Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar 4 – 21 September 2021

The role of a UDI Issuing Agency

Michelle van Wijk

UDI Project Manager
Therapeutic Goods Administration

21 September 2021

TGA Health Safety Regulation

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- Questions – please use the **Q&A** tool when I open this function
  - Q&A will occur after todays presentation
  - Your questions are only visible to the panel
- If you need to contact the moderator – please use the **'Chat'** function
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The role of a UDI Issuing Agency

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TGA Health Safety Regulation

Today's presentation

Invited guest speaker – Géraldine Lissalde-Bonnet

Progress update

Questions and answers

Guest presenter – Géraldine Lissalde-Bonnet Director Public Policy - GS1 Global Office

- Leads the GS1 Healthcare Global Public Policy Work Team, which has the mission to interact with decision makers globally and to provide strategic leadership on the use of GS1 standards in the healthcare sector.

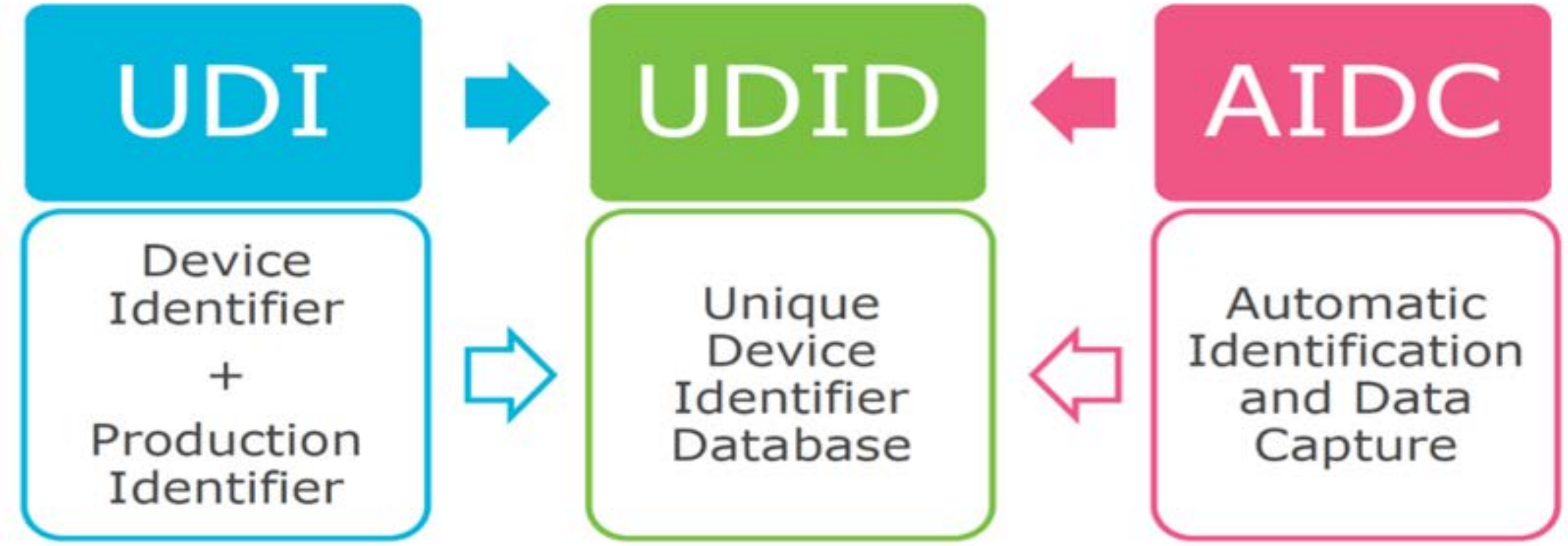
- Works with local GS1 colleagues in 115 countries across the world on regulatory harmonisation through the implementation of GS1 standards in the healthcare industry.

Disclaimer

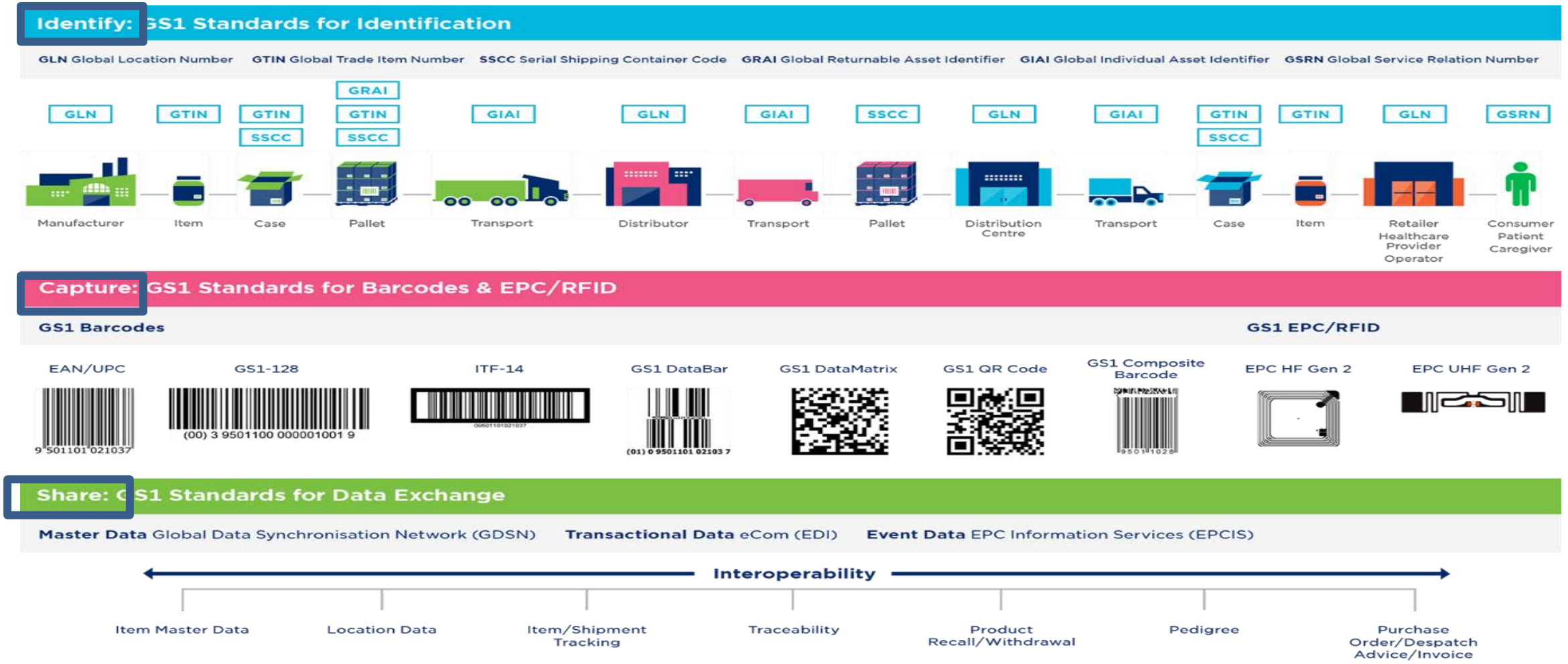
Neither GS1 nor its member organisations nor their staff have *real or apparent authority to speak for the regulatory authorities* or grant exemptions. GS1 offers **advisory services focused on GS1 Standards** after a supplier's staff, including its internal regulatory experts, have determined the correct path to compliance. GS1 is a voluntary organisation and its members have determined and must continue to determine their own course of action. GS1 provides recommendations. GS1 Global Office, GS1 member organizations and GS1 staff assume **no liability for members actions taken upon its advice.**

Importance and benefits of global harmonisation

UDI system as defined by the IMDRF



GS1 system of global standards



GS1 is supporting the IMDRF and is a Liaison Member to the AHWP … supporting global harmonisation

Mandated by ANMAT for traceability of certain devices in Argentina

99% of medical devices identified with GTIN in Japan

MHLW Annual Survey, 2012

£3 million on average saved each year in every NHS hospital in England

Lord Carter interim report, 2015

UDI issuing agency/entity in China, EU, Saudi Arabia, South Korea, Singapore, U.S.A. – and more to come

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

GS1 standards also used for identification of medical devices in Netherlands, Qatar, UK …

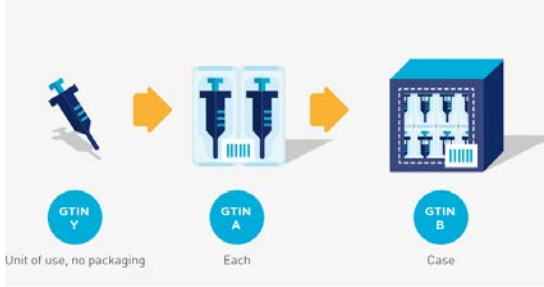
GS1 provides support to regulators as they develop and implement their UDI requirements

Acronym decoder:

IMDRF – International Medical Device Regulators Forum
ANMAT – National Administration of Drugs, Foods and Medical Devices (Argentina)
GTIN – Global Trade Item Number
AHWP – Asian Harmonization Working Party
NHS – United Kingdom National Health Service
MHLW – Ministry of Health, Labour & Welfare (Japan)

Identify: UDI in GS1 AIDC terms

UDI regulatory requirements	GS1 Standards
Required in the EU **Basic UDI-DI** « New » level of identification in the EU	**GMN** (Global Model Number) *No Application Identifier (AI) for regulated medical devices*
UDI-DI * Device Identifier (DI)	**GTIN** * Global Trade Item Number
UDI-PI * Production Identifier (PI) *(if applicable)*	**AI** * Application Identifier (AI) • Expiration date AI(17) - e.g. 141120 • Batch – lot AI(10) - e.g. 1234AB • Serial number AI(21) - e.g. 12345XYZ • Manufacture date AI(11) - e.g. 250717
Production Identifier data will vary by medical device type and manufacturer current practice.	
UDI-DI + UDI-PI = UDI	**GTIN or GTIN + AI(s) = UDI**



* **Note:** The Human Readable Interpretation (HRI) formats shall follow the rules of the UDI Issuing Entity

GS1 Healthcare GTIN Allocation Rules

Purpose and regulatory disclaimer

This document aims at providing a globally harmonised framework for the implementation of the GS1 standards in order to improve supply chain efficiency and ensure patient safety.

Important: The Healthcare GTIN Allocation Rules represents a minimum requirement. Please be advised that there may be regulation(s) in your market area that are more stringent and SHALL be adhered to. Refer to the Healthcare Public Policy Interactive Map for more information.

The rules of the issuing agency and the rules within a regulation form two layers of the requirements that work together to identify products throughout their lifecycle, across the supply chain and through to patients – and beyond. The issuing agency and the regulators are working to ensure alignment. The rules within a regulation always supersede the rules of the issuing agency.

Alignment on identification rules

Guiding Principles for making good decisions

At least one of the following **guiding principles** must apply for a GTIN change to be required

Product Contained in Package: Is a stakeholder (e.g. care providers, consumers, patients, regulatory authorities and/or trading partners) expected to distinguish the changed or new product from previous/current products?

Label/Package: Is there a regulatory or liability requirement to disclose a change to the consumer and/or trading partner?

Label/Package: Is there a substantial change impacting the supply chain (e.g., how the trade item is shipped, stored, received or handled in the clinical setting)?

GTIN Management | GS1 - The global language of business

Capture: Examples of UDI marking using GS1

Label Example

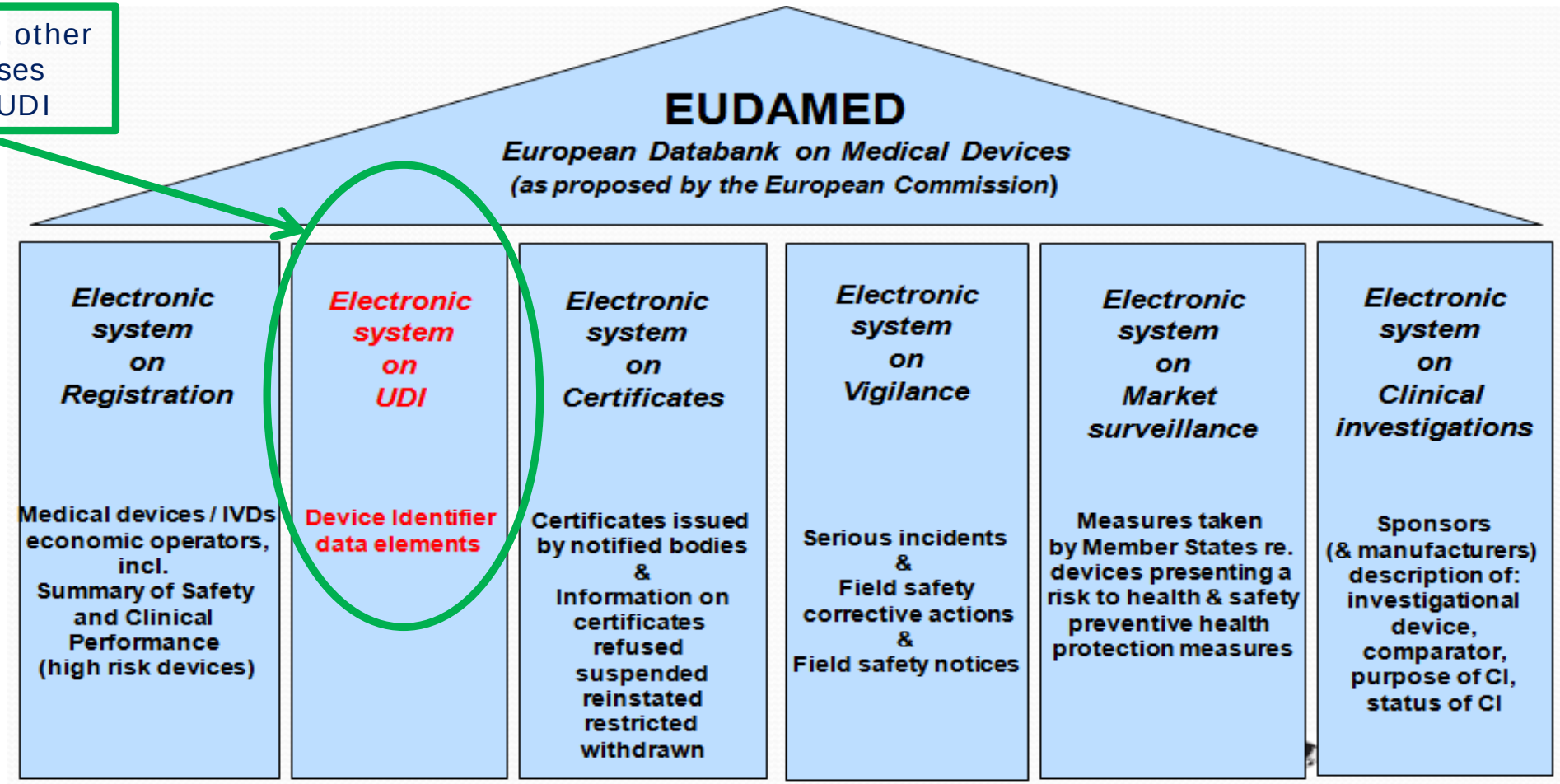
Direct Part Marking

Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers
(e.g. lot number, expiry date)

Share: UDI regulatory databases

As of today, other UDI databases focuses on UDI



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Data attributes: minimum viable elements focus

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Issuing Agency	Organization accredited by EU to operate a system for the issuance of UDIs.	Choose a value from the drop down.	single	MAN	alphanum, 30	GS1; HIBCC; ICCBBA	Yes
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing a full UDI.	GS1 - 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	single	MAN	numeric or alphanum, 6-23 characters		Yes
Device Count	Number of medical devices in the base package. For example : Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	Enter a numeric value.	single	MAN	numeric, 7		Yes
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	GS1 - 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.	single	MAN - if device count is > than 1	numeric or alphanum, 6-23 characters		No
Manufacturer DUNS Number	[illegible]	[illegible] DUNS Number from drop down.	[illegible]	[illegible]	[illegible]	[illegible] DUNS in [illegible]	No

There will be local differences, but hopefully maximum alignment

Data submission: machine-to-machine submission is essential for data quality

[Machine-to-Machine-data-submission-discussion-paper-FINAL.pdf (gs1.org)]

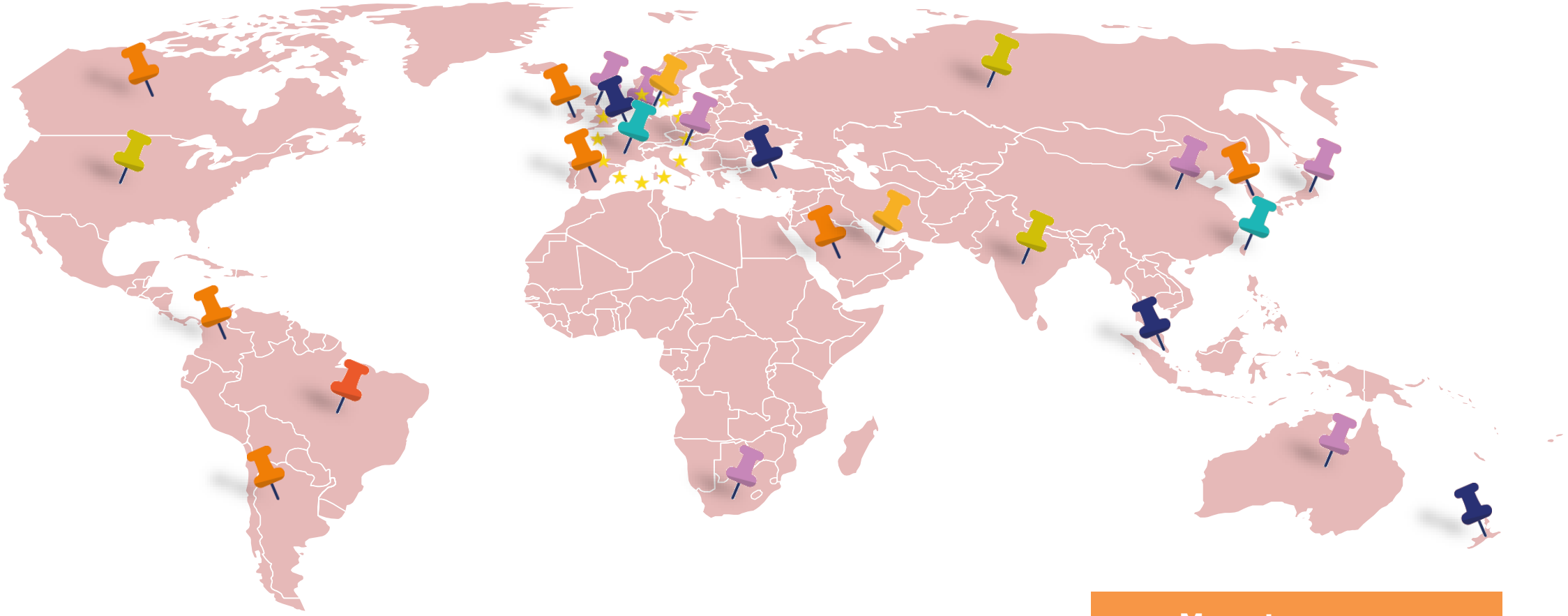
The need to align on a global UDI framework

- UDI is very beneficial - it is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system:
  - N7:2013 Unique Device Identification guidance document
  - N48:2019 Unique Device Identifier (UDI) Application Guide
  - N53:2019 IMDRF guidance on data elements, use of Data Elements across IMDRF Jurisdictions

➢ This will ensure :
- highest levels of patient safety beyond borders
- harmonised identification systems for medical devices globally

Need for collaboration and knowledge sharing among stakeholders

Requirements for medical devices identification



More to come...

Joint Initiative Council:

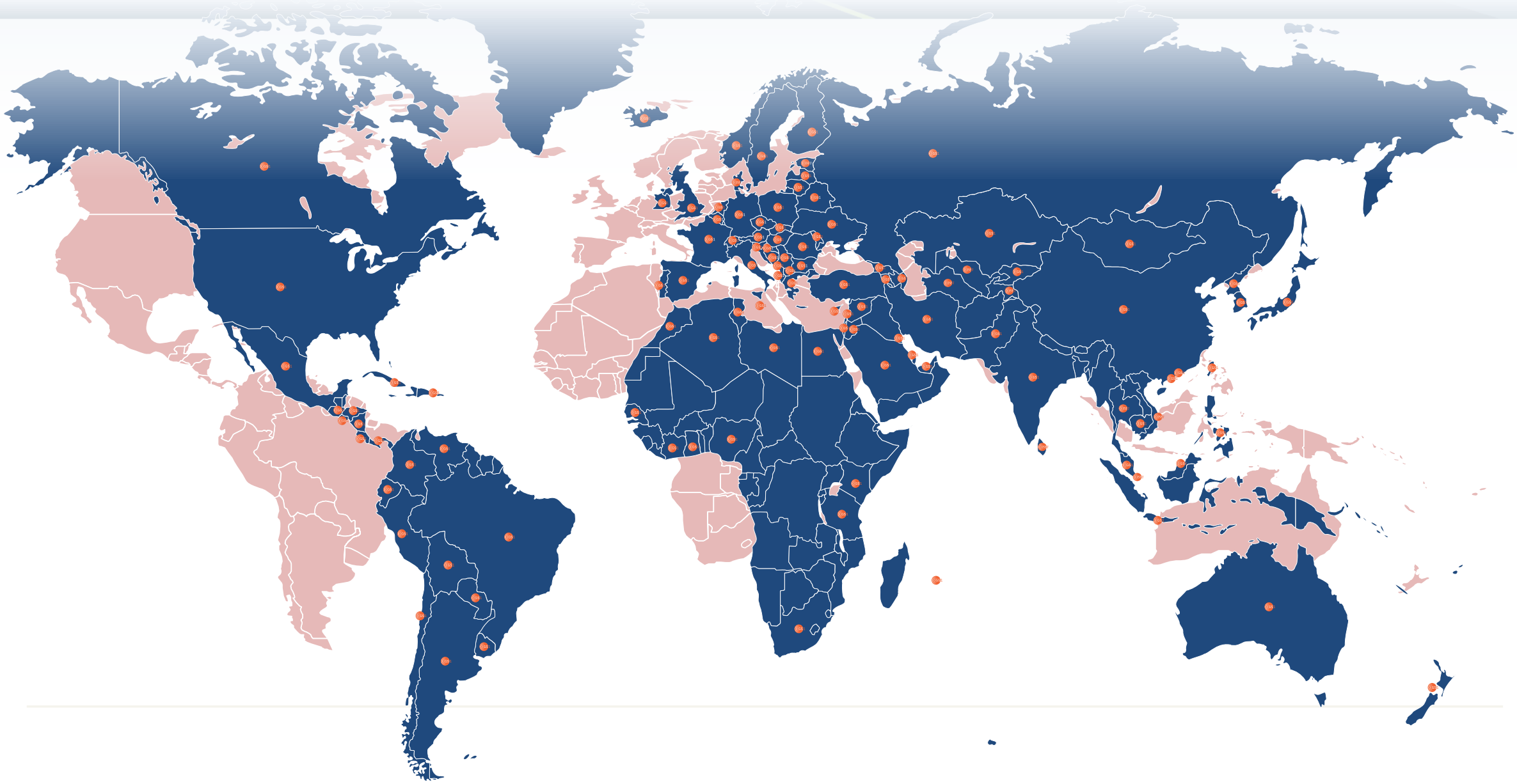
Raising awareness for the role of GS1 standards in the future digital health ecosystem, where high-quality data is available to the right people, at the right place and at the right time for high-quality decisions and care.
First cross-SDO webinar end of February, second one in June on the IPS and a third is planned for 9 Dec. 2021.

CEN Health Informatics TC251 · cdisc · GS1 · HL7 International · SNOMED International · DICOM Digital Imaging and Communications in Medicine · ISO Health Informatics TC215 · IHE Integrating the Healthcare Enterprise · Joint Initiative Council

GS1 holds the chair of this group until February 2022

Acronym decoder:
SDO – Standards Development Organisation
HL7 – Health Level Seven
ISO – International Standards Organisation
IPS – International Patient Summary
DICOM – Digital Imaging and Communications in Medicine
IHE – Integrating the Health Enterprise

GS1 has 115 local member organisations …



UDI system step by step

1. Assess which products fall under the scope of the relevant Regulation
2. Assess which Class is relevant for each type of product
3. Define/select your Issuing Agency. If GS1, who is/are your GS1 Member Organisation(s)?
4. Which products are already identified and which are marked? Is it aligned with the UDI requirements?
5. Create and assign Basic UDI-DI (GMN) and UDI (GTIN & AIs)
6. Apply the barcodes and HRI (deadlines depending on the risk class)
7. Regulated data registration in the UDI Database
8. Maintenance

How to work with GS1 Member Organisations

- To obtain a ‘UDI’, manufacturers need to get a licence for a GS1 Company prefix from any GS1 Member Organisation around the world
- GS1 Member organisations assign a GS1 Company Prefix to the company that is then used to generate:
  - UDI-DIs
  - Basic UDI-Ds
  - The prefix can also be used to create other identifiers used across the supply chain
- Other services provided by GS1 member organisations:
  - support in applying or implementing GS1 standards
  - Assistance with ensuring solutions used to implement are standards compliant
  - training to members on specific topics

In these difficult times we learned that…

COLLABORATION AND HARMONISATION ARE NEEDED

We are **ALL** dependent on an **efficient supply chain** across countries and continents

We need to be able to interact clearly and unambiguously with each other – using a **global standards**

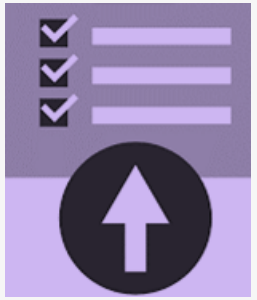
We need to **prevent substandard and falsified products** entering our supply chains and markets, putting patients and caregivers at risk

We need to make sure that the resources and supplies needed are effectively made available to support our **health systems** in the best possible way

Benefits of UDI implementation

Benefits of UDI for regulators globally

Visibility (inventory)and documentation of devices placed on the market and used at point of care.



Information on devices and on usage to be leverages for insurance, price control, tender requirements, etc

Market surveillance and customs control preventing dangerous and/or fake medical devices.

A globally harmonised system across borders, aligned with the IMDRF framework.

Please note: this is not an exhaustive list. There are also variations with regard to the role of regulators, so some points may not apply in Australia to the regulator and instead the benefits listed may apply to other parts of government or the healthcare system

Benefits of UDI for manufacturers

Tracking (inventory) and tracing of the individual product improves visibility to accurately plan production and distribution.

Information on product usage and impact on patients (e.g., adverse events).

Brand and counterfeit protection preventing fake medical devices entering the supply chain.

A safe and efficient supply chain with the help of standards build trust in the manufacturer and its products.

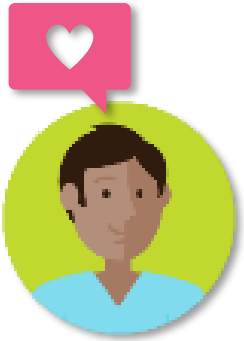
Please note: this is not an exhaustive list

Benefits of UDI for healthcare providers

Unambiguously identify medical devices

More efficient product recalls and verification of the legitimacy of medical devices

Having access to accurate and up-to-date product information, enable eHealth records



More accurate reports of adverse events and reduction of errors

Capture automatically data about products used for patients, to allow clear cost allocation and optimisation

Optimization of supply chain for purchase orders, responses, invoices and other business messages

Please note: this is not an exhaustive list

St. Joseph's Hospital, Chinese Taipei:
Unique Device Identification for better care and patient safety

Challenge

Like many hospitals in Chinese Taipei, St. Joseph's Hospital once used paper records, manual processes and no specific methodology to manage its medical devices and materials.

Approach

St. Joseph's Hospital launched a Unique Device Identification (UDI) project that automated its business and clinical processes by implementing GS1 standards to uniquely identify all medical devices and materials. With this foundation, the hospital was able to establish a traceability system for implanted medical devices and collect real-time data about their use and associated inventory levels.

Significant improvements in inventory management with automated processes

Increased patient safety with full product traceability and auto alert functionality

50%

of processing time saved per order

96%

scanning rate after only two months

Denmark: Cardiac Catheterisation Laboratory improves traceability, workflow and reduces items in stock

Challenge

The hospital department had a non-standardised manual process for handling stock inventory. The process was time-consuming and increased the risk for human error. In addition, the department had limited visibility of inventory levels, leading to low turnover of inventory on shelves and significant waste.

Approach

To optimise the reordering process while freeing up more time for patients, the department implemented a system using GS1 standards for scanning the barcodes of existing items in stock and all newly purchased items. The manual reordering process was replaced with one that was automated with nurses scanning all items that were used. This automatically generated a reordering list. All staff nurses were trained in how to use the new system, old scanners were reconfigured until they worked perfectly and new scanners were purchased.

Reduction in stock items

Increased level of staff satisfaction

3

nurse positions freed up due to the automated process

No cancellation of procedures due to out-of-stock items

Lessons learned

- The identification and barcoding requirements must be aligned with the IMDRF global framework and the UDI Issuing Agencies' specifications to ensure efficient implementation.
- Flexibility in barcode choice is needed as the scope of medical devices includes many different products.
- The UDI Database is managed by the regulator and data requirements are focused on minimum legal requirements.
- Data quality validation rules are included in the UDI Database functional specifications.
- Machine-to-machine data submission is possible to enable submission of large data volumes while ensuring data quality.
- The healthcare stakeholders are consulted and informed as feedback from users is important to improve the UDI system.
- Guidance for specific types of devices is needed to drive consistent implementation: e.g. kits, combination products, software

http://www.gs1.org/healthcare/udi

Unique Device Identification webinar

- Guest speaker
- **Progress update**
- Questions and answers

International alignment – UDI workshop

- On September 9 there was an International Medical Device Regulators Forum (IMDRF) and Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA) joint workshop on UDI

- The TGA along with other regulators, manufacturers and industry groups presented on progress in implementing the Australian UDI database

https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop.html

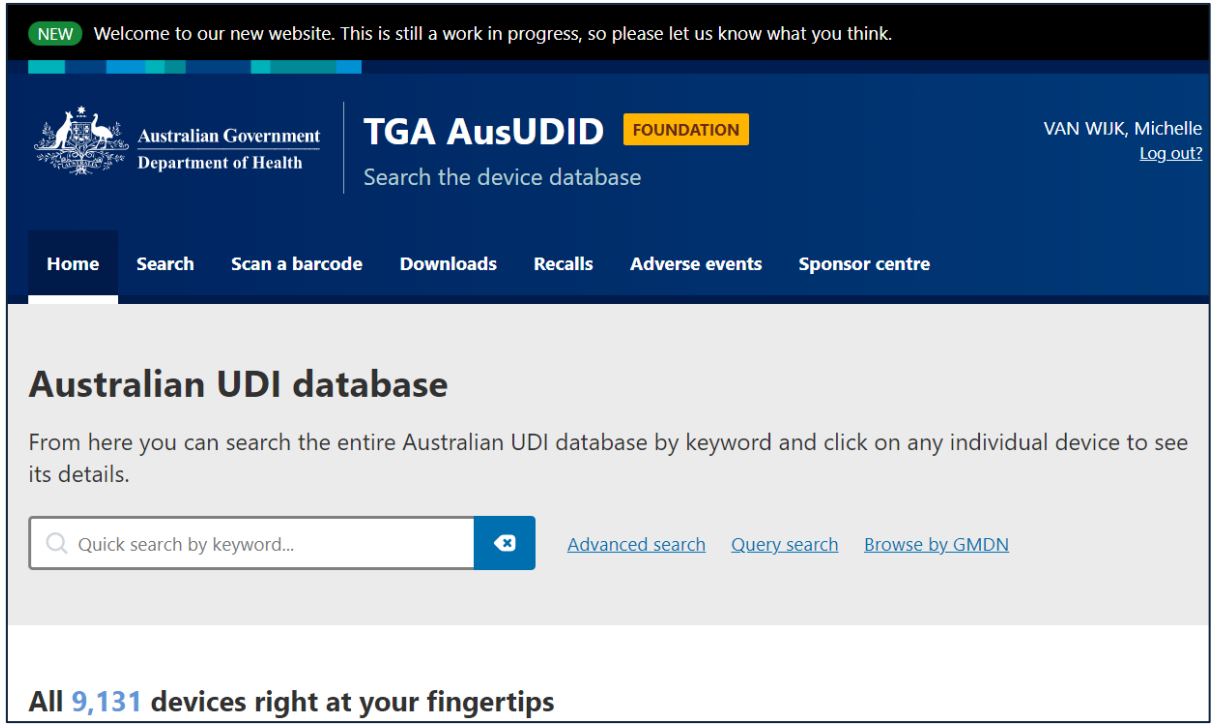
Early Adopters

Queensland Health Project

- ✓ Business Case approved
- ✓ Scoping continues on selection of hospital and devices

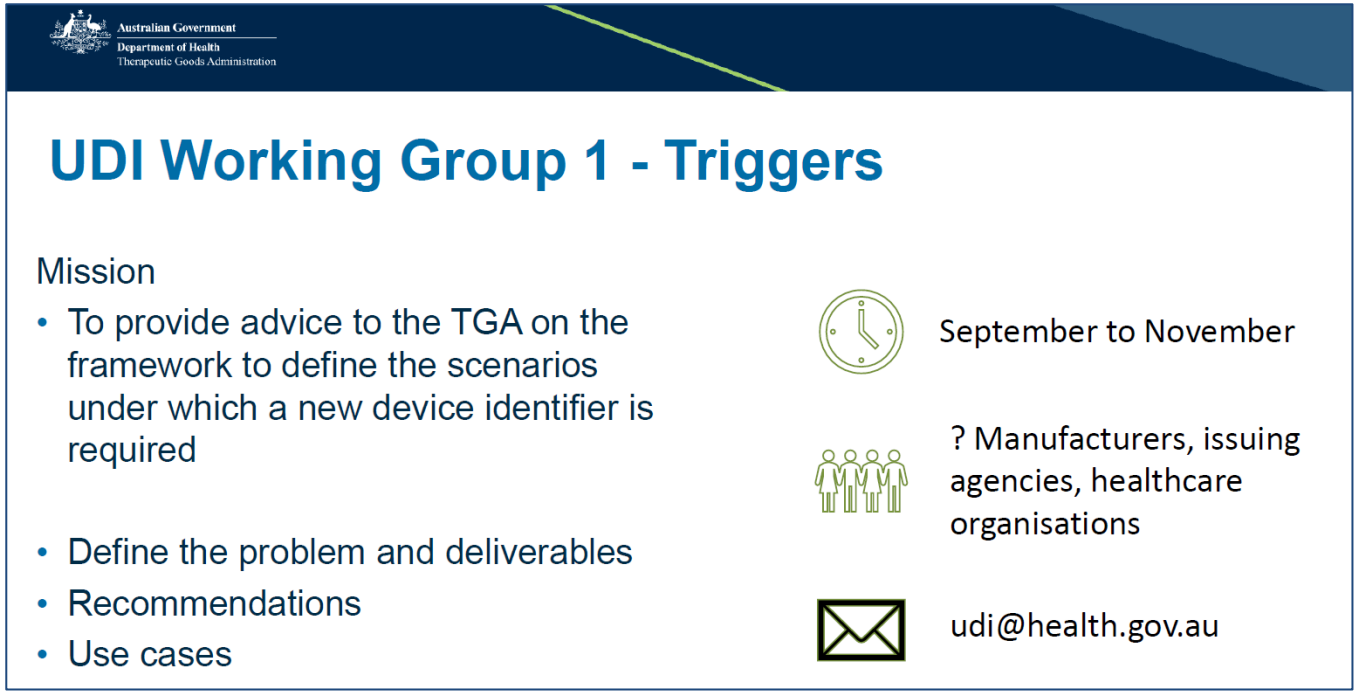
Other early adopter work

- ✓ Early discussions with registries, software organisations, healthcare procurement and other states and territories
- ✓ We will maintain an “early adopters’ list and be in touch once our framework is sufficiently advanced



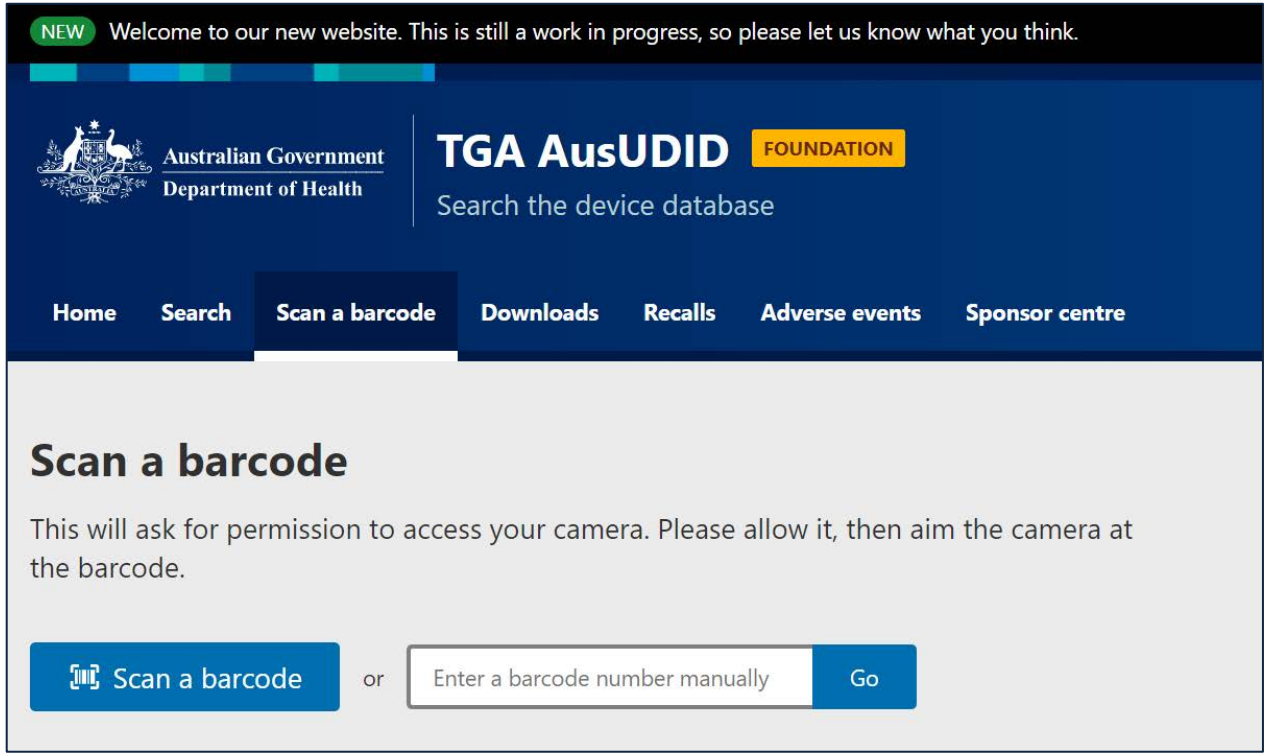
Triggers Working Group

- ✓ Chair – Dennis Black
- ✓ 20 registrations including manufacturers, sponsors, issuing agencies, hospitals…
- ✓ Kick-off meeting being scheduled for late September



Next Steps

- ✓ Planning for regulatory consultation (Q1/Q2 2022)
- ✓ Connect a beta version of the National Product Catalogue with the ‘sandpit’ Australian UDI database
- ✓ Continue to develop functionality in the Australian UDI database and test with user groups



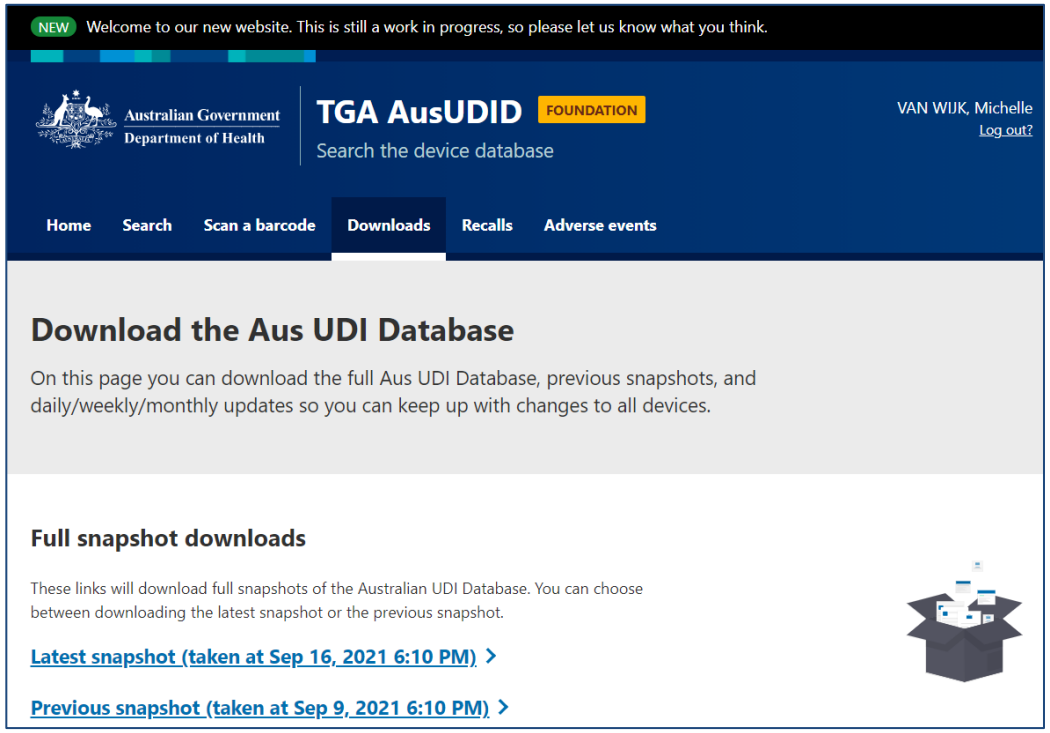
Unique Device Identification webinar

- Guest speaker
- Progress update
- **Questions and answers**

Questions to date

Over 150 questions received to date, key themes are emerging:

1. Implementation timing
2. International alignment
3. Scope of devices included
4. Alignment with the ARTG and existing TGA processes
5. The Australian UDI database and data provision
6. Global Medical Device Nomenclature
7. Generation of UDIs and Issuing Agencies
8. Labelling
9. Use in clinical systems and patient records
10. Collaboration and engagement



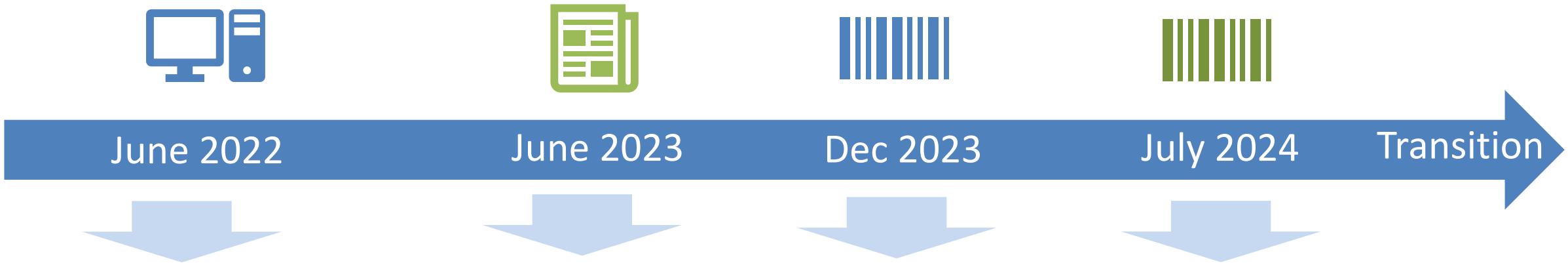
Implementation Timing

- The transition period and details are still to be confirmed but will begin with high-risk implantable devices
- We will continue to explore the possibility to accelerate Australia's transition period, particularly for those devices which are already compliant with U.S. or EU regulations

Our considerations informing these dates include:

- Allowing 12 months from the finalisation of regulations to the first mandatory compliance date
- Consultation feedback that there may be opportunities to speed-up the Australian implementation
- Requests for voluntary provision of data prior to mandatory compliances dates
- The development of the Australian UDI database is well underway

Implementation Timing (indicative)



Sandpit (beta) version of the Australian UDI database

for general use and testing

Regulations and Guidance

Voluntary compliance

for any device class

Mandatory compliance for implantable devices

allocation of UDIs, UDIs on labelling, and provision of data

Scope of devices

What we know

- Where software that is a medical device is regulated by the TGA it must meet the UDI requirements unless it is exempt or excluded
- UDI will be required for every model of device

  This will be different to our Australian Registration of Therapeutic Goods, which contains information at the “kind of” device level, which is less granular

What we are still exploring

- *Will non ARTG registered products be eligible to utilise a UDI?*
- *Will Class 1 devices be in scope?*
- *Will legacy devices be in scope?*
- *Kits, systems, procedure packs*
- *Exempted and excepted devices (patient-matched, custom-made devices)*


IMDRF/UDI WG/N48 FINAL: 2019

IMDRF International Medical Device Regulators Forum

Final Document

Title: Unique Device Identification system (UDI system) Application Guide

Authoring Group: IMDRF UDI WG

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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International alignment

U.S. FDA alignment continues to be the initial focus for alignment
(*align with U.S. and then 'fold in' EU requirements*)

Next steps – low-level detailed analysis of alignment between IMDRF, U.S. and EU

- Document areas where aligned
- Specific focus to resolve and come to a view where:
  - 'lessons learnt' feedback has suggested improvements to U.S. approach
  - U.S. and IMDRF differ
  - U.S. and EU differ

+

TGA Health Safety Regulation

Minimal additional requirements
ARTG ID
Patient Information Leaflet URL
Prosthesis Billing Code

Australian Register of Therapeutic Goods (ARTG) and existing processes

What we know

- Each device record in the Australian UDI database will also include a list of all ARTG IDs that relate to that model of device.
- Under current regulations, UDI is mandatory for the Patient Implant Card (PIC) if the device has a UDI.

What we are still exploring

- *Will the Sponsor be required to submit a variation for each ARTG to provide a copy of the updated labels with the UDI on it?*
- *Linking of TGA data for ARTG, UDI, adverse events, recalls*

Australian UDI database and data provision

What we know

- The majority of the UDI data will be made publicly available through a web interface and through data downloads.
- We will provide Machine to Machine capabilities for data transmission from Day 1.
- MRI compatibility is included in the IMDRF data set, and we are planning to capture it in the Australian UDI database.
- We will be providing a web interface to allow the entry data for one device at a time, and functionality to allow data provided in bulk.

What we are still exploring

- *Should the manufacturer be able to provide UDI data directly to the TGA?*
- *Use of the National Product Catalogue (Global Data Synchronisation Network) for the provision of data*
- *How is TGA considering the practical elements of this where a sponsor of a system/procedure pack (for e.g.) might supply multiple devices - thermometers, infusion sets etc. - as part of such a pack?*
- *The final dataset*
- *Does this mean that the manufacturer will have to create a new UDI and packaging for each device that may have multiple sponsors?*

Global Medical Device Nomenclature (GMDN)

What we know

- GMDN will be one of the data elements required to be provided with the device UDI data.
- The UDI will not replace the GMDN.
- Each model of device will require both a UDI, and a GMDN code.
- Currently if there are no changes to the characteristics of a device, the GMDN is valid for the life of the device even if the GMDN agency amends that code or makes it obsolete.
- As part of the Australian Register of Therapeutic Goods clean-up there is no plan to force sponsors to lodge change requests.
- There is no current plan to change the way the GMDN codes are implemented for Australian In Vitro Diagnostic devices.

What we are still exploring

- *Benefits in potentially also collecting European Medical Device Nomenclature*
- *Potential processes for making changes to the GMDN over time*
- *Relationship between ARTG and UDI*

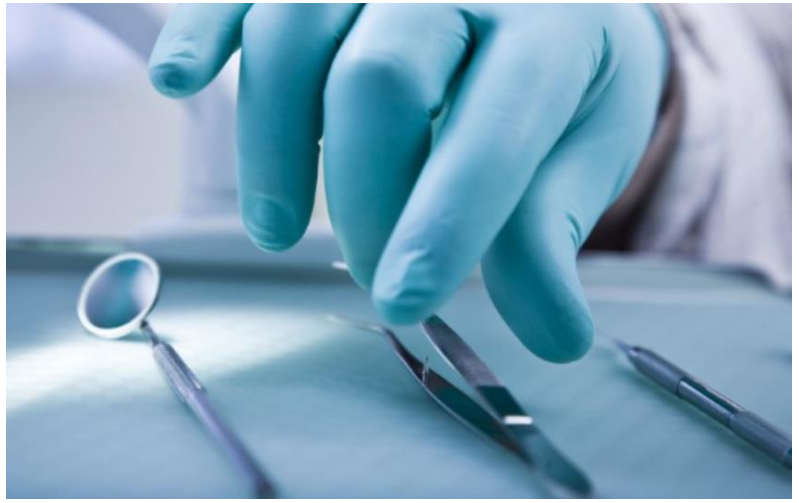
Generating of UDIs and Issuing Agencies

What we know

- Issuing Agencies are responsible for generating UDIs according to international standards.
- Australia is planning to accept UDIs created by GS1, the Health Industry Business Communications Council (HIBCC) and International Council for Commonality in Blood Banking Automation (ICCBBA), including where those have already been applied to devices in the EU and U.S..
- The manufacturer is responsible for obtaining UDIs and allocating them to devices.

What we are still exploring

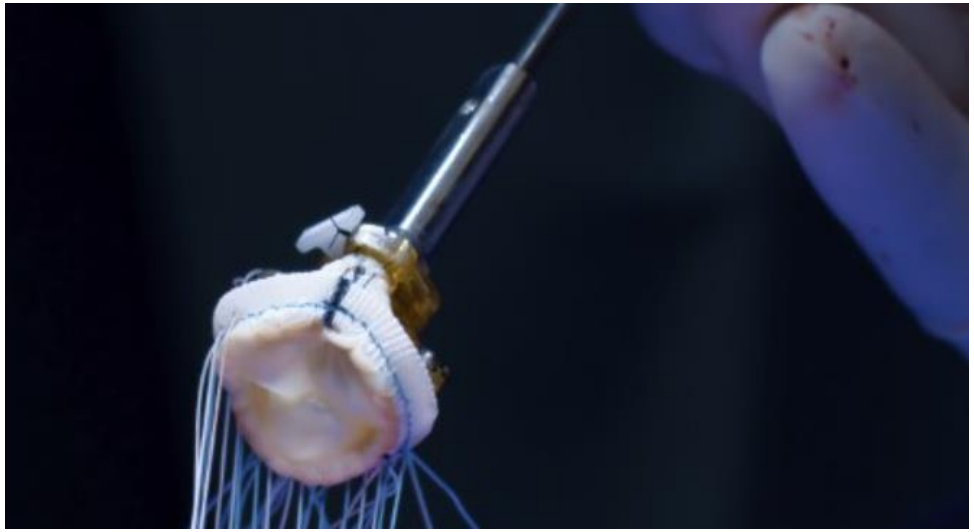
- *While Australia is still considering our position on the Issuing Agency framework, we recognise that there are three issuing agencies that are common across both the EU and U.S. (and other countries).*



Labelling

What we know

- Australia is planning to accept UDIs created by GS1, HIBBCC and ICCBBA, including where those have already been applied to devices in the EU and U.S..



What we are still exploring

- *Will the implementation of UDI barcodes into product labels be considered a substantial change, and is there a requirement for a conformity assessment review or can this be assessed at the next surveillance audit?*
- *What considerations are in place for small products that will be very difficult to put a UDI on e.g. endodontic files, endodontic paper points and GP points?*

Use in clinical systems and patient records

What we know

- The UDI can potentially be captured and linked to a specific patient in any system that stores that data.
- This is outside the scope of the TGA UDI project.

What we are still exploring

- Early Adopter learnings

Australian Government
Australian Digital Health Agency

My Health Record

Collaboration and engagement

What we know

- The working groups are open to all, we welcome all participants.
- To register for an Early Adopter project please email udi@health.gov.au
- Working group information will be shared through our monthly webinars and on the TGA UDI Hub, or by email us at udi@health.gov.au

How did we go?

LIVE POLL

Michelle and Géraldine are currently reading over your submitted questions.

We'll be back shortly for Q&A

Contact us

UDI Project

udi@health.gov.au

Questions?

Website and link references

New UDI hub ★	https://www.tga.gov.au/unique-device-identification-system
Second UDI consultation paper	https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system
First UDI consultation paper	https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia

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More information

TGA website	https://www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Questions?

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Australian Government

Department of Health

Therapeutic Goods Administration