Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian UDI Implementation – Position Paper

Managing UDI data for devices with multiple sponsors

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Executive Summary

Australia's medical device regulations specify the Australian sponsor as the person or organisation legally responsible for complying with Australian medical device requirements.

With sponsors responsible for supplying and maintaining UDI data, this can lead to circumstances where characteristics of the device differ when devices are supplied by more than one sponsor. These differences can create ambiguity in device identification and use, and a departure from the information held by other international regulators, for the same device.

The TGA will use the Australian UDI Database (AusUDID) to help avoid these differences.

To address the challenge, the AusUDID will implement an approach that involves linking the multiple sponsors and their inclusions in the Australian Register of Therapeutic Goods (ARTG) to a single Unique Device Identification (UDI) Device Identifier (UDI-DI). Through this link to a single UDI-DI, sponsors will manage and update the UDI data via a defined, trackable, and intentional action, which can be reviewed by the TGA on request.

Our approach includes:

1. Adding data quality checks to the AusUDID for devices that have more than one sponsor
2. Changes to the AusUDID Data Dictionary to reflect amendments to data element types
3. Notifications to sponsors when changes are made by another sponsor.

The key advantages of this approach include:

1. **Avoiding ambiguity**: This approach ensures clarity for data users, and in particular healthcare providers and consumers. All critical information about the device, regardless of sponsor, is accessible and consistent. This will ensure ongoing integrity of the AusUDID data and its use throughout the healthcare system.
2. **Streamlined process**: The AusUDID will apply a consistent user experience for all sponsors, with one intentional action when a sponsor changes data that should be common across all instances of the device.
3. **No impact to device supply approvals**: The AusUDID data is linked but independent from ARTG approval to supply. The ARTG will remain as the definitive record of a sponsor's approval to supply.
4. **Clear responsibilities:** Sponsors are **only** responsible for the data they provide. Sponsors are not responsible for changes to data made by other sponsors linked to the same UDI record.

This paper:

- Collates the results of extensive consultation and associated industry feedback and outlines the final approach to be implemented by the TGA
- Seeks feedback from stakeholders on this approach, to help inform the Australian Government's direction on the UDI policy.

Introduction

The Therapeutic Goods Administration (TGA) regulates and monitors the safety, performance, and quality of medical devices in Australia. This includes establishing the Australian UDI Database (AusUDID) and facilitating adoption of the UDI throughout the Australian healthcare system.

In establishing the Australian UDI System, the TGA aims to implement a system that:

- reflects the International Medical Device Regulators Forum's (IMDRF) guidance for UDI systems
- is a single system that allows for unambiguous identification of medical devices
- provides healthcare professionals and patients a single, consistent and complete source to identify a medical device and its key attributes.

Central to realising these outcomes is the AusUDID. The AusUDID will be a key medical device database holding the information essential to identifying all applicable devices supplied in Australia, which in addition to enabling device identification will:

- Increase the consistency of the TGA's regulatory systems through higher quality data
- Minimise the duplication of data and data entry across many stakeholders' systems
- Inform manufacturers and related parties about data quality issues
- Support the tracking of corrections, data quality improvements and responses regarding the information submitted.

Following approval by the Australian Government for the TGA to establish the Australian UDI System and UDI database, the TGA is now defining the final features of the Australian UDI System.

Consultation history

To help inform considerations on specific policy areas, the TGA has engaged with the UDI community through a series of industry consultations and working groups with subject matter experts and stakeholders, discussing issues impacting UDI implementation and adoption across the Australian healthcare system and identifying potential solutions.

The final approach described in this document takes into account a range of stakeholder consultations that the TGA has undertaken on this one topic: managing changes to UDI data when a device has more than one sponsor.

Consultations undertaken include:

- UDI consultation paper 3: Detailed considerations for implementing the proposed medical device UDI Regulatory Framework
- Targeted discussions with Sponsor organisations and medical device industry organisations
- A series of Technical Working Groups through 2023 and 2024, with the final informal consultation in April 2024.

Through these consultations the TGA sought feedback on:

- Options for managing multiple sponsors in the AusUDID
- Options for managing changes to data when there is more than one sponsor including possible options for holding and reviewing changes to certain data elements
- Proposed changes to the Australian UDI Data Dictionary.

This paper collates the results of these consultations and associated feedback and outlines the final approach to be implemented by the TGA.

The challenge: Ensuring consistent data in the Australian UDI Database

To help ensure high quality of UDI data, the IMDRF recommends that *"the manufacturer should create and maintain globally unique UDIs on his devices"*[1]. This approach has been adopted by the US Food and Drug Administration (USFDA) and the European Union (EU), with both requiring the manufacturer to supply the UDI data to their respective UDI databases.

However, as Australia's medical device regulations specify the Australian sponsor as the person or organisation legally responsible for complying with Australian medical device requirements, the sponsor will be responsible for ensuring up-to-date device data is submitted and maintained in the Australian UDI database.

With device sponsors responsible for supplying and maintaining UDI data, this can lead to circumstances where characteristics of the device are different for devices supplied by more than one sponsor. These differences can create ambiguity in device identification and use and departure from the information held by other international regulators.

The approach: The AusUDID to help maintain quality data

To maintain the consistency of the Australian UDI data and avoid ambiguities in a device's identification, the AusUDID will include data quality checks and system functionalities that reduce ambiguity in the device's identification and consistency in the UDI data relating to the use or operation of the device.

These checks will apply when changes are made to those UDI data elements the TGA has ascertained as reflecting the information a manufacturer is expected to supply to all sponsors. These data elements are referred to as 'Device Data'.

Device Data

The data fields classed as Device Data are:

- Primary DI and Issuing Agency
- Brand Name
- Model or Version
- Device Description
- Secondary DI and Issuing Agency
- Previous DI and Issuing Agency
- Device Count
- Unit of Use DI
- Direct Marked DI and Issuing Agency
- Restricted Number of Uses

[1] See page 10 of International Medical Device Regulators Forum's (IMDRF) UDI Guidance (IMDRF/WG UDI/N7Final:2013)

- Device Subject to Direct Marking (DM), but Exempt
- Direct Marking DI Different from Primary DI
- Is the medical device software or does it incorporate software?
- Is the medical device a kit?
- MRI Safety Status
- Intended for Single Use?
- Device labelled as “Not made with natural rubber latex”
- Device required to be labelled as containing natural rubber latex or dry natural rubber?
- Device Packaged as Sterile?
- Requires Sterilisation Prior to Use?
- Clinical Size
- Sterilisation Methods(s)
- Storage and Handling
- Production Information Flags
- Manufacturer ID and Name.

The AusUDID will keep the data in these data elements consistent between all sponsors of the device.

The AusUDID will apply these consistency rule across all the AusUDID data submission methods: online, Bulk Upload Spreadsheet, HL7 and the National Product Catalogue (NPC) (noting the Bulk Upload Spreadsheet only supports the creation of AusUDID records and cannot be used to update existing records).

Sponsor Data

The remaining AusUDID data fields are referred to as ‘Sponsor Data’ and include:

- ARTG ID
- Sponsor ID and Name
- GMDN Code
- Device Class
- Catalogue Number
- Commercial Distribution End Date (Sponsor)
- Package including Package Commercial Distribution End Date (Sponsor)
- Supporting Documents (PIL, eIFU).

The AusUDID will support the supply of different Sponsor Data by each sponsor.

Each will sponsor create and update their own Sponsor Data, and changes to Sponsor Data can be made at any time using any of the AusUDID channels (noting the Bulk Upload Spreadsheet only supports the creation of AusUDID records and cannot be used to update existing records).

The approach: Managing change in common data

The AusUDID seeks to provide a consistent experience for all sponsors, including those that share the supply of a specific device, with one difference applying when a sponsor is seeking to change data classified as Device Data.

In this circumstance, the AusUDID will prompt the sponsor to acknowledge they are changing Device Data by registering the data change as a “Correction” of the UDI record. This will be managed via the existing Corrections feature of the AusUDID.

The following contrast the differences when a device has a single sponsor, and when a device has more than one sponsor.

Initial supply of data and changes to data

Single sponsor

If a device has a single sponsor, that sponsor supplies and maintains all data elements in the AusUDID, per the existing AusUDID requirements. That is:

- The sponsor adds the UDI record to the AusUDID
- The sponsor can update their Sponsor Data at any time
- The sponsor can update the Device Data at any time
- Changes to Trigger data elements will result in the sponsor being prompted to create a new UDI record, unless the sponsor registers the change as a ‘Correction’ and provides a reason for this correction.

In this circumstance, the TGA recognises the sponsor is responsible for providing data that reflects the specifications and information provided by the manufacturer.

Multiple sponsors

A device has multiple sponsors, when more than one sponsor is linked to a single UDI record via their respective ARTG inclusions.

A new UDI record will be created by one sponsor through the existing AusUDID features, and ensuing sponsors can link to this record and add their Sponsor Data. This is current AusUDID functionality.

Each sponsor may change their Sponsor Data at any time.

The following conditions will apply when a sponsor changes Device Data for a shared device:

- The sponsor making the change will be notified that they are changing Device Data and there are multiple sponsors supplying the device, and changes to this data is to be via the ‘Corrections’ functionality of the AusUDID
- If the sponsor wishes to change Device Data, they will be required to enable this through the existing ‘Corrections’ functionality of the AusUDID.

If the change is submitted to the AusUDID via a machine to machine transaction (e.g. a HL7 or NPC message), the AusUDID will return the message to the user via the machine to machine interface. As per existing AusUDID functionality, the sponsor can mark the one or more UDI records for ‘Correction’ and re-submit the machine to machine transaction.

The TGA recognises the sponsor making the change is responsible for the data and presumes a change to Device Data will only be made if the manufacturer has advised a change to that data.

In addition, the TGA will implement methods so that:

- Other sponsors linked to a device are notified of a change to its Device Data
- Sponsors linked to the UDI record can request a review by the TGA if they consider the data is incorrect.

The approach: Changes to the Australian UDI Data Dictionary

Revised data elements and validation

This position will result in amendments to the data validation rules presented in the DRAFT version of the Australian UDI Data Dictionary.

These changes are summarised in the table below.

AusUDID Data element	Element type	Summary of change	Rationale
Model or Version	Device (Trigger)	Model or Version will no longer be conditional based on Catalogue Number. It will be a mandatory data element.	By separating Model or Version from the Catalogue Number field, Model or Version will become mandatory and be classified as Device Data.
Catalogue Number	Sponsor	Catalogue Number will change from being categorised as Device Data to Sponsor Data. Catalogue Number will be optional and is not a Trigger field. Catalogue Number will no longer be conditional based on Model or Version Number.	Change allows each sponsor to provide the Catalogue Number relevant for their own practices and systems. This change reflects feedback received from sponsors.
Sponsor Commercial Distribution End Date	Sponsor	The definition for Commercial Distribution End Date will be revised to clarify this data relates to the sponsor's supply of the device in Australia. The Sponsor Commercial Distribution End Date will be optional and will not be a trigger field. If there is at least 1 active ARTG and the (Sponsor) Commercial Distribution End Date is either not entered or is today's date or later, the AusUDID will display the distribution status as 'In Commercial Distribution.' Otherwise, the status will be	Adjustments in the field definition and naming recognises each sponsors' supply of the device. This change is based on feedback received.

AusUDID Data element	Element type	Summary of change	Rationale
		"Not in Commercial Distribution."	
Device Class (Manufacturer or sponsor)	Device	If the manufacturer supplies the UDI data, the AusUDID will allow for manufacturers to supply the Device Class they hold. This data is optional and sponsors are not required to provide the manufacturer's Device Class. Manufacturers are not required to provide the Device Class as used by the Sponsor. For public views and downloads, only the ARTG recorded Device Class will be included. For Sponsor views and downloads, both the supplied Device Class and ARTG recorded Device Class will be included. Only 1 Device Class can be provided per ARTG.	Change allows data to be initially supplied by the manufacturer, in the circumstance where the manufacturer supplies the data to the AusUDID. While the AusUDID will hold this data, the Device Class of the linked ARTG inclusions will be displayed to healthcare and public users. This change is based on feedback received.
GMDN Code (Manufacturer or Sponsor)	Device	If the manufacturer submits the initial UDI data, the manufacturer can provide the GMDN Code they have recorded for the device. This data field is optional and sponsors are not required to provide the manufacturer's GMDN Code. Manufacturers are not required to provide the GMDN Code as used by the Sponsor. For public views and downloads, only the GMDN Code (and Term Name/Description) from the ARTG will be used. For Sponsor views and downloads, both the manufacturer supplied GMDN Code (and Term Name/Description) and the GMDN Code (and Term Name/Description) from the ARTG can be displayed. Only 1 GMDN Code can be provided per ARTG.	Change allows data to be included based on the manufacturer data, if supplied. While the AusUDID will hold this data, the GMDN Code of the linked ARTG inclusions will be displayed to healthcare and public users. This change is based on feedback received.

The approach: TGA review of data changes

Since each sponsor may make changes to the UDI record, cases may arise where a sponsor disagrees with changes already made by another sponsor. The TGA will provide a mechanism for a sponsor to request a specific change be reviewed by TGA.

This process will initially be via a request to the UDI Support team, which will manage the review of the data held in the AusUDID as well as review the history of data changes, via the AusUDID audit trail.

For this review, the TGA may request further information from the impacted sponsor(s) to assess the data and the impact on the UDI record.

The TGA will advise all sponsors of the device of the outcome and in the case where a change is rejected, may request the sponsor who made that change to correct their own records and update the UDI record.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	UDI Project Team, Devices Reforms Taskforce	July 2024

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