Medical Device Unique Device Identification (UDI) system in Singapore

Medical Devices Branch

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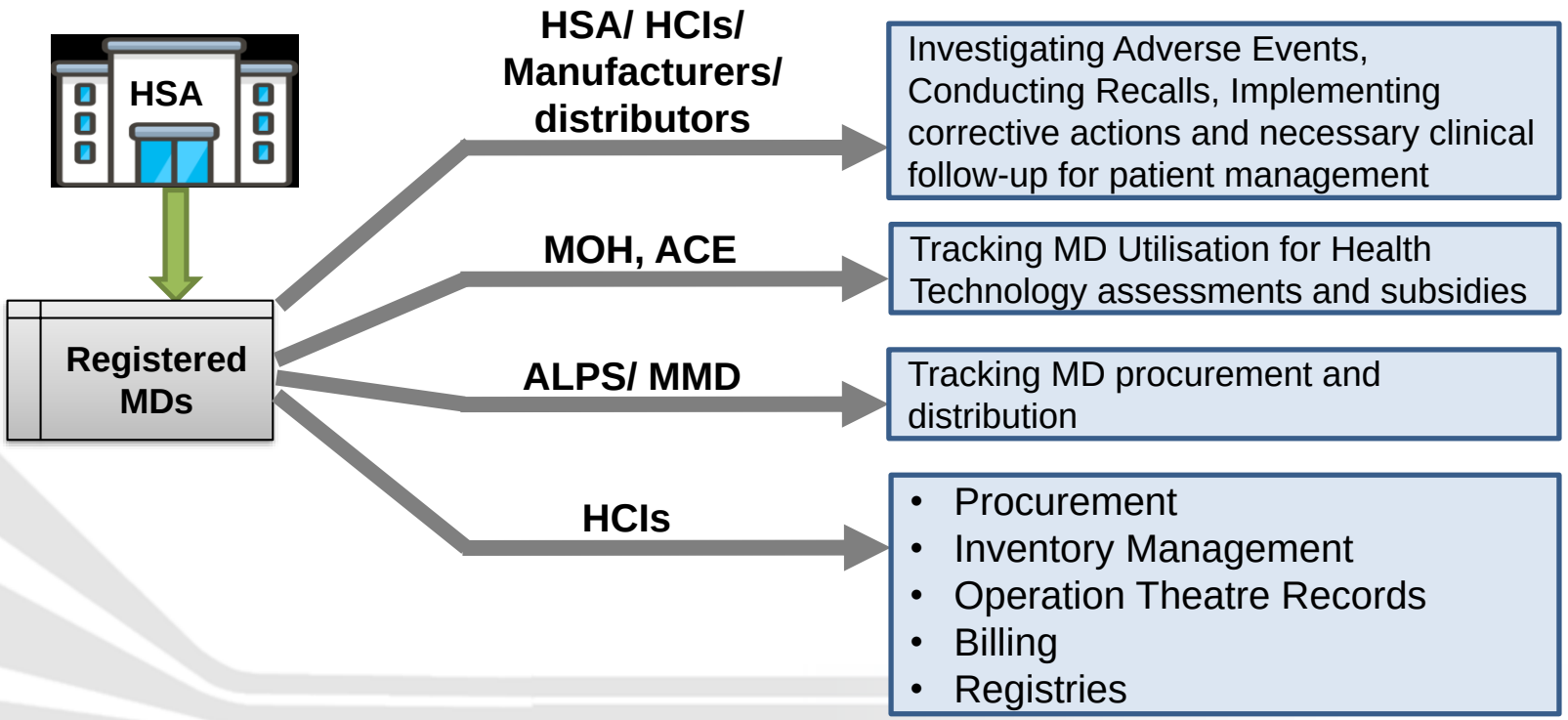
Overview

- Current system of tracking MDs
  - Limitations
  - Consequences
- Unique Device Identifier (UDI)
- Global UDI implementation status
- Implementing UDI in Singapore
  - Implementation Approach
  - Phased implementation plan

Tracking MDs in our healthcare system

- There are over 17,500 moderate and high risk medical devices registered in Singapore; they are used very widely in the healthcare system (e.g. implants such as stents and heart valves, ventilators and vital signs monitors, surgical instruments and consumables such as catheters, guidewires and sutures)
- Medical devices are tracked for various purposes as illustrated below:



Limitations of the current tracking system

- Lack of standardised identification code
  - Currently there is no standardised identification code or system in Singapore resulting in:
    - lack of synergy in information captured across multiple databases within the healthcare system, causing poor flow of information
    - inconsistency in the data fields and attributes (e.g. Device name, lot number, model information) captured manually from diverse sources (e.g. device labels, invoice, catalogues)

- Manual recording by hospital users
  - Some users (e.g. operation theatres) continue to manually record implants information in their databases for most MDs used on patients, resulting in:
    - Inefficient and error prone work flow arising from manual data entry
    - Higher probability of inaccurate data capture for certain complex implant systems comprising multiple device models and components (e.g. orthopaedic implants)
    - Valuable healthcare resources for high value care delivery work spent on manual tasks instead

Consequences

- Inefficient/ inaccurate identification of MDs used on our patients
  - Delay in follow-up actions (e.g. stop use of affected MDs) in the event of a recall or device failure or potential adverse event affecting the MD
  - Inaccurate billing within the hospital arising from the inaccurate or incomplete data captured (e.g. human error during manual data entry)
  - Inaccurate or inadequate information on MD utilisation locally

- Delay in identifying and tracing patients treated with the affected MD
  - Delay in delivering recommended or additional patient care or clinical follow-up that could potentially impact patient health and safety

→ Need for a harmonised identification system that could potentially automate tracking of MDs in our healthcare system

Unique Device Identifier (UDI)

- UDI could serve as the “standardised identification code” on MDs used in Singapore to improve the traceability of MDs and identification of patients treated with specific MDs impacted by recalls, device failures or serious adverse events
  - UDI could improve traceability for multiple stakeholders: regulators, hospital users and industry, including manufacturers and distributors

- UDI, if adopted and implemented throughout our healthcare system, could improve efficiency and minimise data capture errors

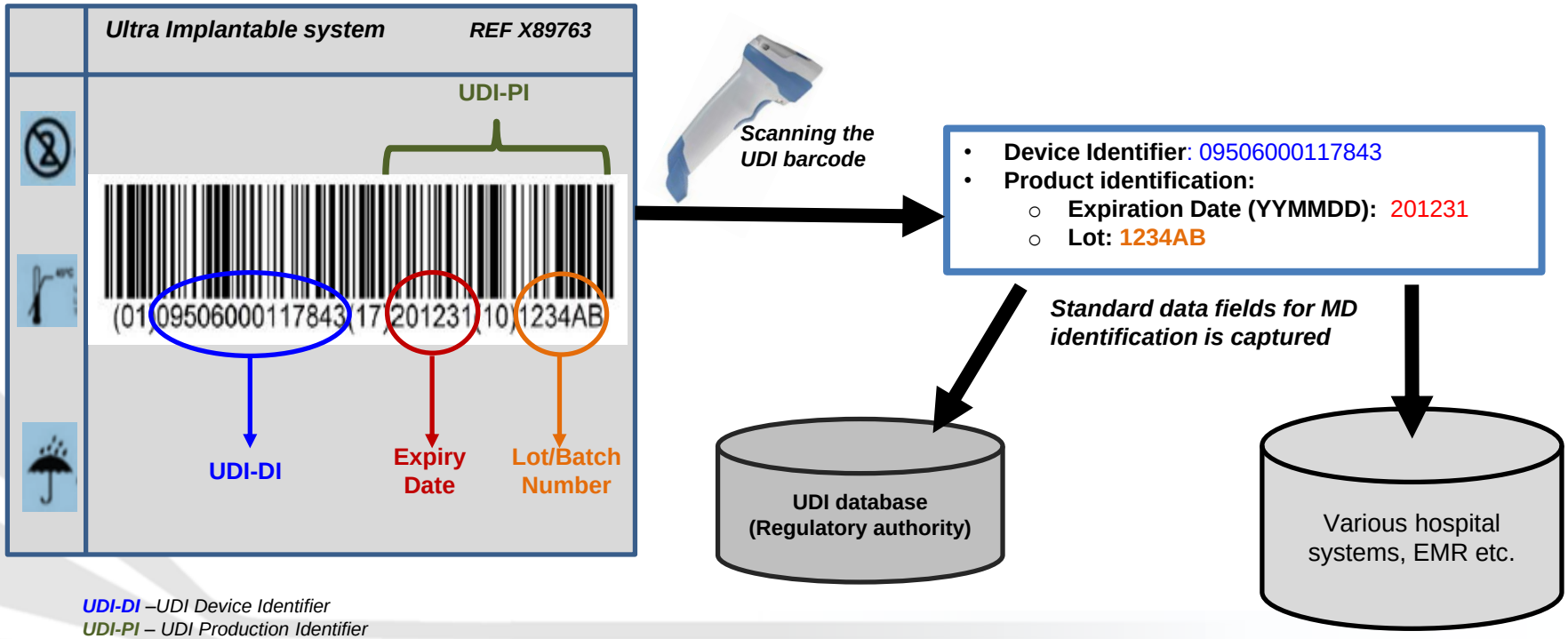
UDI

- A numeric or alphanumeric code that comprises of two parts: UDI-Device Identifier (UDI-DI) and UDI-Production Identifier (UDI-PI)

  - Device Identifier (UDI- DI)
    - A unique numeric or alphanumeric code specific to a model of medical device
    - Mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package configuration
    - Used as the "access key" to information stored in a UDI database (UDID)
  - Production Identifier (UDI- PI)
    - A numeric or alphanumeric code that identifies the unit of device production
    - Includes serial number, lot/batch number, software version and manufacturing and/or expiration date
  - Data Delimiters
    - Included in the Human Readable Information of the UDI to allow for legible interpretation of the coded information
    - Different pre-determined Data Delimiters are used by different issuing agencies (e.g. GS1 – (01), (11) etc.; HIBCC - $, $$7 etc.; ICCBBA - =/, => etc.)

UDI System

- An international system for identification of medical devices.
  - Enables automatic capture of standard information by a single barcode scan
  - The key information is also presented in human readable interpretation (HRI) format below the barcode



UDI-DI –*UDI Device Identifier*
UDI-PI – *UDI Production Identifier*

Global implementation status

- UDI is an international system for identification of MDs, and is adopted by the IMDRF (International Medical Device Regulators Forum)
  - Provides a harmonised approach to the implementation of UDI globally

- The UDI requirement for MDs is in different stages of implementation globally
  - **USA:** UDI has been implemented for all MDs (except some lowest risk MDs)
    - Phased implementation started with high risk MDs in 2014
  - **EU:** Implementation will start with high risk MDs in 2021
  - **Australia:** UDI requirements under consultation
    - Published for consultation in 2018 and 2019 respectively
  - **China and Korea**: Started UDI implementation process.

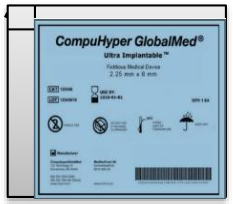
2 key parts for UDI implementation in healthcare system

Manufacturer

Submit/
Update UDI
information

HSA

MD online database



UDI labelled MD

Tracking MDs
by scanning
the UDI
barcodes

Other Uses

Procurement

Inventory

Payment System

Registries

EMR

Improve Identification
& Traceability during
MD recalls or safety
issues

HSA, MD Industry

HCIs, MOH, IHiS

PART 1: Making UDI available on the labels of MDs in Singapore

PART 2: Implementing & using the UDI in our healthcare system for MD Track and Trace

PART 1: Making UDI available on MDs in Singapore

Implementing UDI on MDs in Singapore

- Aligned to internationally harmonized principles outlined in the UDI guidance published by the International Medical Device Regulators Forum (IMDRF)
  - UDI guidance in 2013 (IMDRF/UDI WG/N7FINAL:2013)
  - UDI Application Guide (IMDRF/UDI WG/N48 FINAL:2019)

- Adopt a risk-calibrated approach to implementation of UDI

- Recognise the following organisation to operate a system for the assignment of Unique Device Identifiers according to specified requirement:
  - GS1
  - Health Industry Business Communications council (HIBCC)
  - International Council for Commonality in Blood Banking Automation (ICCBB

Implementing UDI on MDs in Singapore

- The approach to implementing the UDI requirement on MD labels for Singapore, is as follows:

1. Accept the UDI barcodes as is that manufacturers have applied on their MD labels for the **USA and/or EU** (reference agencies)
   - No Singapore specific UDI will be required for such MDs

2. The UDI information will be captured and published on the Singapore Medical Device Register (SMDR), an online database for registered medical devices which is available to the public.
   - SMDR already captures most of the essential data such as intended use, name of product owner, etc for registered MDs
   - SMDR is fit-for-purpose to serve as the database for UDI related information – No new database is required
   - Minimum necessary additional UDI related data fields will be incorporated into our current SMDR database

Implementing UDI on MDs in Singapore

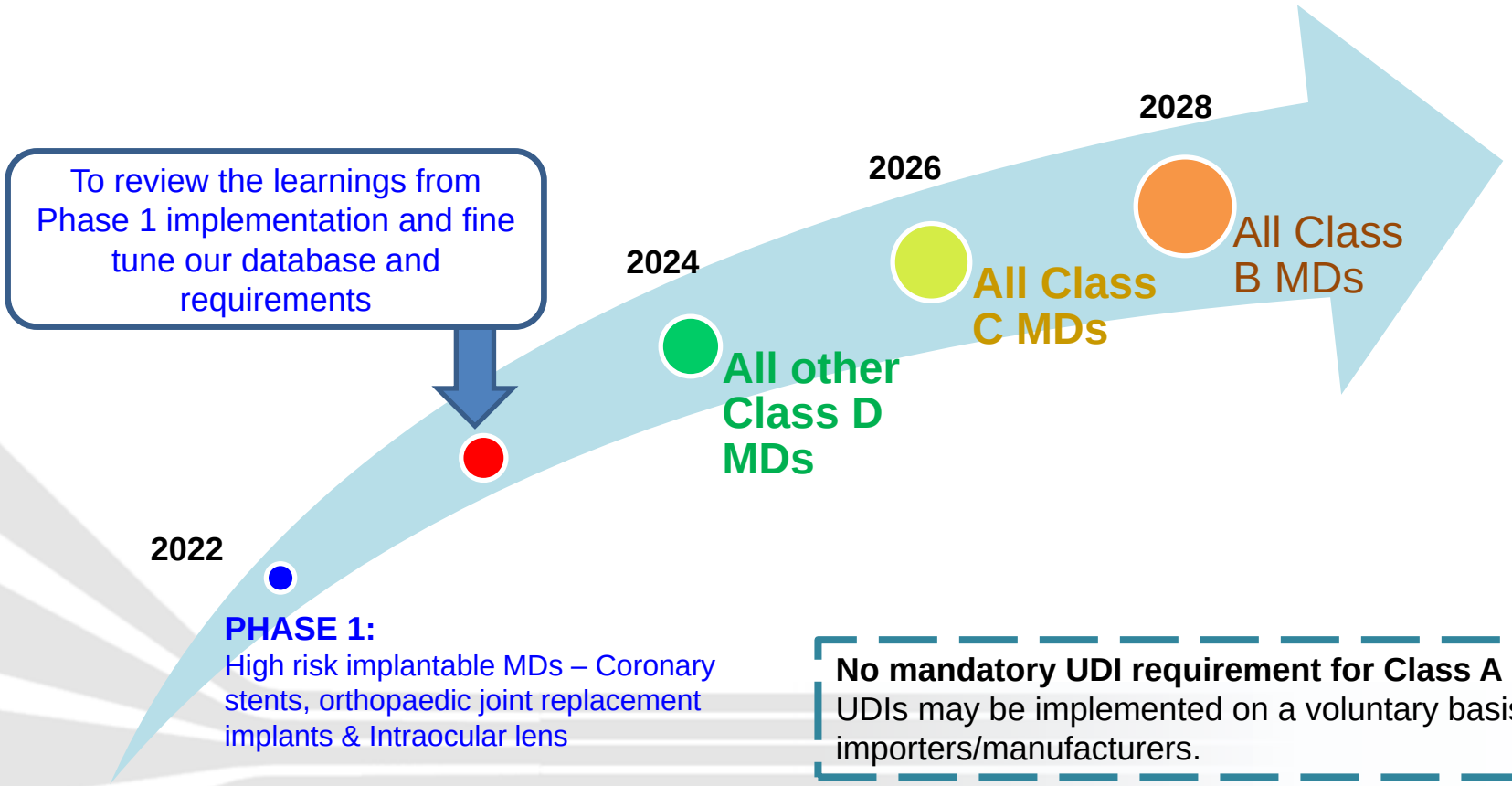
3. Phased implementation approach:

The phase 1 of implementation to start in 2022 (2 years' time) to allow for adequate preparation time for all stakeholders

- In Phase 1:
  - Only **three types** of high risk implantable MDs will be required to be labelled with UDI
    - **Coronary stents, orthopaedic joint replacement implants & Intraocular lens**
- The 3 subsequent phases of implementation will start 2 years after each phase
  - Only medium to high risk MDs will require UDI label
  - For low risk MDs (Class A), UDI will not be mandatory.
    - Can be implemented on a voluntary basis e.g. already labelled in country of origin

Phased Implementation Timeline

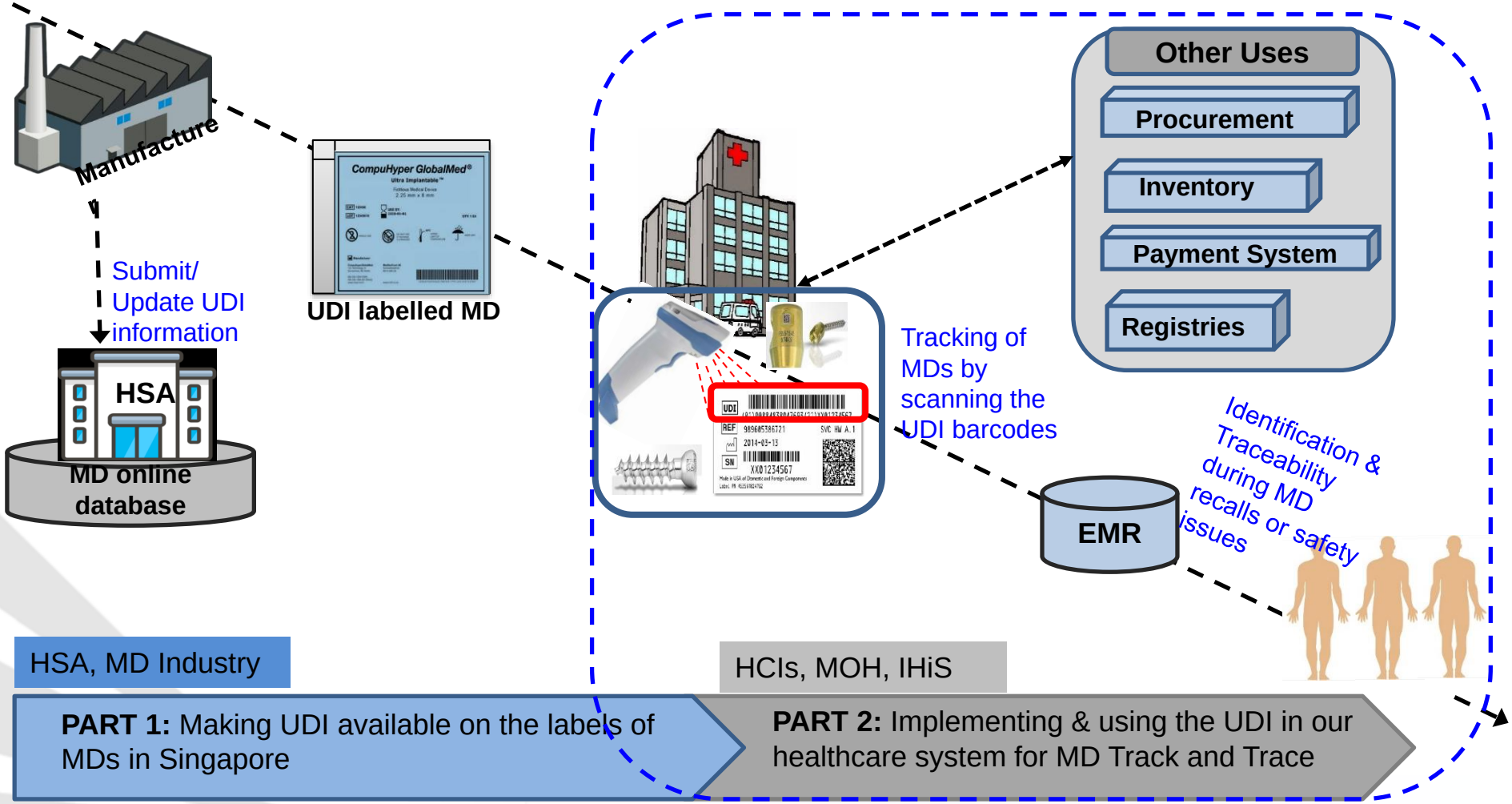
- Information must be submitted to our registered medical device database, Singapore Medical Device Register (SMDR) prior to year 2022.
- Starting from year 2022, the respective categories of MDs in Phase 1 must bear UDI on labels.



No mandatory UDI requirement for Class A MDs. UDIs may be implemented on a voluntary basis by the importers/manufacturers.

PART 2: Implementing UDI in our healthcare system

UDI in healthcare system



Part 2: Implementing UDI in our healthcare system

- Full benefits and purpose of UDI implementation will be realised when both Part 1 and Part 2 of implementation are completed

- Some benefits of adopting UDI in healthcare system include:
  - Consistent and efficient recording of MD related information in the hospital IT systems
  - Better information flow across the various hospital systems (e.g. procurement, billing, patient records)
  - Enable faster tracing of MDs and the affected patients in the event of MD recalls or defects, when HCIs and patients require corrective actions in a timely manner

- MOH, IHiS, ALPS and HCIs are the key players in implementing Part 2

Smoothening Implementation

- To develop guidance on UDI requirements and the steps to submit UDI information on SMDR
- To consult industry stakeholders on the guidance prior to implementation and update contents as necessary
- To engage and assist local/regional manufacturers who do not supply their MDs to any of the overseas markets(USA or EU) to facilitate implementation
  - To work with Industry associations, issuing agencies (e.g. GS1) and other agencies
- An online feedback system catered specifically for UDI related matters has been set up to facilitate the process ***(Link on next slide)***

THANK YOU

If you have feedback or questions related to UDI, please submit them using this online form:

https://form.gov.sg/5f7593fd44ac8c0011c5fd1b

Annex

- Examples of UDI labels issued by each issuing agencies:

Issuing agencies	Link
GS1	http://www.gs1.org/sites/default/files/docs/healthcare/udi_label_samples_-_20150317.pdf
HIBCC	http://www.hibcc.org/wp-content/uploads/2016/02/HIBCC-UDI-Label-Examples.pdf
ICCBBA	https://www.iccbba.org/subject-area/medical-devices/label-examples

Reference: IMDRF/UDI WG/N48 FINAL: 2019