E-LABELING PILOT PROJECT IN INDONESIA

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Presented at APAC e-labeling Regulator's Workshop
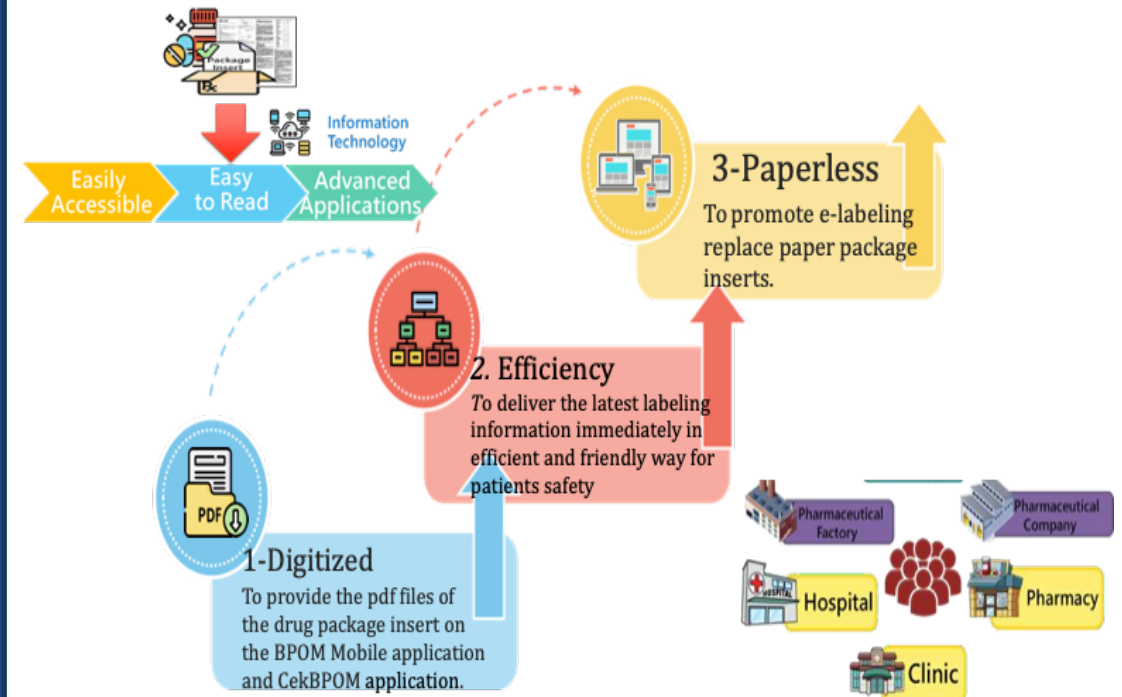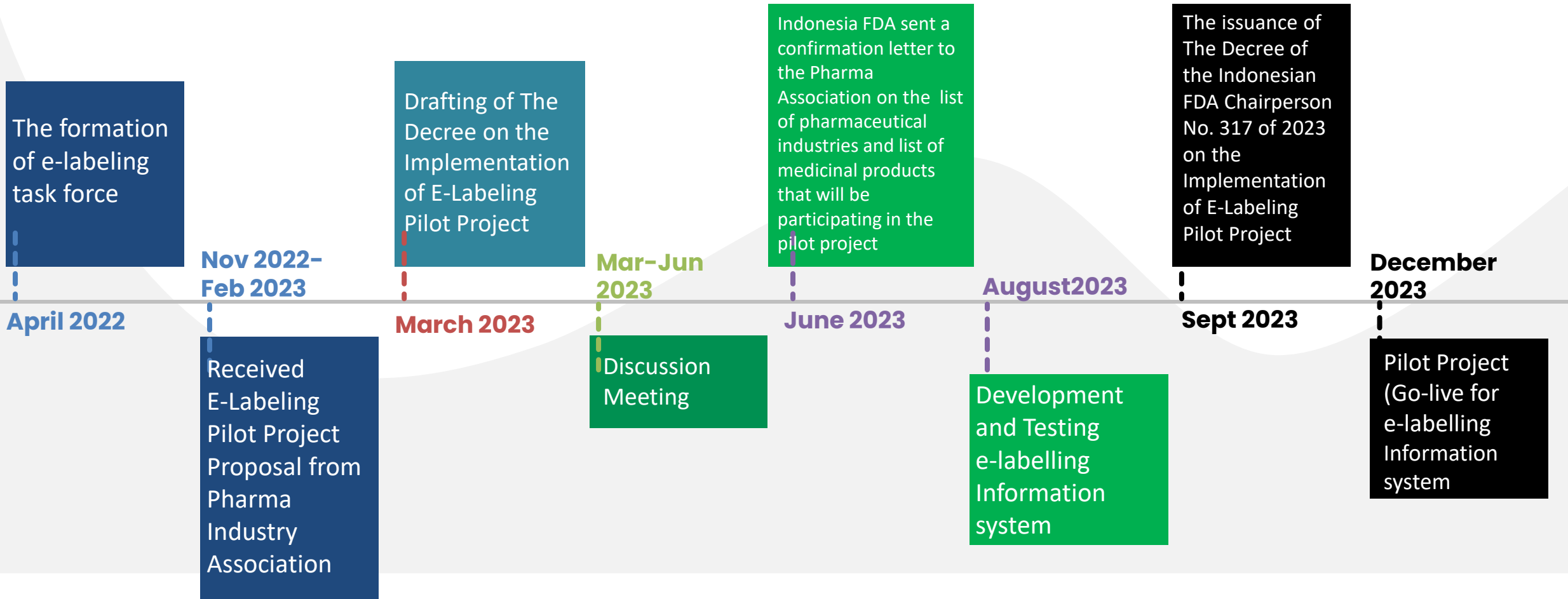April 23th, 2024

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

Easily Accessible — Easy to Read — Advanced Applications

Information Technology

3-Paperless
To promote e-labeling replace paper package inserts.

2. Efficiency
To deliver the latest labeling information immediately in efficient and friendly way for patients safety

1-Digitized
To provide the pdf files of the drug package insert on the BPOM Mobile application and CekBPOM application.

Pharmaceutical Factory — Pharmaceutical Company — Hospital — Pharmacy — Clinic

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

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April 2022
The formation of e-labeling task force

Nov 2022-Feb 2023
Received E-Labeling Pilot Project Proposal from Pharma Industry Association

March 2023
Drafting of The Decree on the Implementation of E-Labeling Pilot Project

Mar–Jun 2023
Discussion Meeting

June 2023
Indonesia FDA sent a confirmation letter to the Pharma Association on the list of pharmaceutical industries and list of medicinal products that will be participating in the pilot project

August2023
Development and Testing e-labelling Information system

Sept 2023
The issuance of The Decree of the Indonesian FDA Chairperson No. 317 of 2023 on the Implementation of E-Labeling Pilot Project

December 2023
Pilot Project (Go-live for e-labelling Information system

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

Paper Label

(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 or electronic label access code on package

Full-scale operation of the e-labelling application

All Safety Information available on BPOM Mobile

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

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
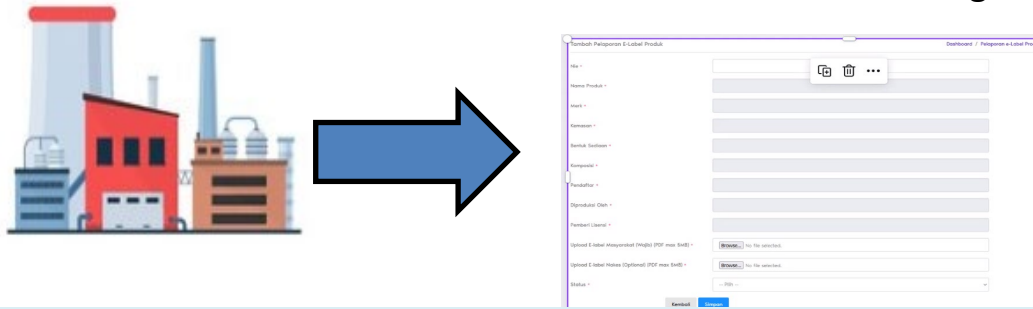
Pharmaceutical Industries Task

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

Process Flow of E-labeling Pilot Project

Track and Trace Apllication (ttac.pom.go.id) hosted by the Indonesian FDA

Module E-Labeling

2D Barcode Authentication

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). Product information will be contained as one of the entities in the two-dimensional barcodes (2D Barcodes) .

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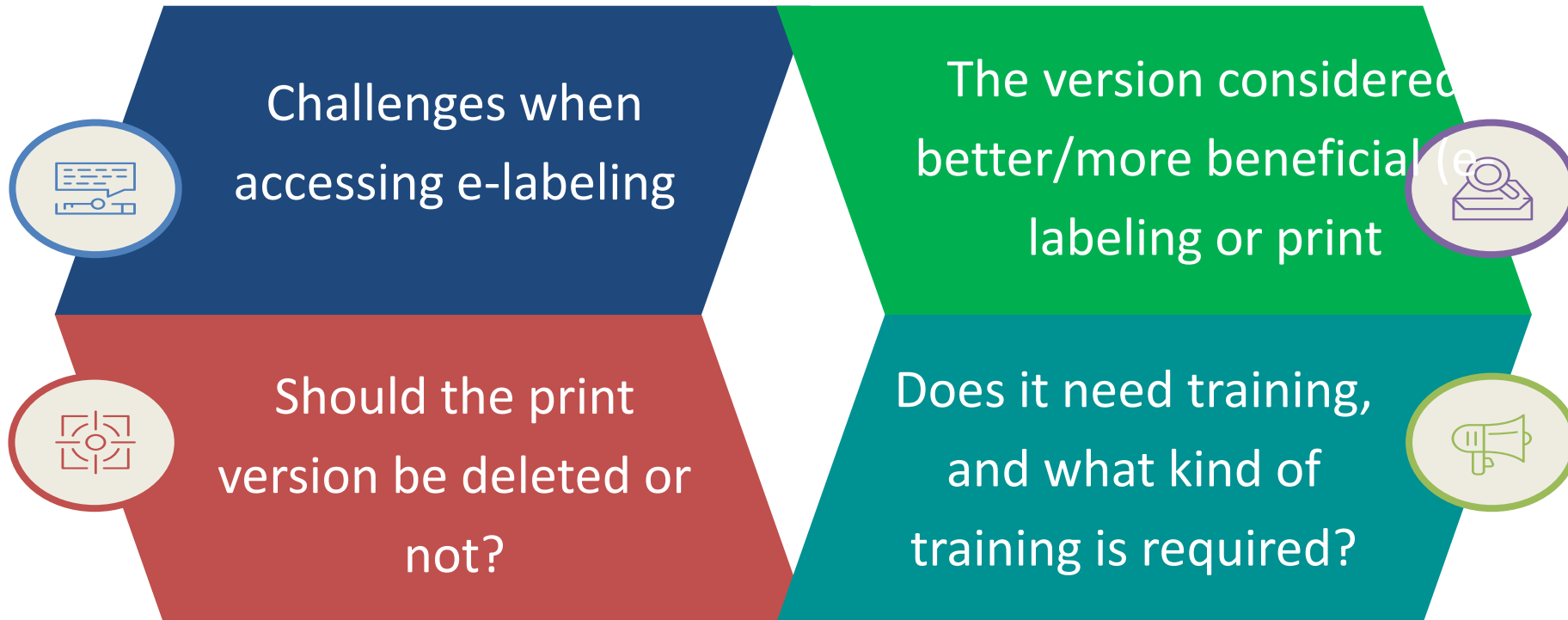
Identification

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/Applestore).
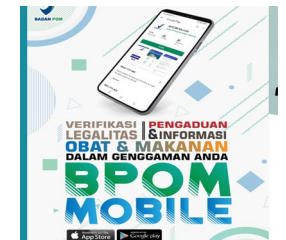
Implementation of the E-labeling Pilot Project Survey

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

Challenges when accessing e-labeling

The version considered better/more beneficial (e-labeling or print

Should the print version be deleted or not?

Does it need training, and what kind of training is required?

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
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

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
2) Filling out the e-labeling survey to assess the effectiveness of e-labeling usage

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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%

66,7% of 24 products have already implemented e-labeling
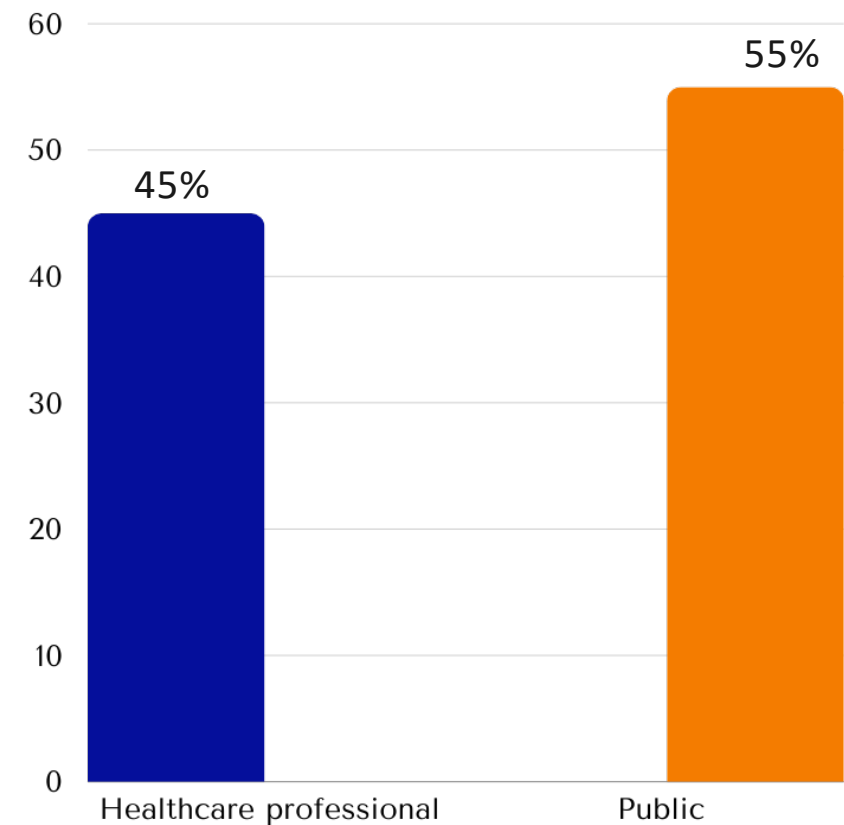
E-LABELING ACCESS BY BPOM MOBILE APPLICATION

94%

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

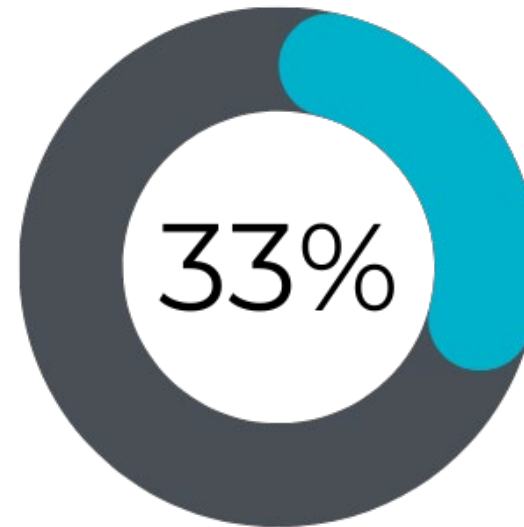Asia Partnership Conference of Pharmaceutical Associations

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

33%

7 out of 24 e-labeling products

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

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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