling will be displayed on “the BPOM Mobile application” (can be downloaded via Playstore/Appstore).



# Implementation of the E-labeling Pilot Project Survey

The survey results will be used for the **evaluation and monitoring** of the implementation of the e-labeling and its **sustainability**





# Role In The Implementation Of The e-Labeling Pilot Project



## Healthcare Professionals

- 1) Scanning e-labeling information on 2D barcode packaging using the BPOM Mobile application / searching for products on the website [cekbpom.go.id/new](http://cekbpom.go.id/new)
- 2) Filling out the e-labeling survey to assess the effectiveness of e-labeling usage
- 3) Educating/informing patients to access electronic product information on 2D barcode packaging using the BPOM Mobile application / searching for products on the website [cekbpom.go.id](http://cekbpom.go.id)



## Public

- 1) Scanning e-labeling information on 2D barcode packaging using the BPOM Mobile application / searching for products on the website [cekbpom.go.id/new](http://cekbpom.go.id/new)
- 2) Filling out the e-labeling survey to assess the effectiveness of e-labeling usage

# THE FIRST STAGE EVALUATION

## of The e-labeling Pilot Project

The first stage has been implemented for 24 vaccine and injection products, starting in December 2023 - February 2024

### IMPLEMENTATION OF E-LABELING BY PHARMACEUTICAL INDUSTRY



66,7% of 24 products have already implemented e-labeling

### E-LABELING ACCESS BY BPOM MOBILE APPLICATION

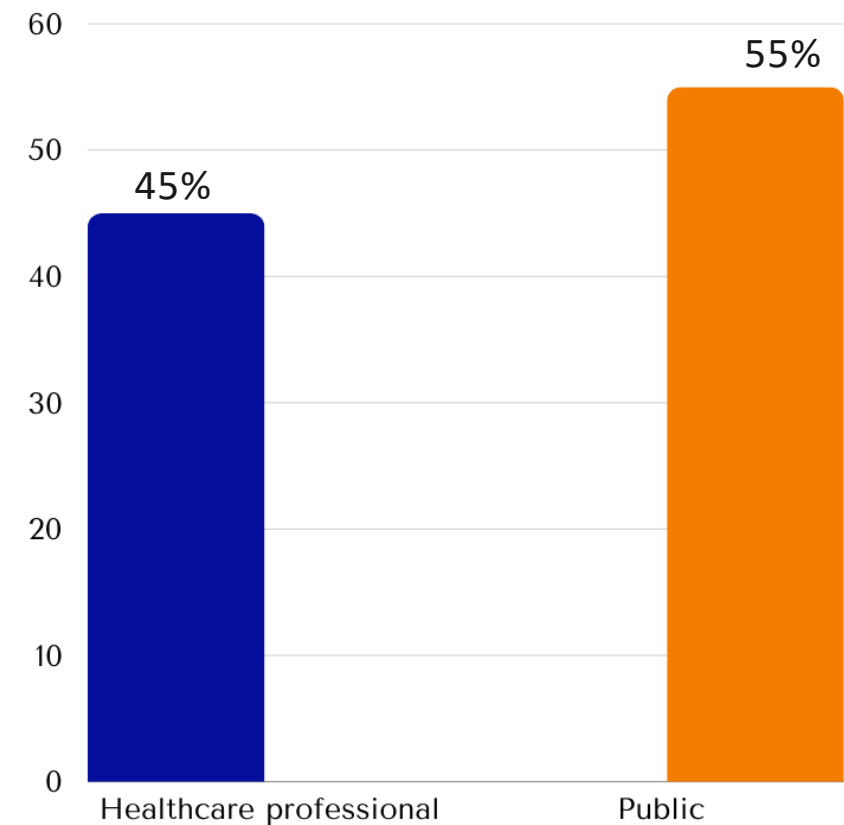


94% of e-labeling products have been accessed through BPOM Mobile application



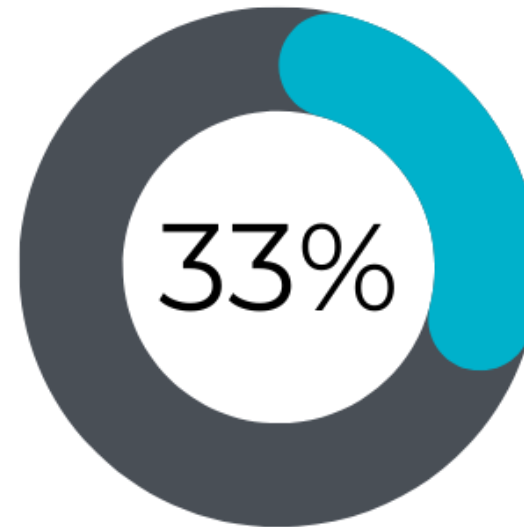
## USE OF E-LABELING BY HEALTHCARE PROFESSIONAL AND PUBLIC

Des 2023 – Feb 2024



# EFFECTIVENESS OF E-LABELING USAGE

Reduction of paper usage by Pharmaceutical Industry



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7 out of 24  
e-labeling products

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have been reported to have  
reduced their paper usage in  
stage-1 e-labeling Pilot Project

# SURVEY SUMMARY OF E-LABELING PILOT PROJECT STAGE 1

01

## Technical obstacles

- Application access
- Internet access

02

## E-labeling version more beneficial

E-labeling version is considered better/more beneficial because it's more preferable and easier

03

## The Print Version still available

Most of survey respondents preferred the print version still available and not deleted

04

## Training and education

The training provided for the use of e-labeling is sufficient, so most of survey respondents don't need any specific e-labeling training or education

# OBSTACLES AND CHALLENGES OF THE E-LABELING PILOT PROJECT

01

The e-labeling pilot project has not yet reached all distribution areas, including remote areas in Indonesia

02

Not all members of the public, including health workers, are aware of the e-labeling pilot project, so wider socialization about e-labeling is needed for the community

03

The reduction in paper usage cannot yet be used as a parameter for the effectiveness of the e-labeling pilot project stage 1 because it's only implemented for vaccine and injection products, and some products still have the print version available

04

There are still obstacles in the process of scanning, reading and downloading e-labeling through the application. Development of technology infrastructure is required, both for the applications used for access and for the applications integrated with e-labeling

# Summary

1. For the implementation of the e-labeling pilot project, it requires readiness of all the key resources including regulation, information system, collaboration, commitment and support from stakeholders to succeed the pilot project e-labelling
2. The Indonesian FDA will continue to oversee the implementation of the e-labeling pilot project to ensure it's runs optimally, and the survey results will be used to assess the sustainability of e-labeling implementation



**BADAN POM**