Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Unique Device Identification Webinar 12

Questions and answers on the AusUDID Sandpit and update on UDI Consultation Paper 3

Michelle van Wijk
UDI Project Manager, TGA

Gary Pascoe
UDI Product Owner, TGA

TGA Health Safety Regulation

16 August 2022

Welcome

- This webinar is being recorded
- Webinar will be made available in the upcoming weeks
- Any relevant links will be broadcasted via the slido app
- Q&A will be open during the session via the slido tool
- A live Q&A session will take place after the presentation
- Live poll – please let us know how we went

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:** 2654 848 1683

Agenda

- **Questions and answers from the July Webinar**
- Sandpit update
- Update on UDI Consultation Paper 3
- Questions and answers

July Webinar Questions and Answers

I may not be able to attend the live event due to the time difference, but will this Webinar recording or slides be available after the event?

All UDI Webinars (presentation, recorded webinar and transcript) are available on the TGA UDI Hub
Unique Device Identification system: Communications and stakeholder engagement.

I have submitted my registration to use the Sandpit. When will I get access?

We are providing access in phases, first phase is data providers and second is data users.

This means that whilst you might have registered, you might not yet have access. If you are concerned we have not received your request, please email us at UDI@health.gov.au

If you have not yet registered, you can complete the Sandpit Registration of Interest form

The UDI Hub doesn't seem up-to-date. Is there another way that you are sharing relevant documentation?

The TGA is launching a new website. The UDI Hub will be updated over August and September to bring it up to date.

In the interim, if you have a request for specific information or documentation, please email us at UDI@health.gov.au

July Webinar Questions and Answers

Will the TGA UDI database be aligned with the EUDAMED database?

The EUDAMED database is being developed to support the EU Medical Device Regulations (MDR) and In Vitro Diagnostic Device Regulations (IVDR).

Australia already has the Australian Register of Therapeutic Goods (ARTG) that contains information on medical devices authorised for supply in Australia. The Australian UDI database will only contain UDI data, noting that the AusUDID data elements are yet to be defined and may differ to EUDAMED.

Can you provide more information on how Australia rules differs from EU, USA, Canada, UK, Switzerland, South East Asia, China, etc.?

The Australian UDI project plans to align where feasible, with International Medical Device Regulators Forum (IMDRF) UDI guidance, and the U.S. and EU, noting in some circumstances the requirements differ and the Australian Government will decide the Australian UDI regulations.

We do not plan to provide information on the similarities and differences across other countries.

How aligned will Australian UDI regs be with IMDRF N48 and EU?

In addition to the above:

We note that there are differences between the EU and the IMDRF requirements, such as the requirement for a Basic UDI-DI and Master UDI-DI.

When will TGA publish the AU UDI data dictionary?

We plan to publish the draft data dictionary as part of the third consultation, and will publish a version on the TGA UDI Hub. The final data requirements will be part of the regulations and we will publish a final data dictionary once the regulations are approved.

July Webinar Questions and Answers

Will plasma / blood products be included in AusUDID?

We will be seeking feedback through the third UDI Consultation paper, as to the scope of the Australian regulatory framework and what should be exempt from UDI requirements.

What is the proposed timeline for the Australian UDID (AusUDID)?

Indicative timelines are

January 2023	Voluntary compliance for high-risk devices (Class II, III)
July 2024	Mandatory compliance for implantable devices (for allocation of UDIs, UDIs on labelling, and provision of data)

When can we expect the third UDI Consultation paper to be released and what time period will we have to respond?

We plan to release the third consultation paper in August and will notify stakeholders of the details at that time.

Once published, the consultation dates and feedback guides will also be available via the TGA website.

July Webinar Questions and Answers

Is data entered into the Sandpit only available to the data owner or can all users view it?

All Sandpit users can search for and view a ‘published’ UDI record.
Users with sponsor and manufacturer access can create, update publish and delete their own UDI records.
A UDI record that has not been published (e.g. is still in a draft state) can only be viewed by the record owner.

Is the Sandpit pre-populated with data from an overseas database?

No. The Sandpit data will be provided by sponsors and manufacturers that enter their UDI records into the Sandpit.

Can more than two people have access? If so, can this be done later?

There is no limit to the number of users who can access the Sandpit. While the registration form limits the number of users who can register on a single form to two, multiple additional registrations are permitted.

The registration process will be open for the entire Sandpit period.

Will the production environment allow for multiple records per bulk upload spreadsheet?

The TGA has received feedback on the Sandpit bulk upload functionality.
We are currently reviewing this feedback and assessing options for potentially updating the bulk upload process.

We plan to consult with stakeholders in coming weeks on these options.

July Webinar Questions and Answers

Can the bulk upload template be provided online to allow for preparation ahead of gaining access to the Sandpit?

Thank you for this suggestion.

The TGA will assess options for making the bulk upload template available on the TGA's UDI Hub website.

Will the Australian Basic UDI follow the same attribute requirements of the EU? It looks optional in the spreadsheet, is this the plan for BUDI?

The Basic UDI-DI has been included in the Sandpit as optional.

The inclusion requirements for Basic UDI and other data elements will be set out in Australia's UDI regulations, as decided by the Australian Government.

Will the Sandpit data be scrubbed when the AusUDID goes live?

The data in the Sandpit is test data supplied by manufacturers and sponsors.

This data won't be in the voluntary compliance version of the AusUDID.

Will the TGA be issuing guidance documents to help sandpit users on testing protocols?

We are preparing simple guidelines to assist those organisations seeking to use some of the more complex features of the Sandpit (such as Machine-to-Machine (M2M) or National Product Catalogue (NPC) data exchange).

Any questions?

- Ask your question now in **Slido**, or get in touch with the dedicated UDI Engagement and Operations team
- Contact
  - Email: udi@health.gov.au
  - Phone: 02 6289 8557 | International: +612 6289 8557
- We welcome all feedback on Sandpit and our Webinars

We'd love to hear your thoughts. Please submit any comments you have using the Give Feedback button located at the bottom right corner of the page.

Sandpit update (as at 6 August)

	Registrations	**250** (from a mix of sponsors, manufacturers, software providers, healthcare professionals and TGA staff)
	Users	**141** users with Sandpit access (45 sponsor/manufacturer organisations)
	Records	**21** UDI records created (using portal and bulk upload)
	Calls	**69**
	Emails	**159**
	Updates	**2** updates to fix errors and make enhancements

Consultation Paper 3 - Progress update

- Will be published on the TGA consultation hub
- Current medical device sponsors and UDI stakeholders (on our list) will be notified

- Focus areas are likely to include:
  - Should Australia accept EU and US FDA compliant labels and data?
  - Scope of devices and exemptions
  - Phased implementation approach
  - Who should provide and maintain the data?
  - Labelling
  - Fees and charges
  - Considerations for adoption and use

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/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
Previous webinars	https://www.tga.gov.au/unique-device-identification-system-communications-and-stakeholder-engagement

Contact us

UDI Engagement and Operations Team

UDI@health.gov.au

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

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration