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

Question no.	Text	Comment
1	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?	We welcome TGA's approach to base the Australian UDI System on IMDRF UDI Guidance.
2	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?	We recommend TGA to follow the IMDRF guidance "UDI Guidance. Unique Device Identification (UDI) of Medical Devices (IMDRF/UDI WG/N7FINAL:2013)" and specify exemptions for certain devices in alignment with other existing regulations. For example, US 21 CFR 801.30 defines general exceptions for certain device categories that should be considered as exemptions in Australia as well.
3	It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?	We recommend TGA acknowledge and rely on globally accredited UDI Issuing Agencies, such as GS1, HIBCC, HBBCC, ICCBA. Recognition of globally accredited agencies will further the goal to secure a single, globally harmonized system for positive identification of medical devices.

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4	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?	We recommend the manufacturer be permitted to upload data in an automated fashion machine-to-machine. This approach is consistent with approaches seen in other mature regulatory markets. For example, in the US and EU a foreign manufacturer is able to enter required data into the database. Regarding further amendments to clarify responsibilities between the sponsor and manufacturer, we recommend language that allows flexibility that would enable parties to define this relationship and clarify obligations by contract or other legally binding agreement. This is consistent with how other aspects of regulation often are handled between parties.
5	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?	We have no concerns with the proposal that the TGA establish and manage the AusUDID, and believe that is a reasonable approach. If AusUDID is delegated to a third party or parties, we recommend establishment of clear criteria; we are happy to provide such criteria should TGA go down that path. The AusUDID should allow manufacturers/sponsors to update information for their own products free of charge, and should be accessed by the general public free of charge.

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6	What core data elements and other relevant information should be entered into AusUDID?	We recommend core data elements be based on the IMDRF UDI Guidance and encourage TGA to avoid Australian specific information requirements (e.g. product registration number). Consistency in core data requirements drives development of a secure single, globally harmonized system for positive identification of medical devices. Additionally, this optimizes the use of TGA resources as well as the data generated regarding UDI.
7	How should we link the ARTG and the UDI database? What information should they share?	We prefer the ARTG and UDI systems are linked instead of asking users to enter information twice. This will avoid duplicate information, unnecessary redundancies and potential inconsistencies between the two data bases.
8	Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?	We welcome a risk based implementation plan for transition to UDI, which is consistent with how other mature markets have rolled out UDI. The TGA proposed timeframe for staggered implementation is appropriate.
9	What impacts (including unintended impacts) do you anticipate for you and other stakeholders?	We appreciate TGA posing this question and are committed to working with TGA to implement UDI. In order to implement the TGA UDI system, manufacturers will need to extend their internal UDI IT System and update UDI QMS processes. These updates will require time and financial resources. For that reason, we encourage the TGA to continue its transparent approach to development of a UDI program, with clear and reasonable transition timelines.

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10	Are there any other issues and questions we need to consider when implementing this change?	We urge TGA to eliminate the concept of Basic UDI-DI from UDI requirements. We believe that TGA's use of Basic UDI-DI derives from the concept introduced in the EU planned for implementation in 2020. However, the purpose and function of the EU database differs materially from AusUDID. In contrast to the AusUDID, EUDAMED is not limited to UDI data and also includes pre-market and post-market data (e.g., clinical performance studies, vigilance). Because EUDAMED hosts both pre-market and post-market data, the concept of Basic UDI-DI was proposed because it may simplify certain tasks in EUDAMED. However, the AusUDID does not host the same data sets, and therefore would not see the same potential benefits that are anticipated with EUDAMED. As a result, adding Basic UDI-DI to AusUDID would add complexity to the implementation of UDI in Australia without serving the function of public health and safety. Additionally, while the concept has been introduced in both IVDR and MDR, it is not yet implemented and there remains significant confusion regarding the Basic UDI-DI concept. We therefore recommend TGA remove the concept of Basic UDI-DI from the AusUDID requirements and recognise and adopt international standards and guidelines including IMDRF's, "UDI Guidance Unique Device Identification (UDI) of Medical Devices (IMDRF/UDI WG/N7FINAL:2013)" which does not include the concept of Basic UDI-DI.