— Submission

Proposal to Introduce a Unique Device Identification (UDI) System for Medical Devices in Australia

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products.

General Comments —

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Therapeutic Goods Administration (TGA) consultation on the proposal to introduce Unique Device Identification (UDI) for medical devices.

ADIA is a strong supporter for a regulatory framework for dental products, and medical devices more broadly, that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden.

In May 2018, a consortium of industry peak associations consisting of the Medical Technology Association of Australia (MTAA), ADIA, AusBiotech and Pathology Technology Australia (formerly IVD Australia) published a joint policy paper titled *UDI Implementation in Australia*. In this paper it was recommended that the following principles should be adhered to when implementing a UDI system in Australia:

1. Adoption of a globally harmonized UDI system, in accordance with the IMDRF UDI guidance IMDRF/UDI WG/N7FINAL:2013;

2. Adoption of rules and policies that align with international coding standards of UDI issuing agencies designated in the EU and accredited in the U.S. - Automatic Identification and Data Capture (AIDC) such as linear or matrix bar code, smart cards, biometrics and Radio Frequency Identification (RFID); and Human Readable Interpretation (HRI);

3. Establishment of an Australian UDI database (AusUDID) owned and managed by the TGA; the best practice is for regulatory agencies to build their own UDID database. The AusUDID should allow sponsors to update information for their own products free of charge and should be accessed by the general public free of charge.

In addition to the above principles, the industry consortium supports the recommendations of the Global Medical Technology Alliance (GMTA) in its January 2018 White Paper *Unique Device Identification (UDI): Insights and benefits from a single UDI System in the international arena.*[1]

ADIA continues to support the industry joint policy paper mentioned above.

Specific comments on the TGA Consultation Paper are detailed below:

- Class I non-sterile medical devices should be exempt from UDI requirements in Australia.

    - It is noted that both the U.S. Food and Drug Administration (FDA) and EU Medical Device Regulation (MDR) provide exclusions and or exemptions for some medical devices.

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[1]GMTA White Paper - UDI:
http://www.globalmedicaltechnologyalliance.org/papers/GMTA%20UDI%20White%20Paper.pdf

- o In the US Class 1 medical devices are entirely exempt from UDI requirements if the FDA has exempted them from the good manufacturing requirements of 21 CFR 820. Class 1 devices that contain a Universal Product Code (UPC) on their labelling and packaging are deemed to meet UDI labelling requirements. A range of other general exemptions exist such as for individual single-use devices, devices used solely for research.
  - o Further, the EU exempts medical devices that are sold in retail distribution channels.
  - o For Australia the TGA should consider a similar system of exemption for Class 1 non-sterile/non-measurement devices as exists in the EU and U.S. and recognise that Class 1 products complying with either EU MDR or U.S. FDA requirements are deemed to comply for the purposes of Australian regulatory requirements. Australia has a robust system of product safety and recall procedures and the TGA should rely on these regulatory requirements for low risk Class 1 non-sterile/non-measurement medical devices rather than creating an additional cost burden for industry.

- Consistent with the processes adopted in the EU & U.S., ADIA recommends that an open UDI system is established, which allows any issuing entity that complies with accreditation requirements to become a designated Issuing Entity; and no unique Australian requirements are adopted. ADIA does not support the designation of a single issuing entity in Australia, avoiding the anticompetitive situation that could result from this.

- Accreditation should not be linked solely to Australian entities as issuing Agencies, but also overseas agents that are issuing UDI e.g. in Europe

- Establishing the AusUDID within the TGA infrastructure, consistent with the approaches adopted in the US & EU with linking capabilities to the Australian Register of Therapeutic Goods (ARTG) and other TGA databases as appropriate. It will be important that the ultimate solution does not impose a significant cost burden on industry.

- The TGA timetable for adoption of UDI's should not precede the EU transition deadlines, as this would impose a significant cost to Industry, and potential supply disruption.

- No additional or unique requirements should be included in Australian database over and above the internationally adopted requirements.

- Manufacturers comply with their regulatory obligation often using common labelling across a number of markets, including smaller markets such as Australia. Any unique label requirements in Australia consequent to the introduction of UDI's would increase costs. These costs would be either passed on to customers, increasing the cost of dental care in Australia, or potentially lead to product withdrawal or non- introduction in Australia, which contributes to limiting product choice and innovation in Australian dental care.

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ADIA appreciates the opportunity to engage in this consultation and looks forward to working with TGA to implementing an appropriately balanced UDI system in Australia.

12 February 2019

ADIA An Introduction —

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of ninety-five percent of the products used in Australian dentistry.

The ADIA membership ranges in size from the local operations of multi-billion dollar corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. To this end, ADIA is a strong advocate for reforms that cut red-tape and allow businesses in the dental industry to grow, create jobs and operate sustainably.

Australia's largest healthcare trade show, *ADX* Sydney, is convened biennially by ADIA and attracts nearly ten thousand stakeholders from across the Asia-Pacific's dental and oral healthcare community. ADIA also convenes regional trade shows in Adelaide, Brisbane, Melbourne and Perth that provide a platform for the growth of member businesses.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports skills development across the dental industry. An pioneering partnership with MEGT sees the group training model used to employ apprentices and trainees across the industry and the *CSU – ADIA Graduate Certificate in Small Business Management* provides support for mid-career professionals. Consistent with ADIA's role as the peak body for manufacturers and suppliers, ADIA is a member of the Australian Chamber of Commerce & Industry (AusChamber), the nation's foremost grouping of employer organisations. Amongst other affiliations is ADIA's membership of the association of International Dental Manufacturers (IDM), the Swiss-based global body for the dental industry.

The ADIA national office is based in Sydney and the Association is active in all mainland states.

More information can be found online at www.adia.org.au

■ ADIA MEMBER BUSINESSES ■

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