Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unique Device Identification Webinar 13

Consultation Paper 3 information and project update

Michelle van Wijk
UDI Project Manager, TGA

Gary Pascoe
UDI Product Owner, TGA

TGA Health Safety Regulation

20 September 2022

Agenda

- **AusUDID Sandpit update**
- Consultation Paper 3
- Questions and answers

Sandpit update (as of 19 September 2022)

	**Registrations**	**325** (from a mix of sponsors, manufacturers, software providers, healthcare and TGA staff)
	Users	**316** users with Sandpit access
	Records	**62** UDI records created (using portal and bulk upload)
	**Calls**	**190**
	Emails	**307**
	**Updates**	**4 updates to fix errors and make enhancements, including:** • Improved support for user sign-up and account creation • Associated Supplier Global Location Number (GLN) with device sponsor to support National Product Catalogue (NPC) data exchange • Enhanced data validation rules for Storage Handling and Device Description fields • Removed errors with device search field when certain wild card searches conducted • Improvements to device information and device status

Sandpit update

- Machine-to-machine function is now being used to provide data
- Provision of data using the National Product Catalogue to start this week
- Changes being made to Excel upload functionality based on feedback
- Starting to be used in Early Adopter work
- TGA users also providing feedback

Technical Working Groups

- Established early 2022 for feedback on the design and implementation of the AusUDID
- Representation from a range of medical device manufacturers, sponsors and other stakeholders from within the healthcare system
- Meetings re-started 15 September 2022

If you wish to join, please email udi@health.gov.au with your name, role and organisation name (if applicable)

Agenda

- AusUDID Sandpit update
- **Consultation Paper 3**
- Questions and answers

Consultation Paper 3 - Overview

- Changes to the *Therapeutic Goods Act 1989* passed by parliament February 2021
- Now need to operationalise the requirements in the Medical Devices Regulations
- Australian Government will decide on the regulatory changes and make the regulations
- The TGA is now seeking detailed feedback to inform the Government's decision
- Seeking input across a broad range of stakeholders including hospitals, health care professionals, clinical quality registries, manufacturers, sponsors, issuing agencies, regulatory agents

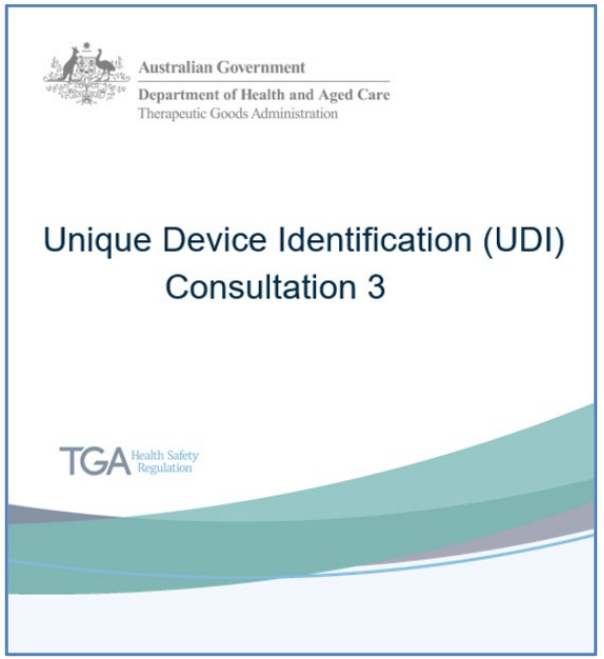
Consultation in parallel with UDI Early Adopter Projects and the release of the "Sandpit" Australian UDI database

Consultation Paper 3

Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework

Including seeking feedback on:

- the impact of accepting both European and USA compliant labels
- acceleration of delivered benefits through a phased implementation approach
- scope and exemptions in applying the UDI
- providing and maintaining data over the full life of the device
- UDI related fees and charges
- UDI labelling and supporting documentation
- any potential regulatory burden
- adoption and use in the broader healthcare setting



This consultation has been written to describe the intent (rather than proposed text for any future regulations)

Patient safety first

In addition to patient safety, the five key underpinning principles are:

1. **Alignment with the International Medical Device Regulators Forum** (IMDRF) (UDI Guidance and Application guides)
2. **The needs of all users will be considered** **(**with priority given to accelerating adoption and use in clinical and hospital settings)
3. **The regulator will make core UDI data accessible to the public** **(**free of charge)
4. **Minimising the burden on manufacturers wherever feasible** many of which are required to comply with differing UDI regulations across many countries
5. **UDI data held by the regulator should be current, correct, and easy to access and maintain** (should be high quality and be designed to maximise usage and value. For example, comprehensive data validation, minimising use of free-text fields and providing values for drop down lists)

International alignment

We propose to:

- align the Australian UDI system with the IMDRF framework, and
- accept UDI labelling that complies with either USA or European (EU) requirements

We understand a number of manufacturers are already working towards a ‘universal device label’ for this purpose and/or are creating a ‘core’ set of UDI data and augmenting that with country-specific requirements to manage the provision of UDI data to multiple countries.

This consultation seeks feedback on the implications of that proposal for data providers and data users (such as hospitals), and with the differences between the USA and EU data elements, whether the TGA should also accept and store both USA and EU compliant data.

IMDRF International Medical Device Regulators Forum

Existing regulatory framework

It is proposed that the Australian UDI system be implemented within the existing framework for the regulation of medical devices within Australia.

Principally through amendments to the Medical Device Regulations to:

- establish the database
- require the inclusion of UDIs and related information in the database
  (these requirements are proposed to be included as part of the Essential Principles)
- include related requirements in the Essential Principles, such as labelling

In Australia, the sponsor is principally responsible for ensuring that the regulatory requirements are met for devices supplied in Australia.

This may add complexity when a labeller is undertaking some activities on the sponsor's behalf (such as attaching a label to a device). In most instances, the labeller will be the manufacturer or sponsor, but in some instances, it may be a specialist third party acting on behalf of the sponsor or manufacturer.

Proposed scope of devices

It is proposed that most kinds of medical devices would be required to comply with the UDI requirements, unless identified in the Essential Principles as kinds of devices for which a UDI is not required.

The following are proposed to be in scope:

- medical devices in the emergency stockpile
- medical devices that are exempt from inclusion in the ARTG
- replacement parts where the original part was in scope
- Class I devices

Low-risk high volume devices (Class I)

Globally, it is recognised that there are specific challenges relating to requiring UDIs for Class I devices, which are generally lower-risk kinds of medical devices.

The U.S. Food and Drug Administration (FDA) for example, has recently released guidance relating to Class I (non life-supporting or non life-sustaining) compliance dates, and requirements relating to Class I Consumer Health Products. The guidance noted that “As UDI implementation has progressed, FDA has gained further insight into the public health benefits and potential burdens of UDI requirements for Class I devices, which generally pose the lowest risk.”

Considerations related to Class I devices include:

- confusion for consumers if some devices are in the AusUDID and others are not
- some Class I devices are both consumer health products and used in hospitals (such as specimen containers)
- what might the challenges be in relation to procurement and hospital inventory systems if some devices have UDI and others do not – will two separate processes be required?
- should the TGA consider a grouping mechanism to reduce the number of UDI records that might be required?

Proposed Exemptions

It is proposed that UDI requirements would not apply to the following kinds of medical devices and IVDs:

- Class 1 General laboratory IVD medical devices (such as pipettes)
- Medical devices that are surgical loan kits (at the kit level)
- Medical devices and IVD medical devices imported into and supplied in Australia under the Special Access Scheme (SAS) or Authorised Prescriber Scheme or any other exemption pathways (such as for clinical trials)
- Export only medical devices and IVDs
- Individual single-use disposable devices contained within a system or procedure pack, which are not intended for individual use outside the context of the system or procedure pack
- Devices that are exempted from bearing a UDI carrier on the relevant level of packaging, when included within a system or procedure pack
- Custom made medical devices
- In-house IVDs

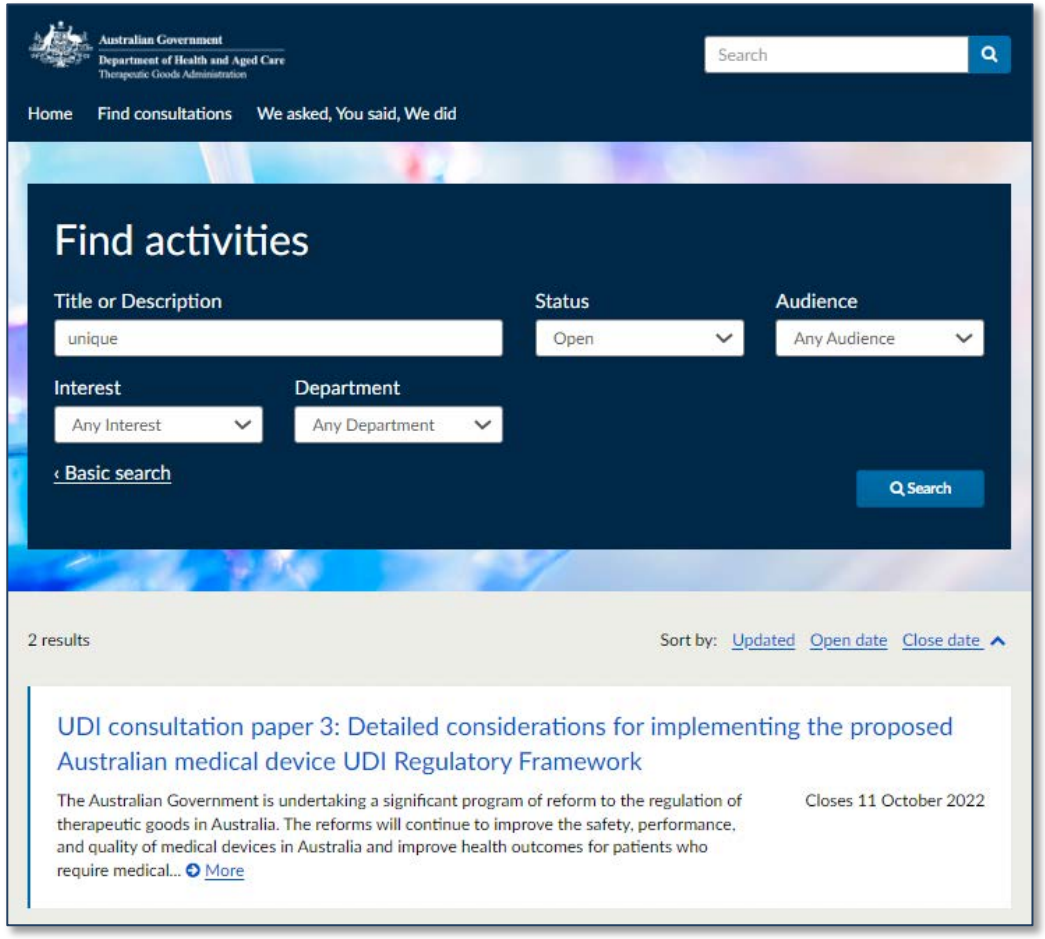
Proposed phased implementation

Australian Device Class	Devices	Label/Package to bear UDI, data to be provided to AusUDID	Direct Marking Compliance Date	Labels/packing not required to bear UDI for devices in transit to, or in Australia before	Direct marking not required for devices in transit to, or in Australia before*
Class III (including AIMD)	Included on the ARTG as at 30 June 2024, or supplied after 1 July 2024	1 July 2024	1 July 2024	1 July 2024	1 July 2024
Class II	Included on the ARTG as at 30 June 2024, or supplied after 1 July 2024	1 July 2024	1 July 2025	1 July 2024	1 July 2025
Class I	Included on the ARTG as at 30 June 2026	1 July 2026	1 July 2027	1 July 2026	1 July 2027
IVDs Class 2 IVDs Class 3 IVDs Class 4	Included on the ARTG as at 30 June 2026, or manufactured after 1 July 2026	1 July 2026	1 July 2027	1 July 2026	1 July 2027
IVDs Class 1	Included on the ARTG as at 30 June 2027, or manufactured after 1 July 2027	1 July 2027	1 July 2028	1 July 2027	1 July 2028
	Medical devices and IVD medical devices that are regulated (i.e. required to comply with the Essential Principles) but that are not required to be included on the ARTG	1 July 2027	1 July 2028	1 July 2027	1 July 2028

Please provide feedback

Open until **11 October 2022**

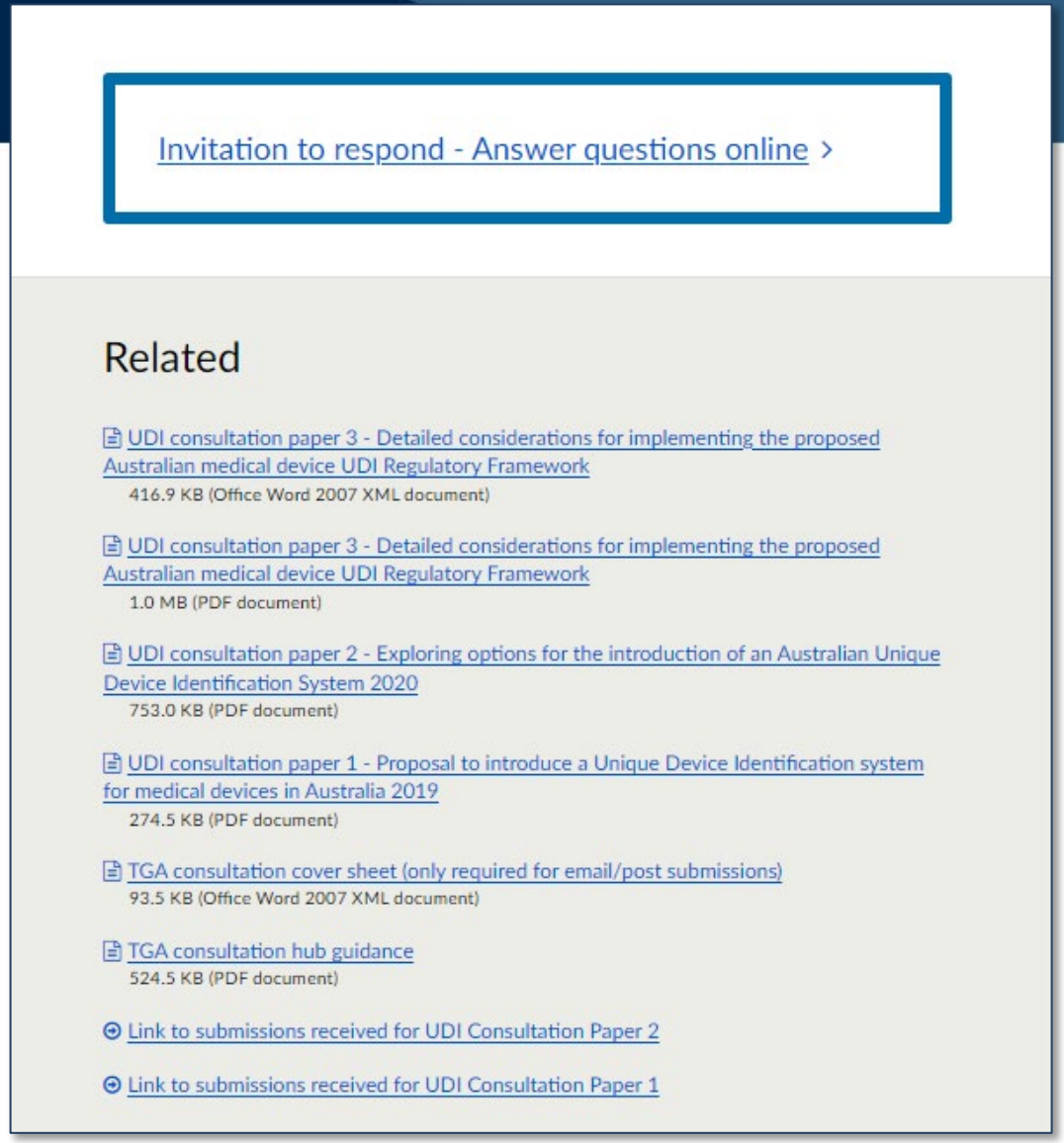
- Feedback through online survey
- Can download copies of the paper (Word or PDF) on the consultation hub



UDI consultation paper 3: Detailed considerations for implementing the proposed Australian medical device UDI Regulatory Framework
https://consultations.tga.gov.au/tga/udi-consultation-paper-3/

The Australian Government will decide on the regulatory changes and make the regulations.

The TGA is now seeking detailed feedback to inform the Government's decision.



UDI consultation paper 3: Detailed considerations for implementing the proposed Australian medical device UDI Regulatory Framework
https://consultations.tga.gov.au/tga/udi-consultation-paper-3/

Agenda

- AusUDID Sandpit update
- Update on UDI Consultation Paper 3
- **Questions and Answers**

Questions and Answers

Michelle van Wijk
UDI Project Manager
TGA

Gary Pascoe
UDI Product Owner
TGA

Contact us

UDI Support Team

UDI@health.gov.au

Phone: 02 6289 8557
(+61 2 6289 8557 International)

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

Website and link references

UDI hub ★	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system
Third UDI consultation paper	UDI consultation paper 3: Detailed considerations for implementing the proposed Australian medical device UDI Regulatory Framework - TGA)
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
Previous webinars	Unique Device Identification system: Communications and stakeholder engagement | Therapeutic Goods Administration (TGA)

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration