Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar #2 – 20 July 2021

Considerations for the Australian UDI

Michelle van Wijk

UDI Project Manager
Medical Devices Surveillance BR
Medical Devices and Product Quality DIV
Therapeutic Goods Administration

20 July 2021

TGA Health Safety Regulation

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
  - Messages will only be visible to the moderator and speaker
  - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **'Chat'** function
- Relevant links will be sent to you via the chat function box
- Live polls will be conducted throughout this event.

Difficulties hearing from computer?

Check your settings located under "**Audio & Video"** tab located top of your screen:

OR

Dial: +61-2-9338-2221

Access code: 165 133 0583

Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar #2 – 20 July 2021

Considerations for the Australian UDI

Michelle van Wijk

UDI Project Manager
Medical Devices Surveillance BR
Medical Devices and Product Quality DIV
Therapeutic Goods Administration

20 July 2021

TGA Health Safety Regulation

Purpose of today's presentation

To provide you with

- progress update
- considerations for the Australian UDI
- opportunity to ask questions

Unique Device Identification webinar

- **progress update**
- considerations for the Australian UDI
- opportunity to ask questions

UDI information

- New UDI hub on the TGA website https://www.tga.gov.au/unique-device-identification-system
- Established regular webinars to share information
- Established UDI mailbox for correspondence
- In the process of responding directly to questions we have received from the first webinar, and to our udi@health.gov.au email address (this will be ongoing)
- We will update our hub with answers to frequently-asked questions

Webinars

- Format is evolving
- Start with project update
- End with questions and answers
- Guest speakers

- Please let us know if you have suggestions for guest speakers or webinar content

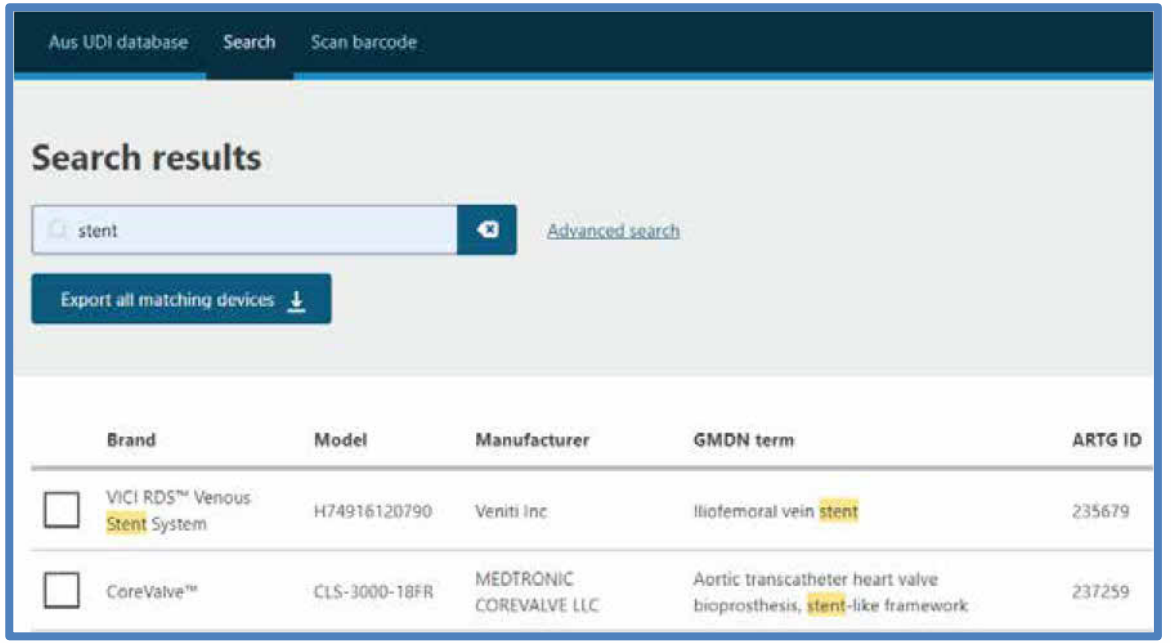
Australian UDI database

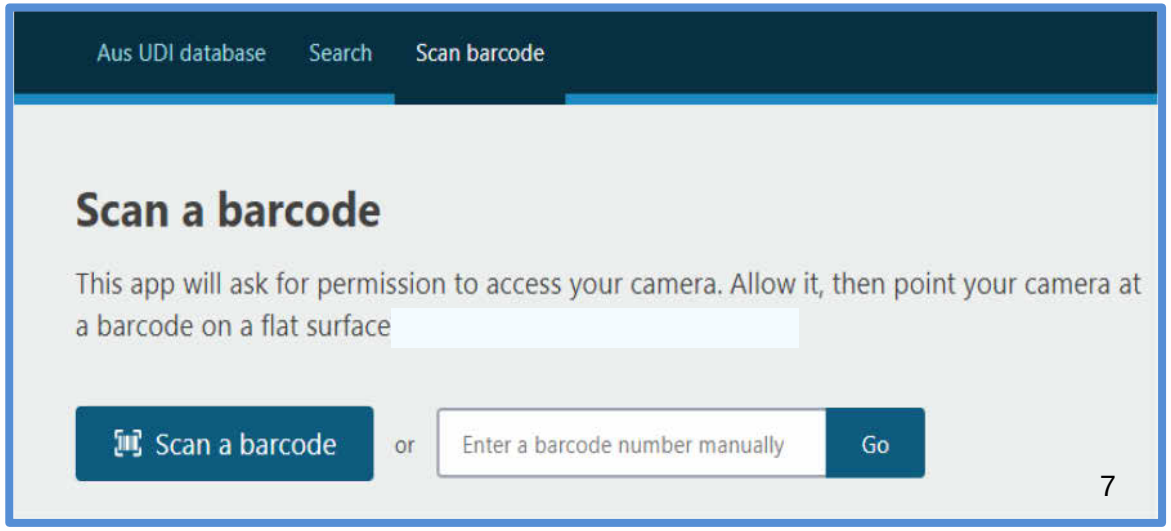
Working with our technology partner to create an initial version of the Australian UDI database

This will form the foundation from which the Australian UDI database will continue to evolve

And enable 'early adopter' use of the device identifiers

- ü subset of U.S. UDI data uploaded
- ü ability to search for devices and view or download results
- ü access the data from desktop, phone, tablet
- ü scan a barcode and see device information





Qld pilot early adopter project - considerations

Queensland Government
Queensland Health

Hospitals
Inventory control

Surgery

Patient Implant Card
Discharge papers

Public patient
Private patient

Patient Outcome **PRO** Analysis

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

$ Invoices

My Health Record

Electronic Medical Record
Non-Electronic Medical Record

National Product Catalogue

Registries

Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturers

Recalls

Devices

International alignment – UDI workshop

- In September there will be 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 will present on progress in implementing the Australian UDI database

IMDRF International Medical Device Regulators Forum

DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Considerations for the Australian UDI

- Global alignment
- Global medical device nomenclature (GMDN)
- UDI data we are proposing to store
- Data submission

Issuing Agency

Public Access

UDI

UDI repository (AusUDID)

Registry

Manufacturer

UDI data

Hospital

Australian Sponsor

Global alignment


IMDRF International Medical Device Regulators Forum

Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

Copyright © 2013 by the International Medical Device Regulators Forum.

Aligned with the International Medical Devices Regulators Forum Guidance - in the process of identifying gaps

- Feedback from the second consultation paper on the possibility of leveraging the U.S. data
- Exploring how we might use/leverage this generally, and especially in terms of the early-adopter project

- Singapore Health Sciences Authority is currently consulting on using both US and EU labels – *'Manufacturer or Product owners whose medical devices are marketed in the USA and/or EU and have been labelled with UDI based on the US or EU requirements can use these UDI as is for Singapore.'*

Global alignment – EU Basic identifier


Medical Device
Medical Device Coordination Group Document MDCG 2018-1 Rev.4

MDCG 2018-1 Rev.4
Guidance on BASIC UDI-DI and changes to UDI-DI

April 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Purpose is to connect devices with same:

- intended purpose
- risk class
- essential design and manufacturing characteristics

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance).

It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Any Basic UDI-DI shall identify the devices covered by that Basic UDI-DI in a unique manner.

" "

? Benefits to Australia

Consultation 2 responses – EU Basic identifier

Equally strong views for and against

- Benefits of including:
  - ability to easily share data with the EU
  - facilitates harmonisation and
  - allows for reliance on CE certificates from EU notified bodies to support local device registrations

- Many suggested the need for a grouping mechanism, and suggested the concept of a ‘product family’

- Others recognised the Australian Register of Therapeutic Goods (ARTG) ID as already providing this grouping mechanism. Comments that EU implementation is still unclear, and the Basic UDI identifier complicates the UDI model

Global alignment – additional ‘master’ identifier

- Purpose is to group similar devices –spectacle lenses and ready readers
- Reduce volume of data to be entered in EU database
- Contact lens solution under development, may be extended to spectacle frames
- First compliance date for labelling for most of these devices is May 2023

? Benefits to Australia

Medical Devices

Medical Device Coordination Group Document MDCG 2020-18

MDCG 2020-18

MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers

December 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

When do you need a new identifier for a device?

When there has been a significant change to a device or its characteristics

Changes that:

- might change product safety and/or performance
- could lead to misidentification of the medical device and/or ambiguity in its traceability
- impact manufacturers or other organisations such as company mergers, acquisitions and divestitures

Some of the challenges to date:

- the IMDRF identified a significant challenge with the assignment of multiple UDI identifiers to products, which share essential design and manufacturing characteristics
- Different requirements (‘triggers’) in different countries

Triggers are different

IMDRF	U.S. FDA	EU
Changes to any one of eight data elements:	**Changes to any one of twelve data elements:[1]**	**Changes to any one of ten data elements:[2]**
Brand name	Brand name	Name or trade name
Need for sterilization before use	Requires sterilisation prior to use	Need for sterilisation before use
Packaged sterile	Device packaged as sterile	Packaged sterile
Critical warnings or contraindications: e.g. containing latex or DEHP	Contains rubber latex or dry natural rubber	Critical warnings or contra-indications: e.g. containing latex or DEHP
Labelled as single use	For single use	Labelled as single use
Quantity of devices provided in a package	Device count	Quantity of devices provided in a package
Device version or model[3]	Version or model number	Device version or model

IMDRF	U.S. FDA	EU
Changes to any one of eight data elements:	**Changes to any one of twelve data elements:[4]**	**Changes to any one of ten data elements:[5]**
Clinical size (including volume, length, gauge, diameter)	Primary DI Number	Manner in which production is controlled if there is a change to the label
	Kit status	Direct marked (if changes from yes to no)
	Combination product status	Change in CMR/endocrine disruptors
	MRI safety information	
	Issuing agency	
Specific changes relating to software		
		Whenever there is a modification that changes: (a) the original performance (b) the safety or the intended use of the software (c) interpretation of data
Other		
	Whenever changes to a device result in a new version or model[6]	Whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability
New packaging configurations	Whenever you create a new device package, you must assign a new device identifier to the new device package	

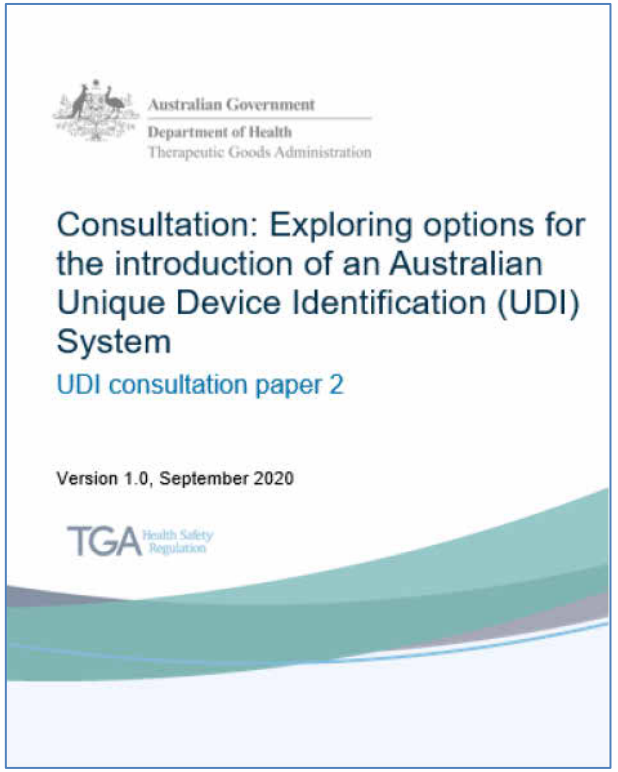
Why does this matter?

- From a post-market perspective, how do we identify what is essentially the same device over time?
- Linking these to each other becomes important (and can become complex)
- Burden on manufacturers

IMDRF	U.S. FDA	EU
Changes to any one of eight data elements:	**Changes to any one of twelve data elements:[4]**	**Changes to any one of ten data elements:[5]**
Clinical size (including volume, length, gauge, diameter)	Primary DI Number	Manner in which production is controlled if there is a change to the label
	Kit status	Direct marked (if changes from yes to no)
	Combination product status	Change in CMR/endocrine disruptors
	MRI safety information	
	Issuing agency	
Specific changes relating to software		
		Whenever there is a modification that changes: (a) the original performance (b) the safety or the intended use of the software (c) interpretation of data
Other		
	Whenever changes to a device result in a new version or model[6]	Whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability
New packaging configurations	Whenever you create a new device package, you must assign a new device identifier to the new device package	

Consultation 2 responses – U.S. or EU alignment?

- Strongly encouraged a system that mirrors the U.S. FDA or EU schemes
- Almost an equal split of opinion on U.S. FDA or EU as the baseline / reference point
- Strong concerns if Australia does vary from U.S. FDA or EU schemes
- Many noted the benefits of the U.S. alignment as it is in use, while the EU is not yet implemented
- Some feedback how to best leverage the U.S. implementation, including the U.S. UDI data
- The TGA could consider the benefits of leveraging data available from other sources (such as the U.S. FDA's Global UDI Database (GUDID) and National Product Catalogue) and that may open up the opportunity for 'simple experiments" across the broader healthcare environment



Global Medical Device Nomenclature (GMDN)

- Integral to Australia's regulatory framework
- Included in the International Medical Device Regulators Forum UDI Guidance
- Used by other regulators
- Plan for it to be required in the Australian UDI database
- Leverage learnings (for example speed of incorporation of new codes)
- Will be at the 'model of device level'
- Consideration to be given to how we best align with the Australian Register of Therapeutic Goods (ARTG) which also includes the GMDN

A standard for naming and grouping medical devices

•GMDN Term Name: Scalpel, single-use

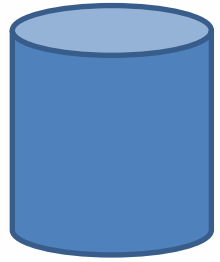
•GMDN Code: 47569

•GMDN Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

How does it work?

Australian Government
Department of Health
Therapeutic Goods Administration

- The GMDN underpins the Australian regulatory framework
- It has been required in Australia since 2002 – sponsors must provide the GMDN code as part of the application process



TGA Business Systems

GMDN Agency (not for profit organisation)

- Manages the codes (~24,000)
- In early years the code set was maturing rapidly, it has become more stable
- Creates a monthly download file:
  - new codes,
  - modifications to current codes
  - codes that have been made obsolete

Over time these have become out of synch

This makes it difficult for sponsors using the TGA systems – particularly for those making a new application – where the GMDN code does not existing in the TGA system

The UDI database

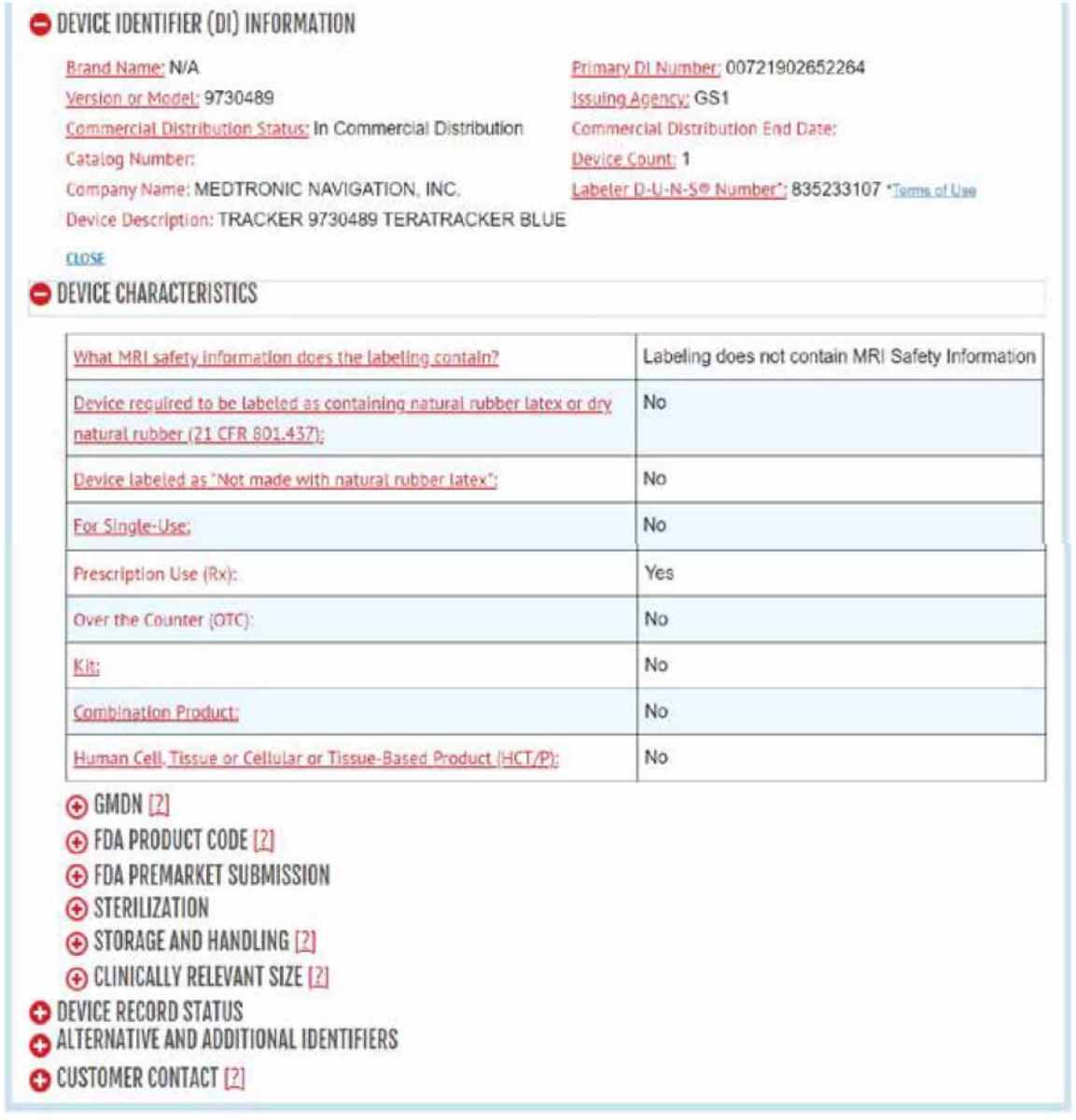
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

The Regulator's database

Only contains static information, and does not include the dynamic production information

Supply chain, hospitals, registries etc.

Potentially will collect more information about the device, including the dynamic production data (batch number, expiry date, lot number, manufacture date)



DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: N/A
Version or Model: 9730489
Commercial Distribution Status: In Commercial Distribution
Catalog Number:
Company Name: MEDTRONIC NAVIGATION, INC.
Device Description: TRACKER 9730489 TERATRACKER BLUE

Primary DI Number: 00721902652264
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 835233107 *Terms of Use

CLOSE

DEVICE CHARACTERISTICS

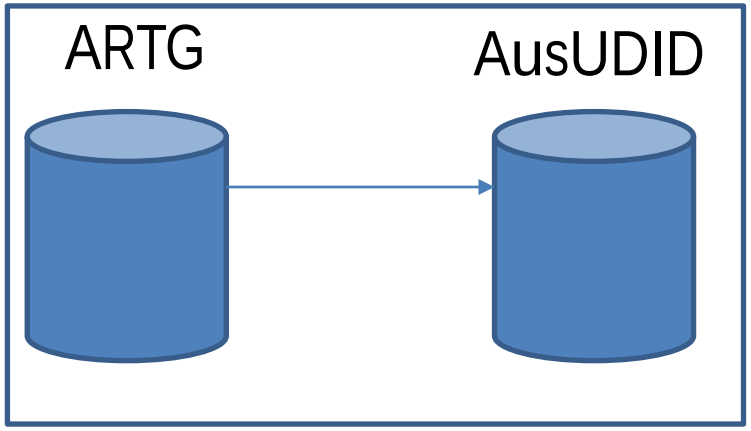
What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	No
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN [2]
FDA PRODUCT CODE [2]
FDA PREMARKET SUBMISSION
STERILIZATION
STORAGE AND HANDLING [2]
CLINICALLY RELEVANT SIZE [2]
DEVICE RECORD STATUS
ALTERNATIVE AND ADDITIONAL IDENTIFIERS
CUSTOMER CONTACT [2]

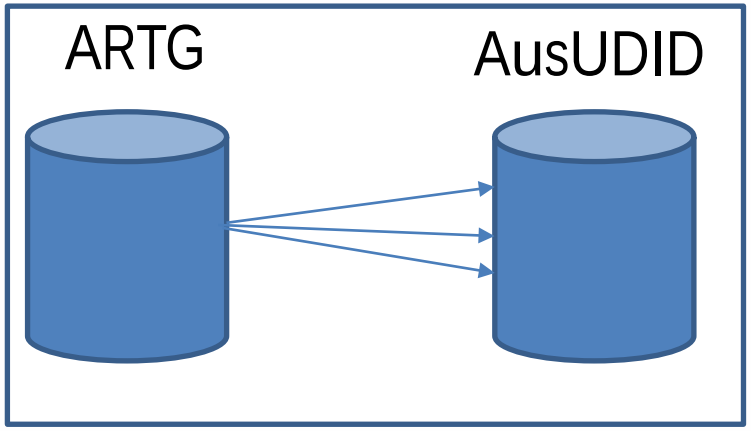
What data are we proposing to store?

- Minimise additional data
- Initial exploration of the U.S. data and its level of match to Australian devices continues
- Will not store production information (UDI-PI, batch number, expiry date etc.)

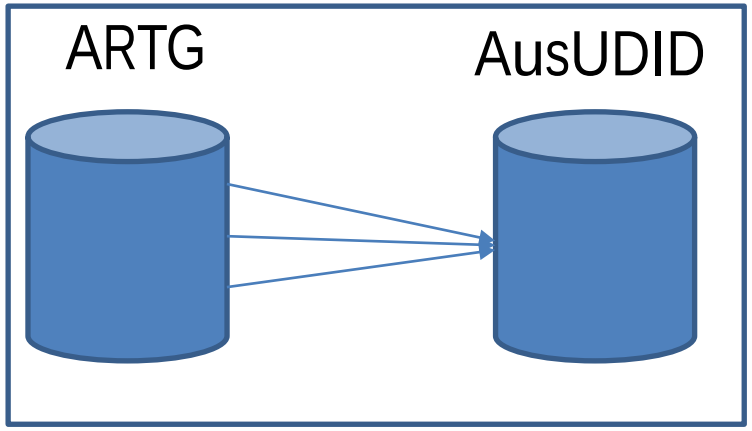
- Will include ARTG ID to link UDI data with the ARTG data



Single device/model



Single inclusion multiple models



Single device, multiple sponsors

UDI data that we are proposing to store

Device information

- Unit of use DI
- UDI-DI (primary)
- UDI Type (IA)
- Additional device DI
- Additional device UDI type (IA)
- ARTG ID

- Brand name
- Device model or version
- Software version
- Reference number
- Catalogue number

- Direct part marking (DPM)?
- Direct part marking DI
- DPM same as primary DI?

Device information

- GMDN code/term

- Configurable medical devices system?
- URL for additional information

- How the device is controlled
  - –serial
  - –lot or batch #
  - –expiry date
  - –manufacture date
  - –software version date or release date
  - –ISBT-128

- Date of discontinuance

Clinical characteristics

- Clinical size
  - –volume
  - –length
  - –gauge
  - –diameter

- Storage conditions
  - –temperature range
  - –needs to be refrigerated
  - –relative humidity range
  - –pressure range
  - –avoid direct sunlight

- Handling conditions
  - –temperature range
  - –needs to be refrigerated
  - –relative humidity range
  - –pressure range
  - –avoid direct sunlight

Clinical characteristics

- Critical warnings
  - –contains latex?
  - –contains DEHP?
  - –MRI compatible?

- Number of reuses
- Additional product description (clinically relevant)

- Labelled as single use?
- Packaged sterile?
- Need for sterilisation before use?
- Method of sterilisation

Manufacturer information

- Manufacturer's name
- Manufacturers address
- Manufacturers customer service contact
- Sponsor's name
- Sponsor's address
- Sponsor contact phone
- Sponsor's contact email

Supply chain information

For every device packaging level:

- Package type ???
- UDI-DI
- UDI type (e.g. GS1)
- Quantity per package
- Additional device identifier
- Additional device identifier type (IA)

UDI data that requires further consultation

- Additional U.S. data

- EU Basic UDI device identifier
- EU Master UDI device identifier
- EU European Medical Device Nomenclature

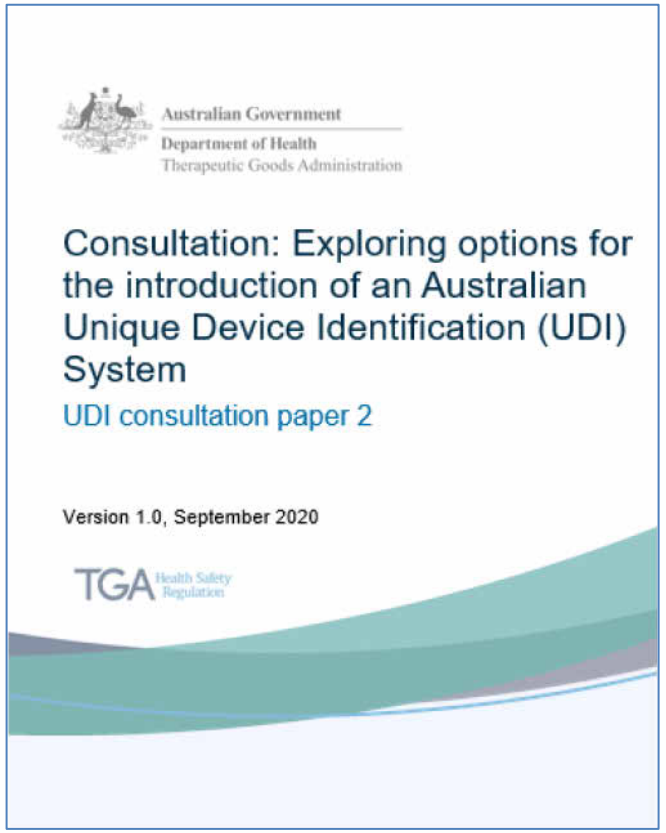
- Package status (U.S. + EU)
- Package discontinuance date (U.S.)
- Package type (U.S.)

What data will be publicly accessible?

- The majority of the data will be publicly accessible
- We envisage this will be useful for consumers, health care organisations, research organisations etc. and will undertake more collaboration
- Likely to be a web accessible portal that allows download of search results
- Exploring benefits of more automated tools

Data submission

- Reduce regulatory burden
- Explore using U.S. Data
- Bulk upload/download
- Bulk upload of changes



Feedback from our consultation:

- Ability to bulk upload, download and upload of bulk changes
- Formats included structured (such as Health Level 7's Structured Product Labelling) and unstructured (such as Comma Separated Values (easy to read in Excel))
- Ability to edit data and correct errors without the requirement of a change in DI
- Triggers were one area of concern, both in terms of the administrative overhead and the differences across jurisdictions
- Requirement for an environment to correct data
- Equal support for the manufacturer (creator of data) and sponsor (as Australian legal entity) to be responsible for the provision of information

Designing the search and download function

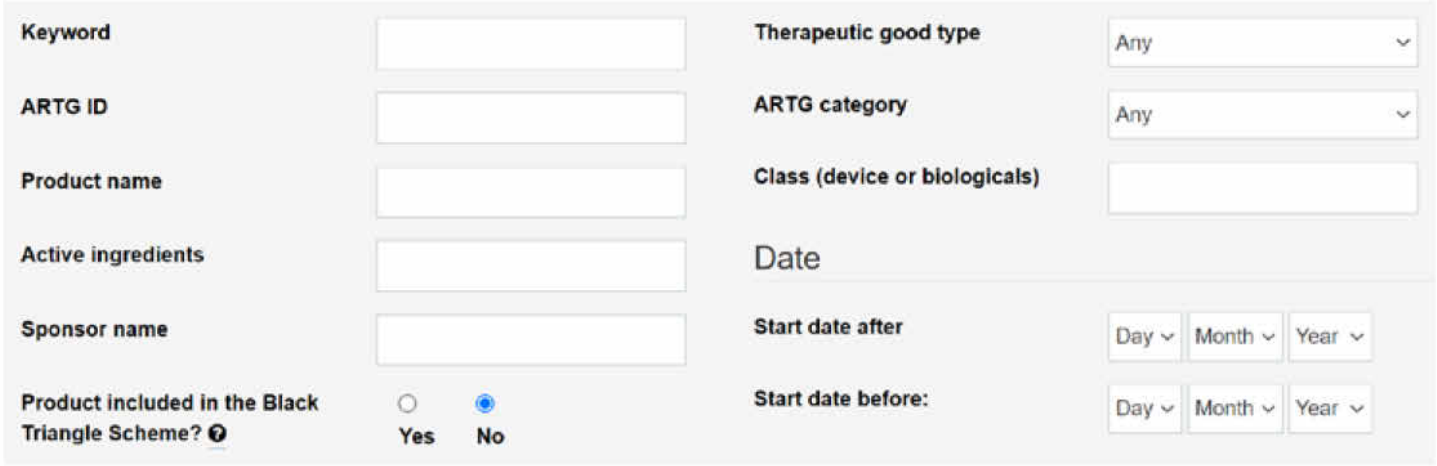
- plan to create an intuitive search function
- may include Collective Terms to assist with navigation
- interested in learning more about how the information will be used to assist with designing search and download capability

Using the ARTG search function

You can search the ARTG for both medicines and medical devices.

Enter your search term into the search box on the TGA website. You can search using:

- the product name
- licence details
- sponsor details
- active ingredient names
- the ARTG identifier number.



What were some of the questions from the last Webinar?

Will the implementation of UDI barcodes into product labels be considered a substantial change, and there a requirement for a conformity assessment review or can this be assessed at the next surveillance audit?

Will Machine to Machine capabilities be available for UDI data transmission immediately?

Can low risk devices submit their UDI data the same time as high risk devices if they choose to?

Will European manufacturers (Italy), already be all over this and have UDI numbering in place? Ie: Is this just new for Australia, or is it new globally?

Curious how it is proposed to align with multiple UDI's applicable to a single ARTG

Will we need an in-country license holder to do the submissions or can we submit UDI data directly?

As UDI becomes more common, is there expectation/ requirement to use the same Basic UDI (Global Model Number) and or "Unit-of-Use DI" across all countries/jurisdictions? And/Or- Does TGA anticipate gathering "UDIs used for this product in other areas

Michelle is currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

LIVE POLL

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

Contact us

Post Market Reform and Review Section

udi@health.gov.au

#AusUDI
#UniqueDeviceIdentifier

More information

#AusUDI
#UniqueDeviceIdentifier

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?

Australian Government

Department of Health

Therapeutic Goods Administration