Consumers Health Forum of Australia

SUBMISSION

TGA Consultation: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System

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Consumers Health Forum of Australia (2020) *Submission to the TGA Consultation: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System.* Canberra, Australia

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CONTENTS

Contents

Overview

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA conducted this consultation as part of the reform program.

This is the second TGA consultation published relating to the proposed Australian implementation of a Unique Device Identification (UDI) System for medical devices. It builds on the first consultation paper, Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia, The potential implementation of a UDI System in Australia is a significant undertaking, involving a broad range of stakeholders, changes to business processes and IT systems, and with a significant level of complexity; particularly around the areas of labelling, provision of data, transition periods, and the management of legacy devices.

Whilst acknowledging the benefits of a globally aligned UDI System, there is the need to consider characteristics unique to the Australian environment. Some of those characteristics include potential linkages between the AusUDID and the ARTG, and the number of manufacturers who supply devices across Australia and other international markets, who may be required to be compliant with other jurisdictions' regulations (the European Union (EU) and United States Food and Drug Administration (U.S. FDA) requirements in particular).

The 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 consumer affairs, including health-based research. We have over 250 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community.

We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest. CHF is pleased to make this submission in response to this TGA Consultation on enhancing medical device adverse event reporting.

Note that this consultation was administered as an online survey and this document has been adapted from the CHF submission to that survey.

CHF Submission

Section 1: What are the benefits of an Australian UDI System across the broader health system?

Group	Anticipated benefits
Patients and consumers	Greater consumer protections in the event of a device recall or notification of potential adverse events. A functioning UDI system will allow for consumers who are suing medical devices to be reliable and rapidly contacted in the event key information about their device e.g. malfunctions, recalls are learned that need to be communicated to them.
Medical professionals (e.g. nurses, doctors, surgeons, pharmacists)	-
Clinical practices, operating theatres	-
Hospitals (private and public)	-
Manufacturers	-
Sponsors	-
Distributors/Supply chain	-
Procurement	-
Patient management and record systems	-
Inventory management, warehousing and stock control	-
Health care administrative systems (e.g. invoicing/billing)	-
Registries (e.g. the Australian Breast Registry or the Australian Orthopaedic Association National Joint Replacement Registry)	-
Health researchers	-
Medical funders (private healthcare	-
The Therapeutic Goods Administration (TGA)	-
Other regulators	-
Are there any key groups that will also benefit that are not listed above?	○ Yes ◉ No
If you have answered 'Yes' please list those groups here	We are not aware of any omitted from the above list
Do you have any suggestions on how we might measure the benefits?	Having a successfully operating and comprehensive database of medical devices in use in Australia with rapid distribution of information about devices targeted to those who need that information.

Section 2- Should the first phase of an Australian implementation be limited to a small number of high-risk devices?

Question	Response
Do you think a limited first phase is a good idea?	◉ Yes ○ No ○ Not sure
What do you see as the benefits of this approach?	Yes, we understand that it makes sense to start with a limited phase to allow for the overall system to be developed and having implementation issues worked out. And it makes sense to start with high risk devices as they are the most pressing/urgent to properly ensure information about them is known and distributed.
What might the disadvantages be?	One caveat on a limited first phase is that there needs to be a clear timeline on how long the first phase will last and when other devices will be added into the UDI. Another possible disadvantage is how limited the 'small number of high-risk devices' is. Arguably all high-risk devices should be in the initial first phase unless there is a clear and agreed way to further delineate and prioritise which ones are higher risk and thus more urgent to be included immediately. Finally, it is important to make sure that the first phase includes enough devices in terms of both volume of devices but also variety of devices to be meaningfully testing the newly implemented systems. If the limited first phase only includes a small number of devices and a small variety of devices, it likely will not be able to identify all the implementation issues that are likely to emerge in a new regulatory system.

Question	Response
Do you have suggestions on the scope?	We would suggest including all high-risk devices to begin with, combined with possibly a few high-volume devices to ensure there is the volume and variety needed to fully test the UDI system before full implementation.
Who should be involved?	☒ Manufacturers/sponsors ☒ Hospitals ☒ Distributors ☒ Procurement ☒ Consumers and patients ☒ Registries ☒ Researchers ☒ Other
If you have answered 'Other' who is missing from the list?	The TGA
How long should the first phase run?	○ 6 months ○ 12 months ○ > 12 months ◉ Other
If you have answered 'Other' please add your comments here	We would suggest that 6-12 months, depending on the exact scope of what devices are included, seems appropriate. Although this may also depend on how much of the timelines following the first phase has been determined. A long first phase followed by a non-defined period before full implementation would not be an acceptable plan.
How will we measure success?	By having successfully set up a UDI system and database that can rapidly distribute information to those with or using devices that need to receive information about those devices
What would industry participants need to do to prepare?	N/A- not an industry body.

Question	Response
What would be required from the TGA for industry participants to prepare?	We would suspect the TGA would need to allocate a significant amount of resources to assist with resolving issues and queries as they appear to ensure the system functions without major problems. Additionally, making it clear that compliance with the UDI system is not optional and having clearly outlined and enforced penalties for non-compliance.
What lead-time might be required before the start of the first phase	○ 6 months ○ 12 months ○ > 12 months ◉ Other
If you have answered 'Other' please suggest an alternative lead-time and any additional comments	Unsure- we are not an industry body. But we expect 12 months would be the maximum period necessary.
What oversight should be in place (i.e. across all participants)?	☒ Working Group ☒ Steering Committee ☐ Other
If you have answered 'Other' please provide any additional comments	-
Would you be interested in being involved?	◉ Yes ○ No
If so in what capacity?	Consumer Advocate representative
Do you have any other comments or feedback?	-

Section 3- If the Australian implementation fully aligns with the IMDRF guidance what will the impact be?

Group	Anticipated benefits
What do you see as the benefits from a globally aligned system?	The key benefit will be the ability to track, combine, compare and react to international level data about medical devices. In addition, aligned standards will minimising the burden of compliance on industry and make consumer engagement and education more effective.
What do you see as the disadvantages from a globally aligned system?	None.
If the IMDRF is taken as the foundational model, what is the potential impact for your organisation in complying with the additional requirements of multiple jurisdictions?	☐ Complexity in IT systems ☐ Complexity in business processes ☐ Requirement for additional staff ☐ Cost ☐ Need to purchase equipment ☒ Other
If you have answered 'Other' please provide any additional information	N/A- not an industry body
What are the potential impacts on organisations that span multiple international markets and are therefore required to comply with multiple jurisdictions?	We would suggest that any burdens markets to comply with a UDI system caused by spanning multiple will be more than offset but the additional income from having access to those multiple markets.
Are there any data elements or other aspects of the U.S. FDA implementation (outside the IMDRF requirements) that we should consider?	○ Yes ◉ No
If you have answered 'Yes' please provide additional information	We note that depending on the device and the markets it is available in; some devices being registered for use in Australia may not be registered with the FDA and thus not have the FDA/US specific details e.g. FDA product code. In which case those fields should have the option to indicate they do not apply for those devices. However, for the devices that do have this FDA/US specific information, including those detail in the Australian UDI system will allow for greater ability for regulator to link cross-jurisdictional data. Hence, we think all the data elements should be included in the Australia UDI system.

Group	Anticipated benefits
Are there any data elements or other aspects of the EU implementation (outside the IMDRF requirements) that we should consider?	○ Yes ◉ No
If you have answered 'Yes' please provide additional information	We note that depending on the device and the markets it is available in, some devices being registered for use in Australia may not be registered for the EU and thus not have EU specific details e.g. Authorized representatives Single Registration Number (SRN) . In which case those fields should have the option to indicate they do not apply for those devices. However, for those devices that do, including those detail in the Australian UDI system will allow for greater ability for regulator to link cross-jurisdictional data. Hence, we think all the data elements should be included in the Australia UDI system.
Are there any gaps in the IMDRF guidance you think we should be aware of?	○ Yes ◉ No
If you have answered 'Yes' please provide additional information	We note we are not subject matter experts in IMDRF guidance and cannot give an informed response to this question.
Would there be any requirement/do you plan to use UDIs unique to each country or market?	○ Yes ◉ No ○ Not sure
If you have answered 'Yes' please provide further detail on what would drive that requirement	Having a different UDI for different jurisdictions would seem to defeat the purpose of each device having a "unique" and universal identifier. This would seem to add an unnecessary layer of additional complications in the system.
How many markets do you sell in (or plan to sell in)?	◉ 0 ○ 1 ○ 2-5 ○ > 5 ○ Prefer not to answer

Group	Anticipated benefits
How many of those markets either have already implemented, are in the process of implementing or are planning to implement a UDI System?	◉ 0 ○ 1 ○ 2-5 ○ > 5 ○ Prefer not to answer
Please list those countries	N/A- not an industry body
Please provide any other feedback	N/A

Section 4- What mechanisms should be considered for submitting the UDI data to the TGA?

Question	Your response
Who is best placed to provide the data to the AusUDID?	☒ Sponsor ☐ Manufacturer ☐ Brand owner ☐ Other
Please provide any comments to support your response	We're not an industry body and will defer to them as best placed to answer this question, but would suggest that as the Sponsor is the one who applies to have the device registered onto the ARTG combining the UDI device into that system would seem most efficient.
What mechanisms might need to be in place to enable the provision of data?	☐ Machine to machine bulk upload ☐ Web interface ☒ Other
If you have answered 'Other' please provide more details	N/A- not an industry body
Do you foresee any complexities we might need to consider where more than one sponsor holds pre-market authorisation for the same device?	○ Yes ○ No ◉ Not sure
If you have answered 'Yes' please provide more details	N/A- not an industry body
Are there any interfaces (such as Health Level 7 Structured Product Labelling (HL7 SPL) that you use now or plan to use in the future that the TGA should consider or be aware of?	○ Yes ○ No ◉ Not sure
If you have answered 'Yes' please provide more details	N/A- not an industry body
Do you see a requirement for the ability to download data you have submitted to the AusUDID for validation or other purposes?	○ Yes ○ No ◉ Not sure
If you have answered 'Yes' please provide additional details	N/A- not an industry body
Are there additional aspects the TGA should consider? For example, are there other data stores or sources the TGA should take into consideration as potential means of providing data into the AusUDID?	N/A- not an industry body

Section 5- What might the benefits be for implementing the EU Basic UDI-DI in Australia?

Question	Your response
Are there any potential benefits for Australia in introducing the Basic UDI-DI?	◉ Yes ○ No ○ Not sure
If you have answered 'Yes' what might these potential benefits be? How might we quantify or measure those benefits?	Global alignment with other regulatory systems will allow for international data to be combined and compared to assist regulation of medical devices.
If you have answered 'No' please provide further information	
If Australia were to implement the Basic UDI-DI what might the potential impacts be on organisations that span multiple international markets (including the EU), and therefore have to comply with multiple jurisdictions requirements?	N/A- not an industry body. But we would presume it would make compliance easier.
Are there any potential negative impacts in Australia introducing the Basic UDI-DI?	○ Yes ◉ No ○ Not sure
If you have answered 'Yes' please provide further information	
Are there other aspects of the Basic UDI-DI you believe we should explore further or consider?	N/A

Section 6- What are the benefits of the Global Medical Device Nomenclature (GMDN) and how is it being used?

Question	Your response
Are you currently using GMDN Terms?	○ Yes ◉ No ○ Not sure
If yes, please indicate how you are using them:	☐ Identify issues related to devices or device use ☐ Include in patient records for improved post-operative follow-up ☐ Identify products to use in a clinical setting ☐ Identify the most effective devices ☐ Manage inventory ☐ Identify suppliers (for example compare volumes of products supplied by each supplier) ☐ Identify supply changes or bottlenecks ☐ To meet regulatory requirements ☐ As mandatory information for procurement ☐ Identify devices that have specific training needs ☐ Identify devices that require servicing to help establish maintenance cycles ☐ Identify devices that require utilities (such as electricity or compressed air for example) ☐ Identify and manage hazardous materials and waste ☐ For research or academic study ☐ Other
If you have checked any of the above boxes can you, please provide more information and/or examples on how you are using the GMDN Terms?	N/A- not an industry body
If you are using the GMDN, please provide more information on the benefits:	☐ Benefits for patient safety in identifying best devices for use and identifying device issues ☐ Improved inventory management ☐ Improved supply management ☐ Improved device management ☐ Reduced wastage ☐ Facilitate analysis through the ability to identify and group devices ☐ Other
If you have answered 'Other' can you please provide more details?	N/A- not an industry body

Question	Your response
If you are using the GMDN, are there any issues or challenges?	N/A- not an industry body
If you are not using the GMDN, is there a specific reason?	☐ IT systems require modification ☐ Alternative coding or reference systems used ☒ Other (please provide further information below)
If you use an alternative or additional coding or reference system, which one(s) do you use and why?	N/A- not an industry body
Please provide any other comments here	Broadly speaking we would support the use of globally standardised terms to allow for international alignment of regulatory systems and more efficient regulation of medical devices. On the proviso that those standardised terms are both comprehensive and well-defined.