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MTAA Submission to TGA consultation:

Proposal to introduce a Unique Device Identification system for medical devices in Australia

February 2019

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1. Executive Summary

On 7th January 2019, the TGA opened the consultation: *Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*. The focus of this consultation paper is, as stated by the TGA, to seek stakeholder feedback on:

- the proposal to introduce a UDI system for medical devices in Australia;
- whether the TGA or another body should be responsible for establishing and maintaining the Australian UDI database (AusUDID);
- the potential scope of regulatory and legislative amendments required to establish the UDI system in Australia.

In May 2018, a consortium of industry peak associations consisting of MTAA, ADIA, AusBiotech and Pathology Technology Australia (formerly IVD Australia) published a joint policy paper titled *UDI Implementation in Australia*. In this paper we recommended that the following fundamental 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]

MTAA's position remains consistent with the industry joint policy paper mentioned above. Additional comments to the TGA consultation paper are provided in the next pages.

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

2. Terminology and minor clarifications

International regulatory agencies use the terms "label", "labeling" and "direct marking" and sometimes these terms mean slightly different things in different contexts. We recommend a clarification that TGA terminology is consistent with the IMDRF terminology outlined in the Principles of Labeling for Medical Devices and IVD Medical Devices of 12 July 20-18, Figure 1:

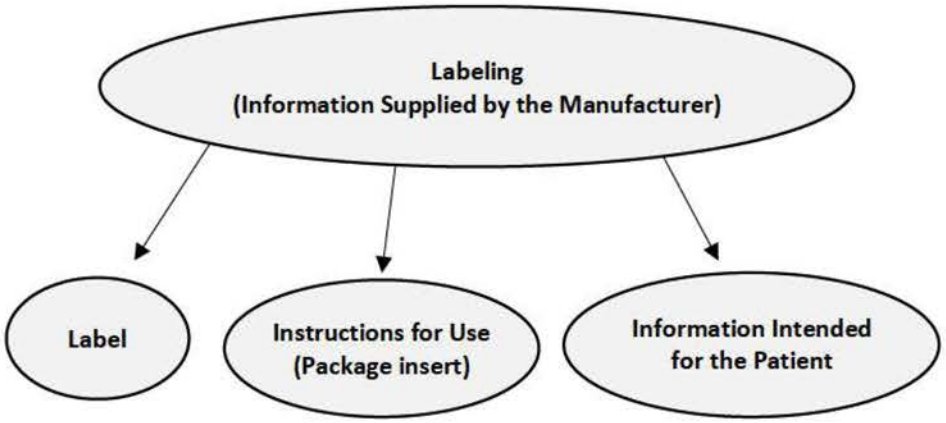

Figure 1: Components of Medical Device and IVD Medical Device Labeling
(Source: IMDRF Principles of Labeling for Medical Devices and IVD Medical Devices, 12 July 2018)

The term "label" comprises the information on the device itself, on the packaging of each unit and/or the packaging of multiple devices (but not on shipping containers) and it is a subset of "labeling". The U.S. FDA term "direct marking" is covered by "label".

To avoid confusion between "UDI" and "UDI carrier" we suggest including a statement that clarifies that the UDI (DI+PI) is assigned to the device by the manufacturer, and the UDI carrier (AIDC+HRI) is placed on the device label. Also, since parts and components are exempt from the requirement to affix an UDI carrier, it would be useful to clarify that UDI carriers are required for finished devices.

For example, the statement under the heading Effect on page 5 could be revised to read: *Sponsors of all medical devices supplied in Australia would be required to ensure that their finished devices bear Unique Device Identifiers (UDIs), placed on the device via UDI carriers, and that relevant information and data is entered into the AusUDID.*

We suggest clarifying the role of the Issuing Entities in the UDI assignment process and the relationship between their symbology standards and regulations. Specifically:

- Issuing Entities assign a globally unique number to each company (referred to as "the labeller" in the U.S. and "the manufacturer" in the EU) which is part of the UDI-DI. The remaining of the UDI-DI is the unique product identification assigned by the manufacturer.

- The regulations and regulatory guidelines must define the requirements for assigning UDI-DI and for marking of medical devices with UDI carriers including acceptable AIDC formats. While the regulatory agencies rely on the standards of the Issuing Entities, if the standards of the Issuing Agencies do not meet regulatory requirements the Issuing Agencies cannot be designated under the regulations.

3. The UDI System

We agree with the TGA position stated in the "Important" box on page 6 of the consultation. While the UDI carrier includes certain information, which is already required by the Essential Principles of the Medical Device Regulations, we understand that the UDI carrier is not intended to replace any other information.

Although the U.S. FDA and the EU require that the UDI string (i.e. the entire UDI string as it would be on the barcode) be placed in human readable form below/alongside the barcode, it is our position that the UDI string was intended to be machine readable and not by humans.

The UDI database is intended to contain information about medical devices placed on the market in that particular jurisdiction, whether they are manufactured within the jurisdiction or imported. Hence the statement on the GUDID should read: *Currently, the GUDID contains information for a majority of medical devices marketed* (not "manufactured") *in the USA.*

The U.S. FDA has so far accredited 3 Issuing Entities: GS1, HIBCC and IBBCCA. Similarly, and the European Commission states in the MDR Article 120 that "Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities." The following statement on page 8: "*the EU Regulations provide that: the Issuing Entities should be designated by the end of 2018*" should be revised accordingly.

4. Proposed implementation in Australia

MTAA supports harmonization with international best practice relevant to UDI for medical devices, specifically:

- Alignment with IMDRF terminology, principles and guidelines;
- Alignment with FDA and EU requirements and guidelines, if appropriate, e.g., reprocessed devices requiring UDI permanent marking, unique identification of product families;
- Alignment with IEC/ISO standards rules and requirements;
- Establishing an open UDI system which allows any issuing entity that complies with accreditation requirements to become a designated Issuing Entity;
- Establishing the AusUDID within the TGA infrastructure, with linking capabilities to the ARTG and other TGA databases as appropriate.

We do not support the designation of a single issuing entity within Australia, as this will allow a monopoly to take hold instead of letting market forces and competition decide which symbology standards for AIDC to use. The accreditation requirements for Issuing Entities should align with those of the U.S. FDA and the European Commission.

We do not support outsourcing the AusUDID to any proprietary commercial offerings and we see no advantages to go that path. The AusUDID must not be (mis)used as a source for profit or for other commercial secondary uses. Therefore, only the TGA, the national non-commercial government regulatory agency, should be allowed to establish and manage the AusUDID. The same principle is being applied in the U.S. and the European Union, where the U.S. FDA and the European Commission own and manage the GUDID and Eudamed respectively.

Note that Eudamed is an integrated database, made of 7 modules, one of them being UDI database. TGA should consider also integrating its various databases – ARTG, IRIS, SARA, DAEN and the AusUDID, into one modular system that allows the same information to be shared within the system without duplicative data entries, and for efficient information tracking throughout the device lifecycle.

The EU MDCG 2018-1 *Draft guidance on Basic UDI-DI and changes to UDI-DI* introduces the concept of unique identification for product families sharing the same intended purpose, risk class and essential design and manufacturing characteristics. We raised the issue of product families in the joint industry policy paper on UDI and would suggest that TGA consider utilising the ARTG identification as a mechanism for grouping similar products by a single manufacturer. The EU lacks a common approval/registration numbering (identification) system, like the ARTG in Australia. This lack of common approval/registration number is driving the development of the Basic UDI-DI for use in the EU and the Eudamed database.

It is worth noting that while the Basic UDI-DI as described in EU document MDCG 2018-1, is intended to identify the devices (group) covered by that Basic UDI-DI in a unique manner, the Basic UDI-DI will only be unique to the EU, not globally, as it will incorporate EU device risk classification and the economic operator Site Registration Number (SRN). Adoption of the EU Basic UDI-DI by TGA could result in confounding data in the AusUDID.

Class I non-sterile products classified as non-devices per Australian regulations should be exempt from UDI requirements in Australia, in alignment with the EU and the U.S.

The TGA guidance on UDI would have to provide clear direction on the following aspects:

- Exemptions from the requirement to bear an UDI, e.g., for parts and components, custom-made devices and investigational-use devices;
- A procedure for applying for exemptions or alternatives from UDI requirements;
- Handling UDI for special device categories such as procedure kits and 3D personalised devices;
- Proposed timelines for a staggered implementation, that allows for a time lag after the AusUDID database requirements have been established;

- Provision for sufficient time to deplete inventory of non-UDI-compliant medical devices in distribution channels and allowances for continued use of reusable medical devices (not direct marked) currently in use;
- Specific requirements for placing of UDI-carriers on devices, their labelling and packaging;
- Specific elements required to be included in contracts between overseas manufacturers and Australian sponsors with regards to ensuring uniqueness of UDIs and uploading data in the AusUDID.

We have the following comments in relation to the definitions on pages 10-11 of the TGA consultation paper:

Term	**Description**
Unique Device Identifier (UDI)	Suggest including the full UDI definition from the IMDRF UDI guidance N7 FINAL: 2013, which includes the note on serialization: *The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI.* *Note: The word "Unique" does not imply serialization of individual production units.*
Device Identifier (UDI-DI)	Note that in the EU the Basic UDI, not the UDI-DI, is the main "access key" to information stored in Eudamed. The definition of the UDI-DI should not contradict the definition of the Basic UDI-DI.
Production Identifier (UDI-PI)	As in MDR Annex VI, Part C, point 3.5, there should be a note explaining that: "*If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.*"
Basic UDI-DI	The statement: [The Basic-UDI] "*is the DI assigned at the level of the device unit of use*" is almost certainly no longer valid. The Basic UDI-DI is, according to the EC draft guidance MDCG 2018-1, the unique identifier for a group of devices (product family) with the same intended purpose, risk class and essential design and manufacturing characteristics. FDA does not have the term "Basic UDI" for product families; this difference in concept, not only terminology, needs to be highlighted and managed.
Unique Device	Clarification will be needed around terms such as "model" - for a product

Identification Database (UDID)	family and for individual devices, both stand-alone devices or individual device versions within a product family, “catalog number”, “part number” etc. and which are to be included in the UDID.
Human Readable Interpretation (HRI)	Suggest adopting the definition in the IMDRF UDI guidance N7 FINAL: 2013: “Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.”

The sentence on page 13: “*Under this option* [TGA being responsible for developing and maintaining the UDI database, AusUDID] *there would be public access to the core data elements entered into the UDI database, but no UDI-PI or commercial information will be made available*” may be misinterpreted as implying that the actual UDI-PIs need to be included in the AusUDID. This is not the case.

Neither the FDA GUDID nor the EU Eudamed require including the actual UDI-PIs, they only require including information on the type of UDI-PI labelled on the device, as per the IMDRF UDI guidance IMDRF/UDI WG/N7FINAL:2013, section 9.2 The core UDID data elements, item # 13.

The actual UDI-PIs consisting of batch/lot numbers, serial numbers or expiry dates of products manufactured, delivered, stored and/or in use are documented in the records and databases/ ERP systems of organizations participating in the supply chain. Duplicative data entry typically introduces information errors and is unnecessary. Therefore, international best practices stipulate that actual UDI-PIs do not need to be included in the UDI database.

We would like to thank the TGA for engaging with industry in this matter and look forward to working together towards delivering a robust and efficient UDI system in Australia.