"Advancing Sustainability and Circularity"

IMPLEMENTATION OF UDI, E-LABELLING, AND E-IFU IN MALAYSIA

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GS1 Malaysia Summit 2025 | 01

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BACKGROUND

What is MDA?

What is happening in the medical device industry now?

About Medical Device Authority (MDA)

1. Federal agency under the Ministry of Health
2. Implements & enforces Medical Device Act 2012 (Act 737)
3. Ensures public health & safety in relation to medical devices
4. Facilitates medical device trade & industry growth

Press & News Highlights

1. Malaysia Launches Regulatory Reliance with China

06

Medical Device Regulatory Reliance Programme

(Launched 16 July 2025 – MDA & China NMPA)

- Mutual recognition of regulatory decisions for IVDs
- Malaysia → China: Access to *Green Channel* (60 working days)
- China → Malaysia: Access to *Verification Pathway* (30 working days)
- Reduces duplication, accelerates market access
- Strengthens Malaysia's role as a regional regulatory hub

Press & News Highlights

2. MOU & Medical Device Regulatory Reliance Pilot with Singapore

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Malaysia–Singapore Regulatory Reliance Pilot

(MOU signed 22 Aug 2025 – MDA & HSA)

- Fast-tracks market access for medical devices
- Uses shared regulatory assessments to reduce duplication
- Built on bilateral discussions (*3 July 2024*)

Press & News Highlights

3. Malaysia Eyes MedTech Leadership at IMDEC

PM Anwar at IMDEC 2024

(Closing Speech – 12 Dec 2024)

- Malaysia to be a regional leader in high-tech medical devices & healthcare innovation
- Government to boost infrastructure, workforce skills & adoption of AI, IoT, 5G
- Supported by RM45 billion allocation in Budget 2025
- As ASEAN Chair in 2025, Malaysia will advance Mutual Recognition Arrangements (MRAs) and integrated regulatory frameworks

Goal: Faster access to safe, effective medical devices across ASEAN

Press & News Highlights

4. MedTech Growth Fueled by Strong Policies

Malaysia’s Medtech Growth

(Minister Tengku Zafrul – Early 2025)

- Malaysia on track to be a global medtech hub under NIMP 2030
- Exports: RM28.15b (2023) → +30% growth in first 9 months of 2024
- Industry encouraged to focus on personalized medicine, digital health & robotics

RECAP

What we did last year

14 | UDI Timeline

*assuming MeDC@St 3.0+ is completed

2024

Pilot Survey

UDI framework development including a pilot survey for Class D and B medical devices and data analysis

2026

Transition Phase*

Voluntary implementation phase for all medical device classes

2027

Class D Mandatory Phase 1

UDI implementation for all Class D medical devices

2028

Other than Class D Mandatory Phase 2

UDI implementation for other than class D medical devices

2030

Full UDI Compliance

Full UDI compliance in Malaysia

15 | Mesyuarat MICC Bil. 1/2025

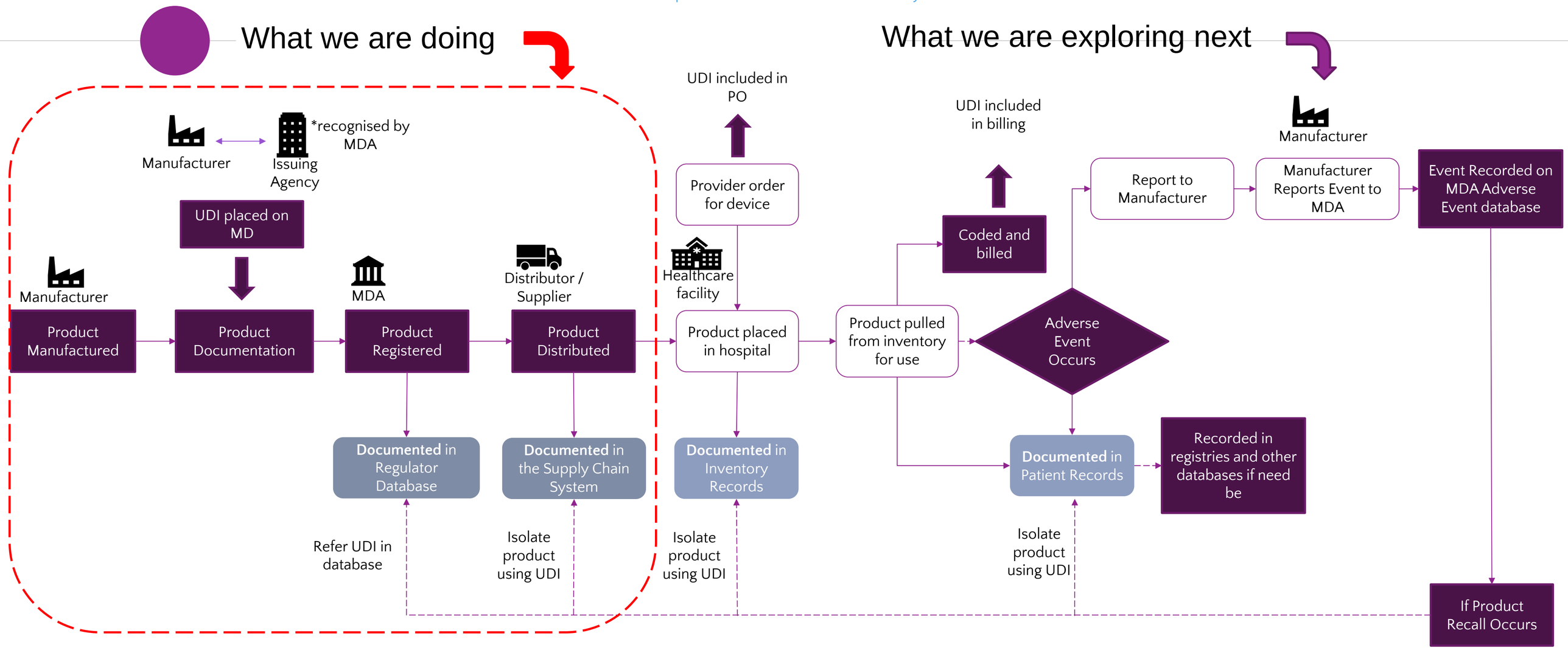
Announced UDI implementation to the medical device industry representatives on the 8th of July 2025

PLANNING

What we are doing next

UDI framework

*Future expectation to be achieved from UDI System



https://www.pewtrusts.org/-/media/Assets/2015/02/PEW_UDI_Implementation_Guide.pdf?la=e

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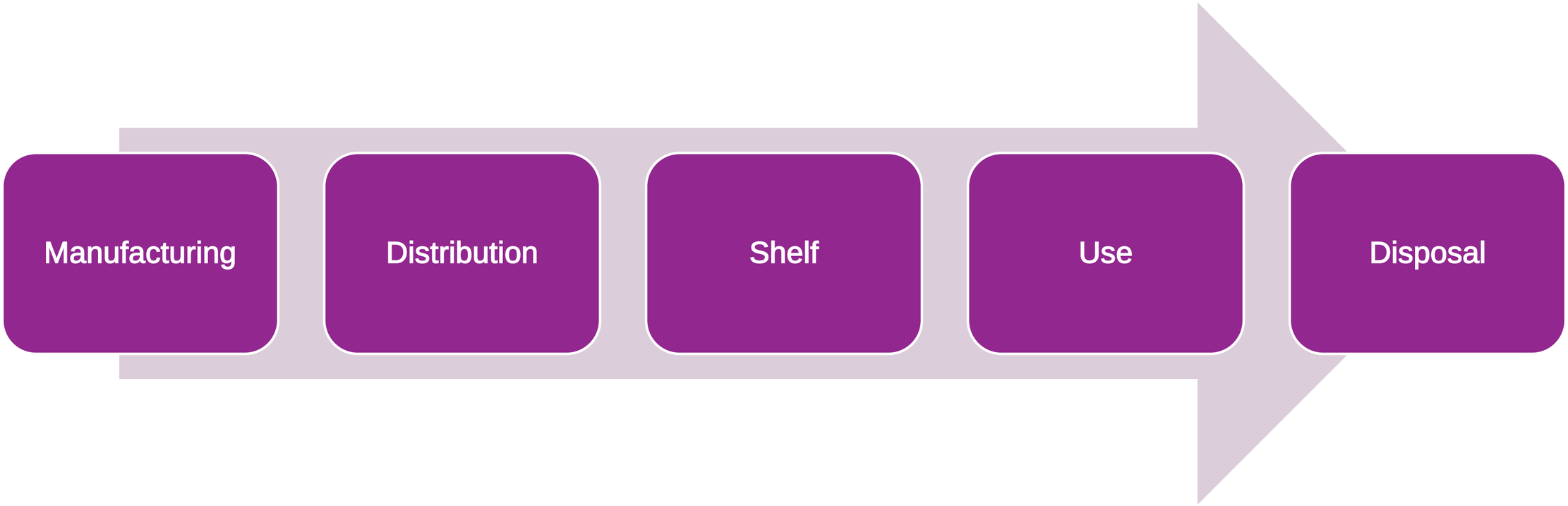
To track and trace medical devices from “cradle” to “grave”



Keyword is “Optimized”

MDA is exploring a track-and-trace system to streamline the medical device industry by eliminating redundant submissions of UDI information.

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“e” stands for electronic

e-Labelling

“Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be accessed (such as through a website).”

e-IFU

“Instructions for Use (IFU) is part of the medical device labelling that provides the information supplied by the manufacturer to inform the user of the device’s proper and safe use, its performance, any precautions, warnings, or contraindications, and necessary maintenance or handling instructions.”

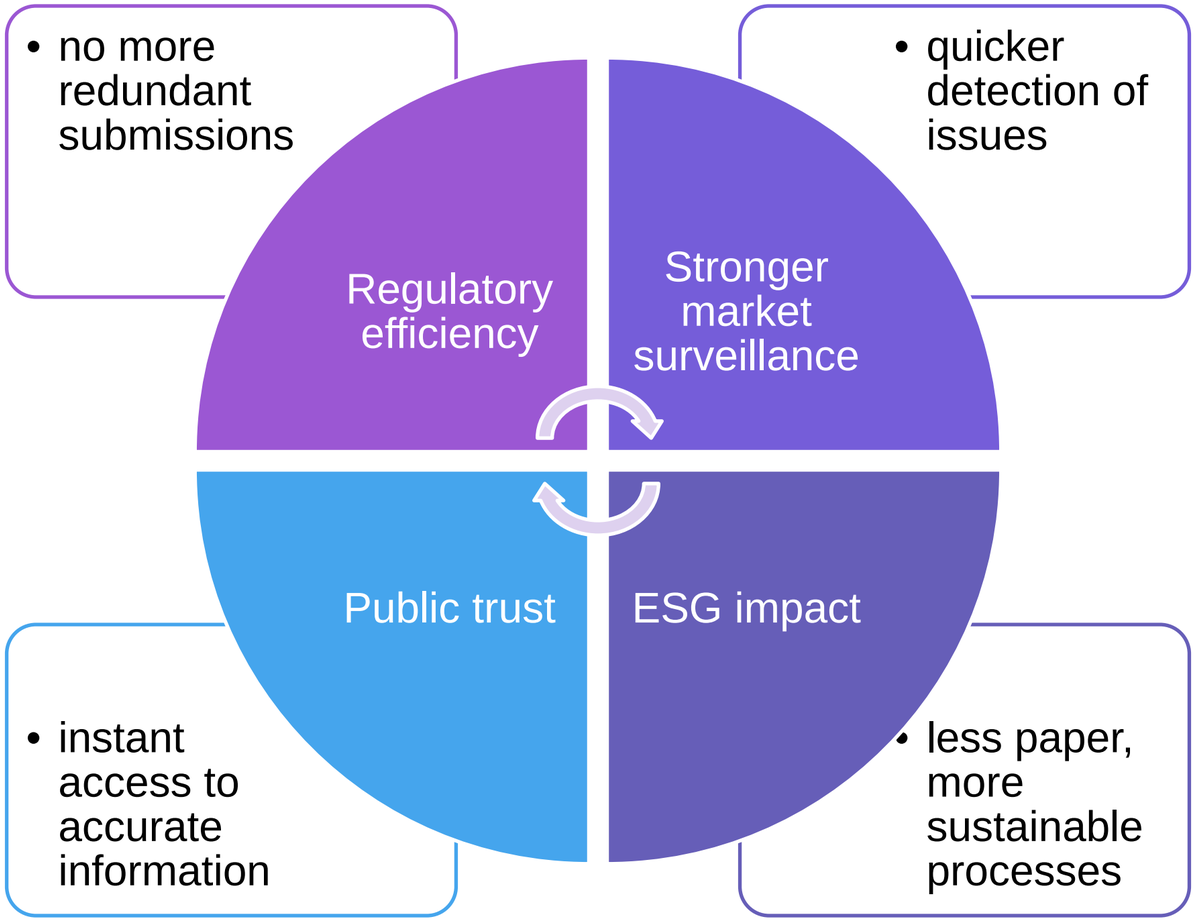
Our Aim for Track & Trace System

To provide a one-stop page containing all relevant information about the medical device.

EXPECTATION

What we expect

23 | Expectation



THANKS!

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