



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

January 2019

**TGA** Health Safety  
Regulation

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## Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, TGA regulates therapeutic goods, and is responsible for implementing the Government's reforms. The Therapeutic Goods Administration (TGA) has issued this consultation paper as part of the Government's reform program.

## Background

Demand is growing for improved traceability of medical devices in the supply chain. There is now worldwide recognition that, in the interests of patient safety and improved industry outcomes, the ability to unambiguously identify medical devices is essential. The development and implementation of the Unique Device Identification System (the UDI System) is widely acknowledged by the industry and regulators as an effective mean of ensuring timely access to complete, accurate and consistent information about medical devices.

The [International Medical Device Regulators Forum](#) (IMDRF) - a group of the major medical device regulators from around the world, including Australia - is working to advance and strengthen international medical device regulatory frameworks, including those governing Unique Device Identification (UDI). [IMDRF guidance documents](#) (IMDRF UDI Guidance) provide a framework within which regulatory authorities and manufacturers can develop and implement their own UDI systems. The aim is to secure 'a single, globally harmonized system for positive identification of medical devices'.

Several international regulatory authorities have already implemented the UDI System, commenced work on implementation, or introduced enabling legislation. This includes authorities from the USA, Europe, Japan, Brazil and some members of the [Asian Harmonization Working Party](#).

## This consultation

We are exploring the feasibility of introducing the UDI System in Australia, including options for development of the UDI database (AusUDID).

We propose to build on the work and experience of the IMDRF, the U.S. Food and Drug Administration (U.S. FDA), the European Union (EU) and other jurisdictions to inform the principles and design of a UDI System for Australia.

**The focus of this paper is to seek your feedback on:**

- the proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
- whether the TGA or another body should be responsible for establishing and maintaining the Australian UDI database (AusUDID)
- the potential scope of regulatory and legislative amendments required to establish the UDI System in Australia.

The introduction of any mechanism that allows unambiguous identification of medical devices in supply chains will impact many stakeholders significantly, especially if UDI is fully integrated into the Australian healthcare system.

In recognition of this proposal's complexity and broad impact, we plan to hold other consultations on further aspects of the UDI System's introduction in Australia, including more detailed discussion on the regulatory requirements and seeking more targeted views on the impact of this change on specific groups of stakeholders.

## Proposed implementation measures: summary

### Aim

The implementation of a globally harmonised UDI system in Australia.

### Proposal

That the [Therapeutic Goods Act 1989](#) (the Act) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Medical Device Regulations) be amended to include the legislative and regulatory powers allowing the TGA to establish UDI system in Australia.

### Effect

Sponsors of all medical devices supplied in Australia would be required to ensure that their devices carry Unique Device Identifiers and that relevant information and data is entered into the AusUDID.

### Your feedback

Are you a patient, manufacturer, healthcare provider, industry representative body, consumer advocacy group, scientist, researcher or other interested party?

We seek your views on the proposed regulatory changes that would facilitate the adoption of the internationally harmonised principles for introduction of the UDI system in Australia. Your input will assist us to address any unintended consequences and to better inform the proposal.

This paper is not intended to be a consultation on the application and use of UDI within the broader healthcare system; however, we will welcome comments on these wider issues.

At the end of this paper (on page 16) is a [list of questions](#) to help you address the proposal in your feedback.

Please submit your feedback directly to the TGA by email (See [How to submit](#) on page 17).



#### **Please note**

This consultation **closes on 18 February 2019.**

Before providing feedback, it is important to read the explanatory material that follows.

## The UDI System

The introduction of the UDI System is an important means of improving the identification and traceability of medical devices. UDI can provide significant support to other reforms designed to improve the effectiveness of pre-market assessments of medical devices and management of post-market safety-related activities.

The UDI System consists of three interrelated parts:

- the development and application of UDI globally harmonised standards
- the requirement for manufacturers of medical devices to create and place a Unique Device Identifier on a device, its labelling and packaging
- the requirement to enter specified information or certain data elements into a UDI database (UDID).

The Unique Device Identifier is a series of numeric or alphanumeric characters created by applying globally accepted device identification and coding standards. The Unique Device Identifier has two parts, the Device Identifier (UDI-DI) and Production Identifier (UDI-PI).



### Important

Any requirement to include a Unique Device Identifier **will not override** the Essential Principles requirements in the Medical Device Regulations relating to the safety and performance characteristics of medical devices; in particular, the requirement to provide patient information and instructions for use.

A UDID contains essential information specific to the model of a medical device (UDI-DI and some key data elements) and allows access to this information.

Further explanation about these and other concepts is provided in the '[Definitions](#)' section on page 9.

## What are the benefits of implementing the UDI System?

Identification of medical devices using the UDI System offers significant benefits throughout the supply chain, including:

- **enhanced effectiveness of post-market safety-related activities**, such as: faster and more accurate identification of problems; improved functionality in the reporting of incidents and adverse events; and more effective management of medical device recalls
- a **more robust pre-market assessment of medical devices** due to the availability of better quality evidence-based data that is presented consistently and which includes post-market data and analysis
- a **reduction in medical and surgical procedural errors** by allowing healthcare professionals and others to quickly trace a device and obtain vital information about its characteristics
- **enhanced analysis and research** through the uniform documentation of devices in electronic health records, clinical information systems, registries and other data sources

- a **more robust and secure global distribution chain**, which helps to tackle diversion and counterfeiting, and facilitates preparation for medical emergencies
- better **sharing of medical device information around the world**.

For these reasons, we anticipate that the proposed establishment of the UDI System in Australia will benefit consumers, healthcare professionals, scientists, researchers, the medical device industry and regulators.

## International activities related to the UDI System

The following provides an overview of international activities related to the UDI system.

### International Medical Device Regulators Forum (IMDRF)

The IMDRF published UDI guidance: Unique Device Identification (UDI) of medical devices (UDI Application Guide) in December 2013. This document provided a high-level conceptual framework of the 'basic core concepts' of a UDI system. However, it has been recognised that further IMDRF guidance is required to better facilitate consistent implementation of UDI systems internationally.

Accordingly, the IMDRF UDI Working Group—which is comprised of IMDRF members and representatives from relevant international industry bodies —was established in December 2017 to develop the [UDI Application Guide](#). It is intended to be used as a supplement to the 2013 guidance and will provide the details and specifications necessary to ensure consistent development of UDI systems in different jurisdictions.

A draft of the UDI Application Guide, together with other relevant information, was published in July 2018 for three months public consultation until 12 October 2018.

#### Important

The IMDRF recognises that national regulation may differ when dealing with certain aspects of the guidance.



While some UDI-related terminology and regulatory requirements are jurisdiction-specific, the regulators participating in the IMDRF UDI Working Group aim to reach in-principle agreement on the fundamentals underpinning the UDI System. This will include those requirements specifically related to UDI standards, data elements to be included in UDI-DI and UDI-PI, and basic principles for building the UDID.

### U.S. Food and Drug Administration

The U.S. FDA introduced its [UDI system](#) in 2013 (the UDI Rule).

#### Labelling

The [U.S. FDA's UDI Rule](#) requires the label and packaging of every medical device distributed in the United States to bear a Unique Device Identifier unless an exception or alternative applies. The Unique Device Identifier must be issued by a U.S. FDA-accredited Issuing Agency (IA) that operates a coding system conforming to international standards. The Unique Device Identifier must appear in two forms on the label and device packaging: easily (human) readable plain text,

and automatic identification and data capture (AIDC) technology. The U.S. FDA requires that a Unique Device Identifier is permanently fixed on certain devices; a process called direct marking. In these cases, the Unique Device Identifier may be in readable plain text or in AIDC form.

### **The Global Unique Device Identification Database (GUDID)**

Specific device-related information and key data elements must be submitted to the U.S. FDA's [GUDID](#), unless the device is subject to an exception or alternative. Currently, the GUDID contains information for a majority of medical devices manufactured in the USA. Most of the information submitted to the GUDID is available to the public through [AccessGUDID](#), which allows consumers, healthcare professionals, industry and other stakeholders to search for medical device UDI information.

### **The European Union (EU)**

#### **Regulation (EU) 2017/745 and Regulation (EU) 2017/746**

Two EU Regulations of the European Parliament and Council on medical devices and in vitro diagnostic medical devices came into force on 25 May 2017. Both [Regulation \(EU\) 2017/745](#) and [Regulation \(EU\) 2017/746](#) (the EU Regulations) include relevant provisions for the establishment of the UDI System in the EU including: definitions; implementation timeframes; the requirement that a Unique Device Identifier be placed on the device, labelling and packaging; the requirement that certain information be entered into the EU's UDID, and registered in the [Eudamed](#).

Specifically, the EU Regulations provide that: the Issuing Entities should be designated by the end of 2018; UDI-DI should be assigned by manufacturers for all devices; and UDI core data elements must be registered in Eudamed by 26 May 2020 for non-IVD medical devices, or 26 May 2022 for IVD medical devices, or within six months after the date when Eudamed becomes fully functional (whichever is the latest). The implementation of the requirement to place UDI carriers on devices and packaging will be staged, depending on a device's classification.

The EU Regulations also require the inclusion of UDI information in certain types of documentation including: certificates issued to manufacturers by notified bodies; manufacturers' declarations of conformity; distribution records; clinical evidence; implant cards.

Significantly, the EU Regulations require that, to the extent possible, guidance developed for medical devices at the international level (in particular guidance from the [Global Harmonization Task Force](#) (GHTF) forerunner of the IMDRF) should be taken into account to promote the global convergence of regulations. Specifically the guidance should, in particular, cover those provisions on UDI, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations. The EU Regulations note that this work contributes to a high level of safety protection worldwide and facilitates better trade.

## **Proposed implementation in Australia**

We propose that the UDI System in Australia be based on internationally harmonised principles as outlined in IMDRF UDI Guidance and informed by the work done by the EU, the U.S. FDA and other regulatory authorities.

It is proposed that the Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other medical devices. For example, in Australia some products are regulated as devices, while the same groups of products are not considered to be



medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class I(m) (with measuring function) and/or Class I(s) (devices supplied sterile)?

While it is highly desirable to align internationally, we seek stakeholders' feedback on proposals for possible exemptions from UDI requirements.

Sponsors will be responsible for ensuring their devices comply with the relevant requirements.

Sponsors who import or supply medical devices in Australia will need to verify that, where applicable, device manufacturers have assigned a Unique Device Identifier to their devices and placed Unique Device Identifier carrier on the device, labelling and packaging as required.

Sponsors must have an agreement with the manufacturer authorising the sponsor to include the key data elements and other relevant information in AusUDID.

### Proposed first actions

It is proposed that the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Devices) Regulations 2002 be amended to enable the establishment of the UDI System and include provisions to:

- allow the designation of Issuing Agencies (or Issuing Entities) and provide these with the power to issue Unique Device Identifiers
- Note:** Further explanation on Issuing Agencies (or Issuing Entities) is provided on page 12.
- prescribe requirements for the placing of Unique Device Identifiers on a device, its labelling and packaging
  - establish the AusUDID (potentially within the TGA infrastructure, see below) and link it to the Australian Register of Therapeutic Goods (ARTG).

Consultation on the introduction of the UDI System will be a staged process. The TGA will undertake further consultations on the proposal in order to clarify the design, scope, cost and information technology interface processes needed to implement the UDI System in Australia.

The TGA is also aware that there are already views of different stakeholders that consider and discuss the need and feasibility of introducing UDI system in Australia.

## The proposed UDI System

The following is a broad description of a potential Australian UDI System—the proposed core definitions, key data elements and main principles for establishing AusUDID. We are seeking feedback about which of these will best contribute to optimal UDI system implementation and operation in the Australian context.

### Definitions

Subject to advice from public consultation, the list of definitions below provides the terms necessary to establish and implement the UDI System in Australia.

The definitions are largely consistent with the IMDRF UDI Guidance, U.S. FDA legislation and the EU Regulations. We note some instances of divergence and these mostly relate to definitions that are specific to the EU Regulations. Publication of the IMDRF's UDI Application Guide in 2019 will further inform this work.



### Important

It is important to think about how these definitions will operate within the wider context of the Australian legislative and regulatory framework for medical devices.

Term	Description
<b>Unique Device Identifier (UDI)</b>	<p>A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards.</p> <p>The Unique Device Identifier allows unambiguous identification of specific devices on the market.</p>
<b>Device Identifier (UDI-DI)</b>	<p>A unique numeric or alphanumeric code specific to a model of medical device. The UDI-DI is used as the 'access key' to information stored in a UDI database (UDID).</p> <p>The UDI-DI is a 'fixed' portion of the Unique Device Identifier and identifies a manufacturer's specific products and package configurations. For example, the UDI-DI may include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number) and ICCBBA ISBT 128-PPIC (Processor Product Identification Code).</p>
<b>Production Identifier (UDI-PI)</b>	<p>A numeric or alphanumeric code that identifies the unit of device production.</p> <p>The UDI-PI is a 'conditional, variable' portion of the Unique Device Identifier and may include the serial number, lot or batch number, software identification, date of manufacture or expiry date, or both of these dates.</p>
<b>Basic UDI-DI</b>	<p>The primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.</p> <p><b>Note:</b> This term is unique to the EU Regulations; it is not used in IMDRF documents or by the U.S. FDA.</p>
<b>Unit of Use (UOU) DI</b>	<p>An identifier assigned to an individual medical device. It serves to associate the use of a device with a patient in instances in which a Unique Device Identifier was not labelled on the individual device at the level of its unit of use, for example, in the event of several units of the same device being packaged together.</p>

Term	Description
<b>Unique Device Identification Database (UDID)</b>	Contains identifying information and other elements associated with the UDI-DI specific to the model of a medical device.
<b>Unique Device Identifier Carrier (UDI carrier)</b>	The means to convey the Unique Device Identifier by using AIDC and, if applicable, it's Human Readable Interpretation (HRI). Carriers can include 1D/linear barcodes, 2D/matrix barcodes and radiofrequency identification (RFID).
<b>Automatic Identification and Data Capture (AIDC)</b>	Technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID.
<b>Label</b>	Written, printed or graphical information appearing on the medical device itself, on the packaging of each unit, or on the packaging of multiple devices.
<b>Human Readable Interpretation (HRI)</b>	<p>A legible interpretation of the data characters used to create the Unique Device Identifier, including the qualifiers UDI-DI and UDI-PI if applicable.</p> <p>The UDI System provides that the label of medical devices include a Unique Device Identifier in AIDC and HRI form and that specified data elements identifying these devices are entered into the AusUDID.</p>
<b>Third party</b>	<p>A company or individual that, based on a contract with a manufacturer, is authorised by that manufacturer to carry out certain operations on their behalf, such as submission of data to the UDI database or the placing of the UDI carrier on the device label.</p> <p><b>Note:</b> It is proposed that in Australian legislation and regulations, the procedure for drawing up a written agreement between the sponsor and manufacturer will include the responsibilities of both parties (see 'Principles for the UDI System' below)</p>
<b>Configurable device</b>	A device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves. Configurable devices include computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological monitoring systems and the radiology information systems (RIS).

## Principles for the UDI System

The principles below outline the basic requirements in the proposed UDI System for manufacturers and sponsors and also outline the requirements of the System's key components including AusUDID data elements.

## Manufacturers and sponsors

Manufacturers must comply with all obligations relating to the UDI System.

The manufacturer must ensure that their quality management system uses an appropriate verification mechanism to assign a Unique Device Identifier to all relevant devices. The manufacturer must ensure the consistency and validity of information entered on the device, labelling and packaging. They must ensure they have provided all information required for entry into AusUDID to sponsors.

A manufacturer of implantable medical devices must also provide patient information leaflets and implant cards (as required) with the respective information on the implant. In particular, that information must include the Unique Device Identifier.

Sponsors must verify that where applicable, Unique Device Identifiers have been assigned by the manufacturer to all devices they supply in Australia, and that they have established procedures with the manufacturer that allow them to enter all required information in AusUDID.

### Please note



We will consult separately to clarify the definition of the sponsor in the *Therapeutic Goods Act 1989*. Here we propose to consider sponsors' specific obligations in the context of the UDI requirements, specifically in the context of the matters certified under section 41FD of the Act and conditions of inclusion of a 'kind of medical device' in the ARTG.

## Issuing Agencies/Entities

Issuing Agency/Entity is an organisation accredited by a regulatory authority to operate a system for the assignment of Unique Device Identifiers according to specified requirements.

[GS1](#), the [Health Industry Business Communications Council](#) (HIBCC) and the [International Council for Commonality in Blood Banking Automation](#) (ICCBBA) are accredited issuing agencies/entities in some jurisdictions.

### Please note



The terminology used by the U.S. FDA (Issuing Agency) and in the EU Regulations (Issuing Entity) is different. However, the scope of responsibilities is largely similar.

The U.S. FDA's UDI Rule permits accreditation of multiple Issuing Agencies (IA) and provides a process through which an applicant can seek FDA accreditation as an IA. U.S. FDA has accredited GS1, HIBCC, and ICCBBA. Pending the European Commission's decision on designation, GS1, HIBCC and ICCBBA are deemed the designated Issuing Entities in Europe.

## AusUDID

It has been proposed by peak industry bodies that the TGA be responsible for developing and maintaining the UDI database, AusUDID, consistent with the principles outlined in the IMDRF UDI Guidance.

Under this option there would be public access to the core data elements entered into the UDI database but no UDI-PI or commercial information will be made available. We seek stakeholders' input as to whether these arrangements are appropriate or whether there are preferable alternative options.

### **Core data elements**

The EU Regulations require manufacturers to enter the Basic-UDI-DI into the UDI database to be used as the primary identifier of the device model, assigned at the device unit of use. It is the main identification code for records in the UDI Database and is referenced in relevant certificates and EU Declarations of Conformity.

The Basic UDI-DI will be linked to other device information via a link between the UDI database and Eudamed. Eudamed contains other information about medical devices including: registration details, certificates, adverse incidents, clinical investigation and market surveillance.

The U.S. FDA requires UDI-DI and some other core data elements to be entered into the GUDID.

### **Core UDID data elements**

The EU Regulations require that the UDI-DI and the following information relating to the manufacturer and the device be provided to the UDI database:

1. quantity per package configuration
2. the Basic UDI-DI as referred to in Article 29 and any additional UDI-DIs
3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number)
4. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient)
5. name and address of the manufacturer (as indicated on the label)
6. the SRN issued in accordance with Article 31(2)
7. if applicable, name and address of the authorised representative (as indicated on the label),
8. the medical device nomenclature code as provided for in Article 26
9. risk class of the device
10. if applicable, name or trade name
11. if applicable, device model, reference, or catalogue number
12. if applicable, clinical size (including volume, length, gauge, diameter)
13. additional product description (optional)
14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)
15. if applicable, additional trade names of the device
16. labelled as a single-use device (y/n)
17. if applicable, the maximum number of reuses

18. device labelled sterile (y/n)
19. need for sterilisation before use (y/n)
20. containing latex (y/n)
21. where applicable, information labelled in accordance with Section 10.4.5 of Annex I
22. URL for additional information, such as electronic instructions for use (optional)
23. if applicable, critical warnings or contra-indications
24. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

There are also additional data elements related to the device that must be provided as part of the registration of the device.

#### **Please note**



As previously mentioned, jurisdictions have different rules about the type of information that must be entered into their UDIDs.

For example, a comparison of regulatory requirements between the U.S. FDA and EU Regulations can be found in the IMDRF consultation document N54: Use of UDI data elements across different IMDRF jurisdictions.

In addition, the IMDRF has agreed on a set of data elements that should be entered into the UDI database.

### **The ARTG and AusUDID**

We propose that ARTG entries for medical devices be linked to the relevant device information entered into AusUDID. When fully developed, the linkage will significantly improve the quality and reliability of data available.

This proposed approach has similarities with the requirements included in the EU Regulations which prescribe creation of Eudamed that will integrate different electronic systems, including UDI database. The objectives of the Eudamed are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, and to streamline and facilitate the flow of information between different participants of the supply chain.

#### **Rules for specific device types**

The UDI System has specific rules that apply to some categories of medical devices, including implantable devices, systems and procedure packs, configurable devices, software as a medical device and contact lenses. We propose to consult separately on these specific requirements.

#### **Incident and adverse event reporting**

Any reports of incidents or adverse events in particular must include the relevant Unique Device Identifier.

Also, any corrective action will be required to include a device's Unique Device Identifier. We propose to incorporate these requirements as conditions of ARTG inclusion.

## Transitional arrangements

It is proposed that transitional arrangements in Australia—for the obligation to place the UDI carrier on the label of the device—will be consistent in each case with the respective transitional arrangements in Europe.

There will be staged implementation of the requirement to enter UDI-DI and other specified core data elements into AusUDID.

Article 123(3) of the EU Regulations provides that UDI carriers must be placed on the label of the device and on all higher levels of packaging for:

- implantable devices and Class III devices from 26 May 2021
- Class IIa and Class IIb devices from 26 May 2023
- Class I devices from 26 May 2025.

For reusable devices that must have the UDI carrier on the device itself, the requirement is imposed from two (2) years after the date referred to in the previous point for the relevant class of devices.

The implementation for IVD devices will be delayed by two (2) years from the requirements for other devices.

Class (and jurisdiction if applicable)	Relevant EU Regulation	Deadline for UDI-DI assignment and registration in Eudamed	Proposed timeframe for placement of UDI carrier on the device / label / packaging in Australia	Timeframe for direct marking for reusable devices in Australia
<b>Class III and implantable</b>	MDR Regulation (EU) 2017/745	26 May 2020	26 May 2021	26 May 2023
<b>Class IIb/IIa</b>			26 May 2023	26 May 2025
<b>Class I</b>			26 May 2025	26 May 2027
<b>Class 4 IVD (Australia)</b> <b>Class D (EU)</b>	IVDR Regulation (EU) 2017/746	26 May 2022	26 May 2023	N/A
<b>Class 2 IVD and 3 IVD (Australia)</b> <b>Class B IVD and Class C (EU)</b>			26 May 2025	
<b>Class 1 IVD (Australia)</b> <b>Class A IVD (EU)</b>			26 May 2027	

## Fees and charges

The funding for maintenance of AusUDID will be based on the activity base costing and will be included in annual charges for medical devices and IVD medical devices.

## Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- provide relevant material on the TGA website.

### Feedback notes

Although we intend to harmonise with international UDI systems, it is important to note that legislative and regulatory frameworks are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. Therefore, because international regulation and legislation cannot always be replicated, your feedback is vital to ensuring that our proposed measures will best implement the UDI System in an Australian context.

### What we invite you to do

In your submission, we ask you to consider the questions below and to provide comments related to any other matters outlined in this consultation paper.

#### Questions

- Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?
- The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?
- It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?
- Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the AusUDID - what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?
- It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?
- What core data elements and other relevant information should be entered into AusUDID?





- How should we link the ARTG and the UDI database? What information should they share?
- Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?
- What impacts (including unintended impacts) do you anticipate for you and other stakeholders?
- Are there any other issues and questions we need to consider when implementing this change?

## How to submit

Complete the [online consultation submission form](#) to upload your submission in either pdf or word format.

Please submit your feedback directly to the TGA by email at: [devicereforms@tga.gov.au](mailto:devicereforms@tga.gov.au).

**This consultation closes on 18 February 2019.**

## Enquiries

If you have any questions relating to submissions please direct them to: [devicereforms@tga.gov.au](mailto:devicereforms@tga.gov.au).

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	07/01/2019

## **Therapeutic Goods Administration**

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