



Consumers Health  
Forum **OF** Australia

SUBMISSION

**CONSULTATION: PROPOSAL TO  
INTRODUCE A UNIQUE DEVICE  
IDENTIFICATION (UDI) SYSTEM  
FOR MEDICAL DEVICES IN  
AUSTRALIA**

February 2019

Consumers Health Forum of Australia 2019  
*Submission: Proposal to introduce a Unique Device  
Identification (UDI) system for medical devices in  
Australia. Canberra, Australia*

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*Consumers Health Forum of Australia is funded by the  
Australian Government as the peak healthcare  
consumer organisation under the Health Peak and  
Advisory Bodies Programme*

# CONTENTS

**Contents**

Introduction .....4  
Consultation Questions .....4

# Introduction

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Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF appreciates the opportunity to provide a comment to the Therapeutic Goods Administration (TGA) proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

*(Maybe mention something about the implant files and/or the mesh inquiry... and the airbag/motor vehicle thing being so much better than the device thing)*

## Consultation Questions

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- *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?*

Yes the CHF agrees with the proposal to establish a UDI system in Australia that is based on the IMDRF UDI Guidance.

However we believe that the process for establishing the AusUDID should begin now, based on the current IMDRF UDI Guidelines. Any subsequent changes to the finalised IMDRF UDI guidelines then incorporated into the AusUDID as appropriate.

- *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?*

CHF believes that any medical device, including Class Is and Im, should be included in the AusUDID. We do not believe any medical device should be excluded from the AusUDID database, with the potential exception of very low risk Class I devices that are excluded from international UDI databases.

The purpose of a UDI database is to ensure the traceability of every medical device; allowing for faults and failures in devices to be identified promptly and appropriately countered. Excluding devices from the UDI database undermines that key purpose and exposes consumers to unnecessary additional risk of having untraceable medical devices used in their healthcare.

- ***It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?***

CHF believes that Issuing Agency requirements for the AusUDID should be consistent with international standards. Having multiple Issuing Agencies is acceptable as long as the separate agencies use compatible systems to ensure the AusUDID is robust and accurate.

- ***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?***

N/a.

- ***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?***

CHF believes that the TGA should establish and manage the AusUDID. We believe that it is a key responsibility, as the regulator, for the TGA to administer this regulation of devices. There are no other alternative organisations or groups of organisations would be appropriate or capable of administering the AusUDID.

- ***What core data elements and other relevant information should be entered into AusUDID?***

CHF supports the inclusion of all the proposed information into the AusUDID. We note that item 20 should be expanding from specifically “latex” to be broader, such as “potential/common allergens such as latex”.

CHF would advocate for the following additional information to be included in the AusUDID:

- For devices models- any reported adverse events locally or internationally involving that device model or related/comparable models. Additionally contact information for the current person or organisations in possession of the device in the event of recall or safety warnings being issued for the device.
- For implantable devices- the date when device was implanted, location device was implanted, name of medical professional who implanted device, contact information of patient in event of recall/critical adverse event report(s).

CHF also believe that clear linkage between AusUDID and the TGA Device Adverse Event reporting function need to be established

- ***How should we link the ARTG and the UDI database? What information should they share?***

The CHF believe that the ARTG and AusUDID should be linked to share the maximum amount of information while maintaining consumer privacy. This would ensure transparency of data, quality of data and reliability of data while streamlining reporting requirements.

- ***Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?***

The CHF believe that the proposed transitional arrangements are appropriate.

- ***What impacts (including unintended impacts) do you anticipate for you and other stakeholders?***

For CHF- none directly.

For Consumers, increased levels of quality and safety of medical devices and corresponding consumer confidence in device industry and regulatory agency.

For TGA and Industry, some increased costs in order to establish, maintain and comply with the AusUDID and other international equivalents.

- ***Are there any other issues and questions we need to consider when implementing this change?***

CHF believe that there is potential to integrate patient specific device information including UDIs from the AusUDID into MyHealthRecord and this should be investigated.

Additionally, the CHF believes the TGA should investigate the ability to use UDIs and AusUDID to manage consumer safety e.g. notifying consumers of device recalls or safety warnings, streamlining and promoting adverse event reporting

CHF believes that cybersecurity of the AusUDID and registered devices, particularly implantable devices which use RFID and other non-direct-contact communication channels to send and receive data, is a key area of concern that will need to be appropriately managed to protect consumer safety and privacy.

Consumer privacy is another concern that will need to be considered when implementing the AusUDID. For example, if the AusUDID was to be made available to academics for research purposes it must be done so in a way that does not compromise consumer privacy.