NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** AUSTRALIA  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Therapeutic Goods Administration  www.tga.gov.au  E: [udi@health.gov.au](mailto:udi@health.gov.au)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical Devices supplied into Australia under the Therapeutic Goods Administration's regulatory framework. |
| **5.** | **Title, number of pages and language(s) of the notified document:** [Unique Device Identification (UDI) Consultation 3 - Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework](https://consultations.tga.gov.au/tga/udi-consultation-paper-3/); (76 page(s), in English) |
| **6.** | **Description of content:** 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 and Aged Care, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms, including the introduction of a unique device identification (UDI) system for medical devices supplied in Australia.  Changes to the *Therapeutic Goods Act 1989* were passed by the Australian parliament in February 2021, to allow for the establishment of the UDI database and the introduction of related requirements. For the system to be operational, there is a need to provide for the establishment of the UDI database and for setting out of related requirements, in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).  This consultation relates to the details of the proposed regulatory framework, including seeking feedback on:   * the impact of accepting both European and USA compliant labels * acceleration of delivered benefits through a phased implementation approach * scope and exemptions in applying the UDI * providing and maintaining data over the full life of the device * UDI related fees and charges * UDI labelling and supporting documentation * any potential regulatory burden * adoption and use in the broader healthcare setting |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The Therapeutic Goods Administration (TGA), is responsible for regulating medical devices in Australia.  The TGA is seeking to amend the *Medical Device Regulations* to require manufacturers to apply unique device identifiers to medical devices manufactured onshore or imported into Australia, to improve patient safety and enhance the ability to track and trace medical devices.  Manufacturers would be required to include the identifiers on packaging of each device (in scannable and human readable form), and supply UDI device data to the TGA.  The device data held in the UDI database will augment data the TGA already stores, and will be publicly available at no cost (to hospitals for example who may wish to scan at the point of care such as prior to implantation for example, and linked to the patient record).  Internationally, many other national regulators have either implemented, are in the process of, or are planning to implement a UDI system. These countries include the UK, the EU, Singapore, Canada, Saudi Arabia, Japan, Korea. The USA implemented its UDI regulatory framework in 2013, with compliance requirements starting from 2014 for high risk devices.  Work to harmonise across country implementations and achieve the benefits of a globally harmonised UDI system has been undertaken by the International Medical Device Regulators Forum (IMDRF) of which Australia is a member. The IMDRF has published two documents - a UDI guidance document (2013) and a UDI application guide (2019) which have been used to inform the Australian system.  Australia is approximately three percent of the global medical device market, and as a result many of the devices imported into Australia are also supplied to other countries, particularly the USA and the EU.  Any medical devices manufactured in Australia and supplied to other countries must comply with the UDI requirements of the country they are supplied to.  In February 2021 the Australian Parliament amended the *Therapeutic Goods Act 1989* to enable the establishment of a UDI database. The TGA is now consulting on the proposed regulatory requirements to operationalise the UDI framework. To maximise global patient safety benefits and reduce regulatory burden, the TGA is proposing to align with the IMDRF guidance, and both the USA and EU requirements wherever feasible. However a small number of Australian-specific requirements are proposed. A consultation paper seeking feedback from a broad stakeholder group including sponsors of existing medical devices, global device manufacturers, regulatory consultants, consumers, peak bodies and the healthcare industry has been released on the TGA website.  Feedback from this consultation will inform advice provided to the Australian Government for its consideration of any proposed regulatory changes.; Consumer information, labelling; Protection of human health or safety; Harmonization |
| **8.** | **Relevant documents:**  [Unique Device Identification (UDI) Consultation 3 - Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework](https://consultations.tga.gov.au/tga/udi-consultation-paper-3/)  This consultation paper is the third consultation paper published by the TGA relating to the Australian implementation of a Unique Device Identification (UDI) System for medical devices. It builds on the two previous consultation papers, [*Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*](https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia), and [*Consultation: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System*](https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system)*.* |
| **9.** | **Proposed date of adoption:** The approach to implementation, including proposed mandatory compliance dates, is one of the areas the TGA is seeking feedback on.  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 11 October 2022; We invite you to complete our online survey (in the links provided).  If you prefer, you can make a submission directly to the Department via Australia's TBT Enquiry Point. |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  <https://consultations.tga.gov.au/tga/udi-consultation-paper-3/supporting_documents/UDI%20consultation%20paper%203%20%20Detailed%20considerations%20for%20implementing%20the%20proposed%20Australian%20medical%20device%20UDI%20Regulatory%20Framework%202022.pdf> <https://consultations.tga.gov.au/tga/udi-consultation-paper-3/> |