Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification | Webinar No. 5

The role of a UDI Issuing Agency (Part 2)

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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
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Today’s presentation

- Invited guest speaker – Allison Mehr
- Progress update
- Questions and answers

Guest presenter - Allison Mehr Vice President, HIBCC

Allison Mehr is the Vice President at the Health Industry Business Communications Council; an industry supported and internationally accredited nonprofit standards development organization. Allison specializes in international medical device regulations and is the key HIBCC point of contact for the European Union's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), and the U.S. Food and Drug Administration's (FDA) Unique Device Identification (UDI) Rule.

Allison oversees the maintenance of the Health Industry Bar Code (HIBC) Supplier Labeling Standard (SLS) and its application in medical device identification regulations globally. Allison works directly with industry stakeholders to provide technical specifications and strategic guidance on the implementation of HIBCC standards.

HIBCC: An EU and FDA accredited issuing agency

Industry-supported, internationally accredited nonprofit Standards Development Organization (SDO) with an exclusive healthcare focus.

Originally founded in 1983 to develop a uniform bar code labeling standard for products shipped to hospitals.

Identified by the European Union (EU) in their Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), as well as the US Food and Drug Administration (FDA) Unique Device Identification (UDI) Rule.

Accredited by American National Standards Institute (ANSI), European Committee for Standardization (CEN), and International Organization for Standardization (ISO).

ANSI American National Standards Institute

ISO International Organization for Standardization

CEN European Committee for Standardization
Comité Européen de Normalisation
Europäisches Kommitee für Normung

HIBCC Unique Device Identifier (UDI) key characteristics

Alphanumeric dataset means:

- *Largest set of possible identifiers*
- *Literal encoding of existing product codes*
- *No cross referencing, no duplicates, and codes never need to be reused*

Variable length fields allow:

- *Labelers can use existing product code, lot, and serial formats*
- *Enables manufacturers to incorporate their exact product identifiers within the data structure, eliminating need to truncate or add digits.*

Registering with HIBCC

Company Prefix/Labeler Identification Code (LIC) registration is a one-time fee.

- *No recurring or annual costs to use the HIBCC system*
- *Accepted globally*
- *One LIC can be used to create all your UDIs and Basic UDI-DIs*
- *Access to the HIBC UDI-Builder included*

To complete the LIC application visit www.hibcc.org.

HIBC UDI structure

A UDI is composed of the Device Identifier (DI) and the Production Identifier (PI).

The DI is the mandatory, fixed portion of the UDI. A HIBCC DI includes the following:

- *Labeler Identification Code (LIC) – Company Prefix assigned by HIBCC*
- *Product/Catalog Code*
- *Unit of Measure (Package level indicator)*

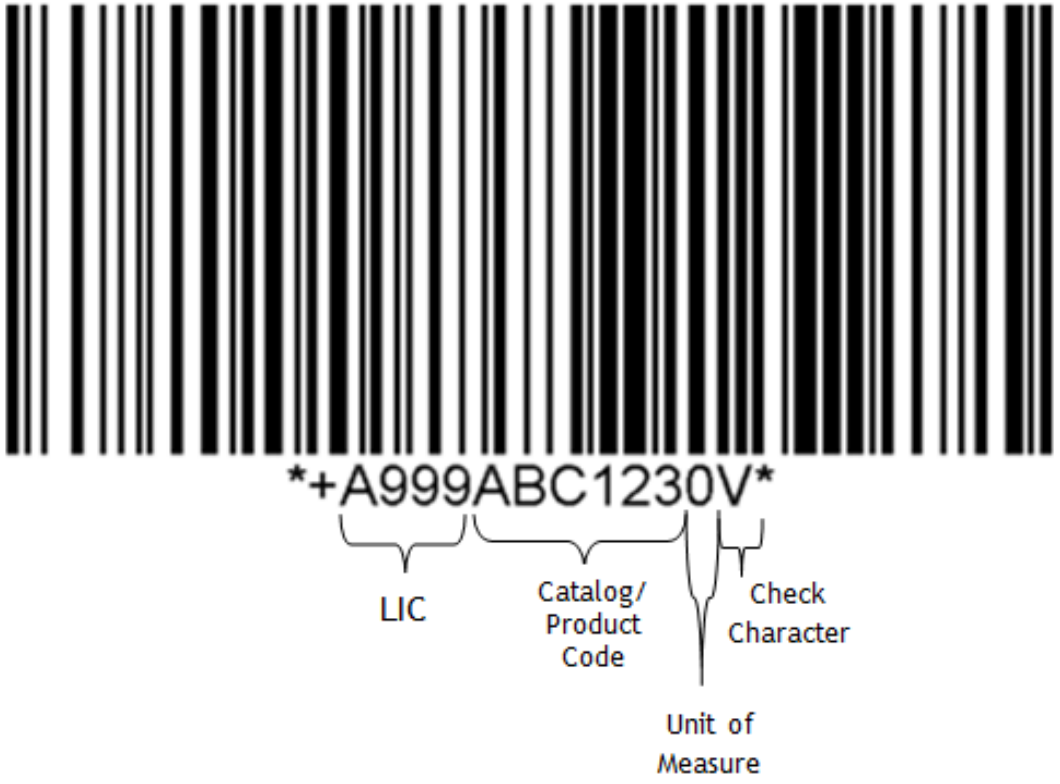
The PI is the variable, conditional portion of the UDI. A HIBCC PI may include one or more of the following:

- *Lot*
- *Serial*
- *Manufacture Date*
- *Expiration Date*

HIBC device identifier

Also referred to as the HIBC Primary Data Structure

Identifies the Organization, the Specific Device Model, and the Package Configuration



HIBC device identifier: Company prefix

Labeler Identification Code (LIC) – Company Prefix assigned by HIBCC

- *4 Characters Alphanumeric*

HIBC device identifier: Product/catalog code

Product/Catalog Code

- *Assigned by the labeler*
- *HIBCC recommends using existing Product/Catalog/Reference Codes*
- *Variable Length (1-18 characters) Alphanumeric*

HIBC device identifier: Package level

Unit of Measure (Package level indicator)

- *Single Digit (0-9)*
- *Always located after the Product/Catalog Code*
- *0 represents a single unit (each)*
- *9 is reserved for devices with variable quantities*
- *1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest*

HIBC device identifier: Package level

Example 1: Single Bandage, Packaged and Labeled Individually

+A999ABC1230V

Example 2: Label on outside of box for Single Bandage

+A999ABC1230V

Example 3: Box of 10 Sterile Gauze Pads, Individually Packaged inside the box

+A999ABC1231W

HIBC device identifier: Allocation rules

HIBC Supplier Labeling Standard (SLS) 2.6:

"A HIBC Primary Identifier shall not be reissued to any other item, even if the item to which it has been assigned has been discontinued, or superseded by another product."

HIBCC advises all labelers to create a new DI in the following scenarios (based on UDI regulatory requirements):

- *Brand new device*
- *New variation or version of an existing device*
- *Re-branding of a device*
- *New packaging level*
- *Change in sterilization requirements*
- *Change in device risk class*
- *Significant change in form and/or function of the device*

HIBC production identifier

Also referred to as the HIBC Secondary Data Structure.

If you have included any of following information in your device label, that information must also be included in the PI portion of the UDI:

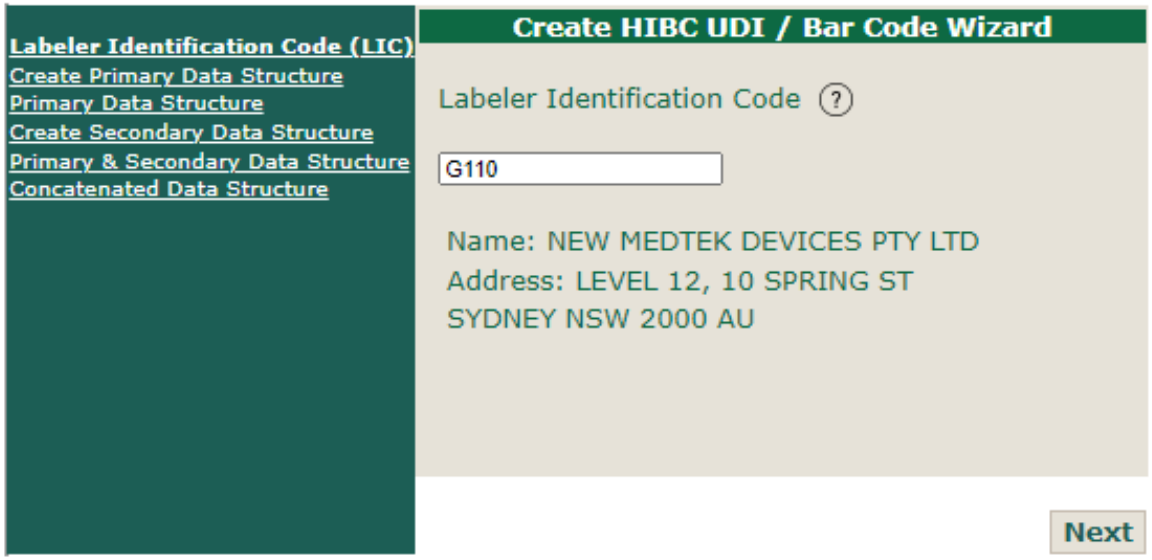
- *The lot or batch within which a device was manufactured;*
- *The serial number of a specific device;*
- *The expiration date of a specific device;*
- *The date a specific device was manufactured.*

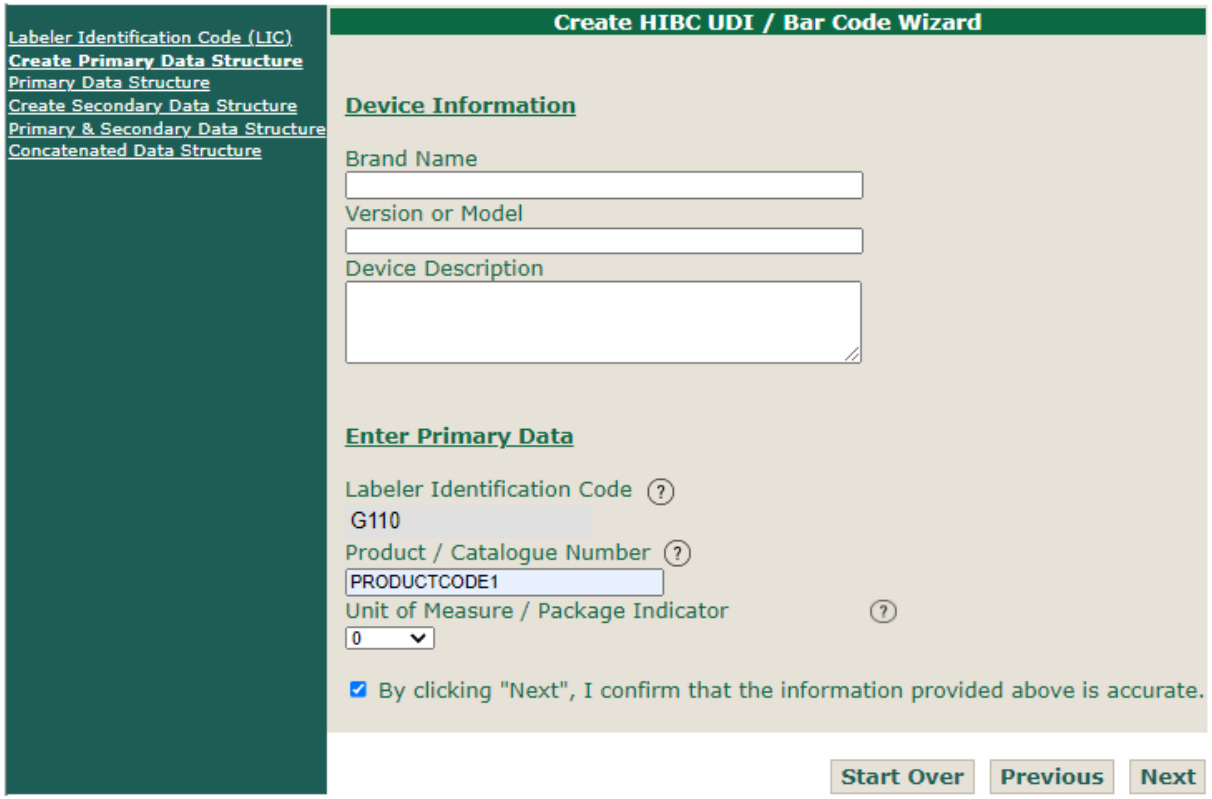
Creating a HIBC UDI

HIBC UDI-Builder:

- *Create, Calculate, Confirm, and Collect UDIs*
- *Free online utility available to all labelers*

Creating a HIBC UDI





Creating a HIBC UDI

Labeler Identification Code (LIC)
Create Primary Data Structure
Primary Data Structure
Create Secondary Data Structure
Primary & Secondary Data Structure
Concatenated Data Structure

Create HIBC UDI / Bar Code Wizard

Device Information

Brand Name: Brand Name
Version or Model:
Device Description:

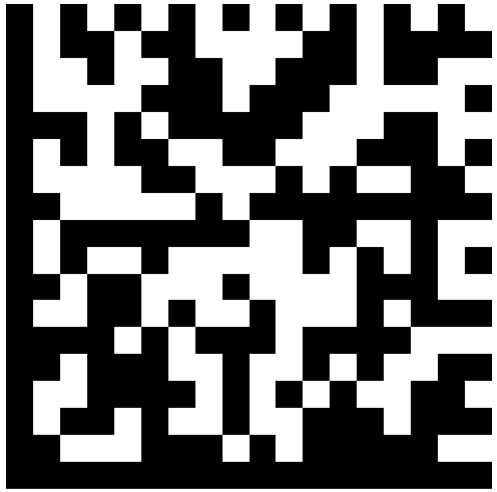
Primary Data Structure

Labeler Identification Code: G110
Product / Catalogue Number: PRODUCTCODE1
Unit of Measure / Package Indicator: 0

Primary Bar Code Data: Generate Primary Bar Code
+G110PRODUCTCODE10P
Text Under Primary Bar Code
+G110PRODUCTCODE10P
Primary Check Character
P
UPN/UDI Device Identifier
G110PRODUCTCODE10

Click "Next" to create the Secondary Data Structure

Start Over | Previous | Next



+G110PRODUCTCODE10P

HIBCC UDI support

HIBCC provides technical and regulatory support to all of its labelers

- *Label/Automatic Identification and Data Capture (AIDC) Review*
- *Regulatory Guidance*
- *Technical Support with HIBC UDI-Builder/software*
- *HIBC Standard Implementation*
- *HIBCC UDI Webinar Series*
- *One-on-One Training*

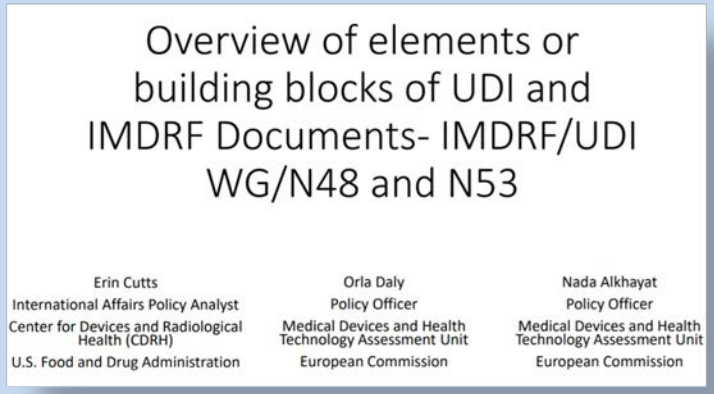
HIBCC UDI links

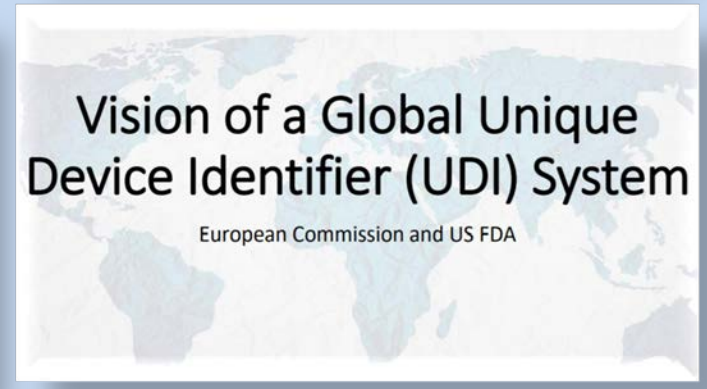
- *HIBCC Company Prefix/LIC Application: https://www.hibcc.org/udi-labeling-standards/apply-for-a-lic/*
- *HIBC UDI-Builder: https://hibccudi.org/*
- *HIBC Supplier Labeling Standard (SLS): https://www.hibcc.org/wp-content/uploads/SLS-2.6-Final.pdf*
- *HIBCC Registered Labelers: https://www.hibcc.org/wp-content/uploads/Current-HIBC-Labelers.pdf*
- *HIBCC's Guide to Understanding Unit of Measure: https://www.hibcc.org/wp-content/uploads/HIBCCs-Guide-to-Understanding-Unit-of-Measure.pdf*
- *HIBCC Sample UDI Labels: https://www.hibcc.org/wp-content/uploads/HIBCC-UDI-Label-Examples.pdf*

Unique Device Identification webinar

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

International alignment - UDI workshop highlights





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

International alignment – UDI workshop

Building blocks of UDI

The IMDRF guidance and procedural documents:

IMDRF/UDI WG/N7FINAL:2013	UDI Guidance: Unique Device Identification (UDI) of Medical Devices - PDF (324kb) UDI Guidance: Unique Device Identification (UDI) of Medical Devices - DOCX (130kb)	18 December 2013
IMDRF/UDI WG/N48FINAL:2019	Unique Device Identification system (UDI system) Application Guide - PDF (3.53Mb) Unique Device Identification system (UDI system) Application Guide - DOCX (12.5Mb)	21 March 2019
IMDRF/UDI WG/N54FINAL:2019	System requirements related to use of UDI in healthcare including selected use cases - PDF (306kb) System requirements related to use of UDI in healthcare including selected use cases - DOCX (10.1Mb)	21 March 2019
IMDRF/UDI WG/N53FINAL:2019	Use of UDI Data Elements across different IMDRF Jurisdictions - PDF (86kb) Use of UDI Data Elements across different IMDRF Jurisdictions - DOC (71kb) Annex - Use of UDI Data Elements across different IMDRF Jurisdictions - XLSX (391kb)	21 March 2019

https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop.html
1.2_Overview_of_elements_or_building_blocks_of_UDI_and_IMDRF_Documents_-_N48_N53_US_EU_V2.pdf

International alignment – UDI workshop

https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop.html
3.1_Harmonizing_UDI_Issues_and_Proposed_Solutions_Zita.pdf

7 Issues affecting adoption of UDI

1. Lack of harmonization within jurisdictional UDI databases leading to additional administrative burden
2. Rules built into the regional databases that cause creation of new device identifiers when a data element is changed
3. Lack of direct “translation” between different Issuing Entities
4. Varying definitions of terms and concepts between jurisdictions causes creation of new UDI-DIs to accommodate different rules
5. UDI Automatic Identification and Data Capture (AIDC) Symbology requirements emerging without regard for the UDI issuing entity standards or the ability to read these symbols in the global supply chain
6. Direct marking of devices is not consistently defined; implementation is being delayed until there is a better understanding
7. Lack of focused education for healthcare delivery organizations and system preparation

These issues

- are contradictory to the spirit of UNIQUE Device Identification and potentially hamper the global interoperability of the UDI system – Industry has been slow to adopt the use of UDI for a global purchasing process and continues to use REF as the identifier for purchasing

- affect traceability of medical devices, adverse event reporting, global data sharing and transparency, and ultimately result in inefficient processes, higher cost and a decrease of patient safety

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Proposed solutions

1. Jurisdictions should adopt the IMDRF UDI guidance documents N7: 2016 Common Data Elements for Medical Device Identification & N48:2019 Unique Device Identifier (UDI) Application Guide
2. Jurisdictions should consider the guidance from IMDRF N53:2019 Use of Data Elements Across IMDRF Jurisdictions
3. Actively participate in this DITTA workshop to discuss these concerns
4. Submit a NWIP for the update to N48 and N53 to support a globally harmonized approach to the implementation of a UDI system
5. Implement according to UDI Issuing Entities together with relevant IEC and ISO standards

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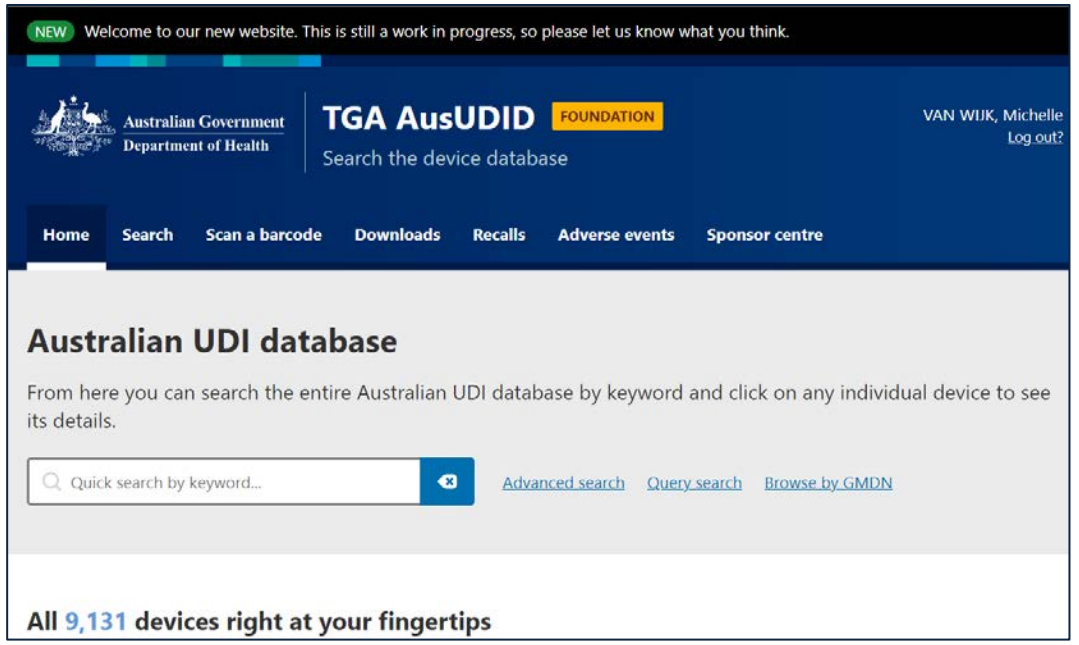
Early adopters

Queensland Health Project

- ✓ Scoping continues on selection of hospital and devices

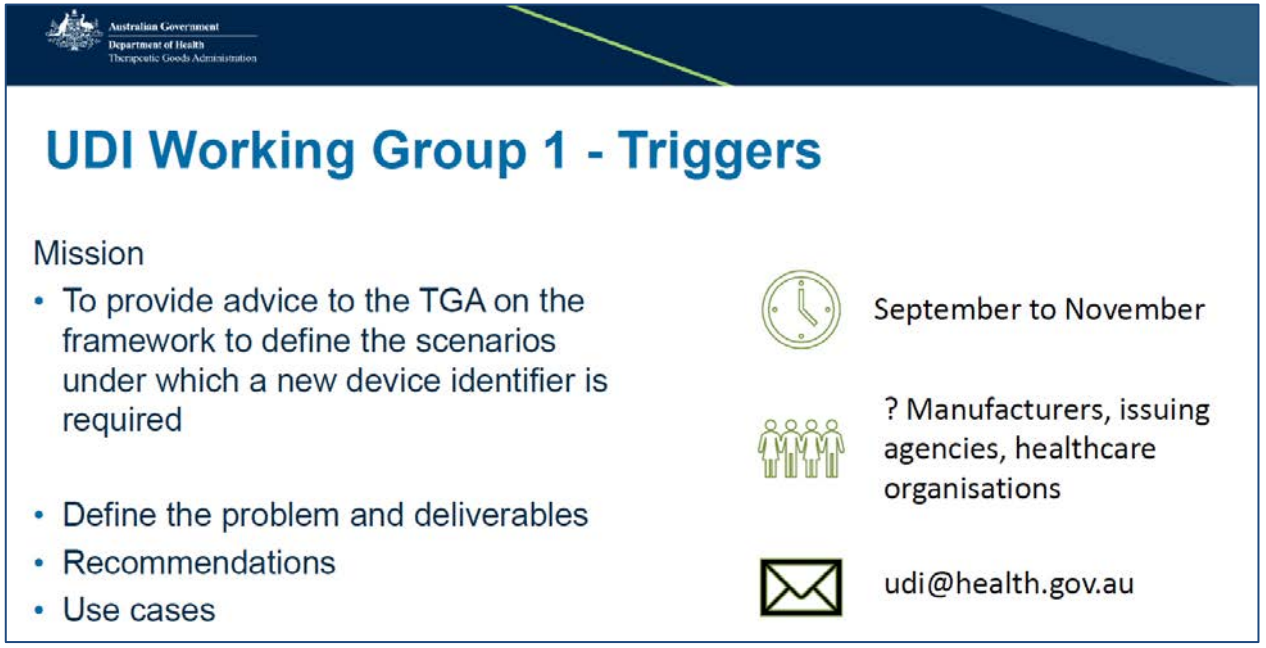
Other early adopter work

- ✓ Discussions with another jurisdiction for a second early adopter project
- ✓ Working with software developers to understand maturity of UDI solution in Electronic Health Record software (such as Cerner for example)



Triggers working group

- ✓ Co-chairs Dennis Black and Dr Oliver Daly
- ✓ 25+ registrations including manufacturers, sponsors, issuing agencies, hospitals…
- ✓ Australian and global participants
- ✓ 4 meetings to date
- ✓ Sharing of information through different ‘lenses’
- ✓ Informing Australian stakeholders



Next steps

- ✓ Preparing for regulatory consultation (Q1/Q2 2022)
- ✓ Connect a beta version of the National Product Catalogue (Global Data Synchronisation Network) with the ‘sandpit’ Australian UDI database
- ✓ Continue to develop functionality in the Australian UDI database and test with user groups
- ✓ New Global Medical Device Nomenclature codes to be added to the ARTG on a daily basis

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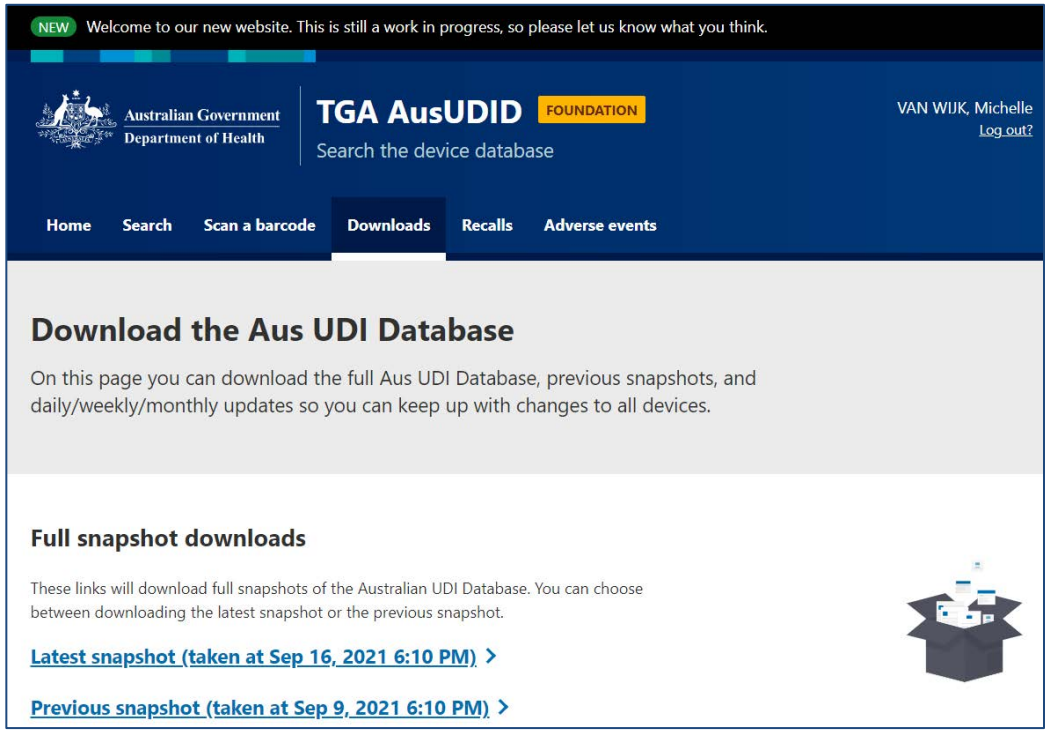
- **Questions and answers**

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



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*

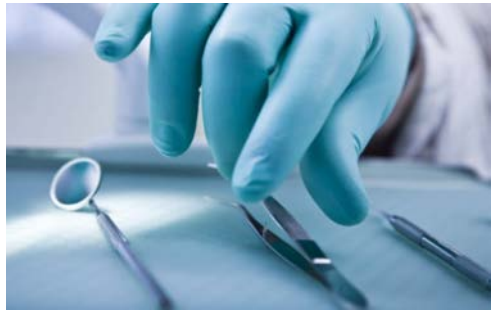
Generating of UDIs and issuing agencies

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

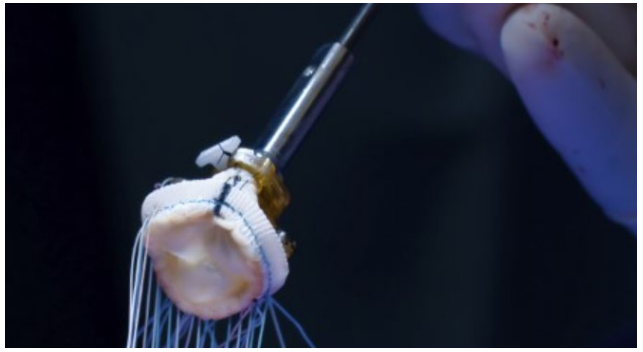
- *While Australia is still considering our position on the Issuing Agency framework, we recognise that there are three issuing agencies that are common across both the EU and U.S. (and other countries).*



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

- 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 Allison are currently reading over your submitted questions.

We'll be back shortly for Q&A

Contact us

UDI Project

udi@health.gov.au

Questions?

Allison Mehr
Vice President, Health Industry
Business Communications Council

Michelle van Wijk
UDI Project Manager
Therapeutic Goods Administration

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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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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