# TGA Consultation

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

## Background

ACT Health appreciates the opportunity to formally respond to the TGA Australian Unique Device Identification Database (AusUDID) proposal consultation.

The responses provided are in support of the AusUDID proposal. ACT Health has successfully implemented GS1 global identification standards to improve patient safety, and are in the process of leveraging the standards to optimise the organisations purchasing and inventory supply chain. The AusUDID has significant potential to further extend unique identification implementations and continue improvement of patient safety and supply chain efficiency.

## Contact information

# Responses to consultation questions:

Do you agree with our proposal to establish the UDI System in Australia, taking the International Medical Device Regulators Forum (IMDRF) UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?

Yes, leveraging the IMDRF guidance and adopting global standards will yield benefits for all parties at all points along the medical device supply chain. Noting that AusUDID will need to accommodate and harmonise the US version (FDA GUDID) and the European version (Eu UDID).

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 understand and agree that the AusUDID will apply to all devices with limited exceptions. Anticipated exceptions are increasingly likely with customised product requirements to support health care delivery and precision medicine. The UDID standards should be complied with unless doing so increases the risk of using the device. Steps would need to be in place to maintain traceability and preserve patient safety using alternate methods to those followed for compliant products. Any exemptions granted should also be the subject for extension of the standards by the IAs to address the specific challenges associated with the exempt devices and ensure exemptions are time limited.

Note: Any exemptions provided will compromise the efficient and integrity of end to end traceability and dilute the benefits that can be yielded at every stage of the supply chain. As such, criteria for exemptions to the UDI standards must be well defined and routinely reviewed to prevent misuse.

We request that where UDID device exemptions are identified by the TGA, such exemptions are given clear and achievable expiry dates bound to appropriate milestones in the AusUDID phase implementation.

GS1 GTIN and AIs will need to be confirmed as complaint to the AusUDID. GS1 Australia would need to publish implementation advice as would Health Industry Business Communications Council (HIBCC) and International Council for Commonality in Blood Banking Automation (ICCBBA). It is suggested that Standards Australian be asked to review the ISO/IEC 15459 standard family to determine if Australian localisation is required. An implementation and adoption handbook may be all that is required.

It is proposed to have the power to accredit one or more Issuing Agencies (IA). What requirements should this accreditation be subject to?

With the view to achieving global harmonisation, consideration of accrediting Issuing Agencies that are unique to Australia should be heavily restricted and only considered in the interest of enabling innovation and global improvement. New identification standards presented by a candidate local IA must:

1. Address gaps/limitations in existing globally adopted standards;
2. Have obtained in principle support from at least two commercially unrelated device manufacturers; and
3. Have clear demonstratable potential to extend or supersede globally adopted standards.

Allowing limited use localised identification standards to be considered UDID compliant will increase the complexity of systems, and impact harmonisation and maintainability. We anticipate the constant evolution of the GS1 standards will be the key enabler in achieving and maintaining global harmonisation, and that any new IAs considered would be limited to cases for major disruptors and transformational changes in technology.

We support the TGA or TGA/NATA performing the function of IA accreditation in alignment with the IMDRF guidance, and with appropriate input from each significant link in the supply chain.

Governance structures for considering and approving an IA (in addition to GS1, HIBCC, and ICCBBA) will need clear terms of reference and strong guiding principles.

If there is an appetite to mandate use of a single IA, GS1 should be that IA due to the breadth and depth of coverage and growing adoption within Healthcare. However, we assume competition regulatory issues may exclude this consideration.

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?

Product manufacturers and sponsors are already (in growing numbers) maintaining product/device data within existing established product catalogues (GS1 National Product Catalogue/Global Data Synchronisation Network).

Leveraging existing product master data sources and processes for manufacturer and sponsor data capture will avoid duplication of effort and identifiers. GS1 already play an active role within Australia working with the Health jurisdictions to increase the breath and quality of product and device data recorded in the registries for end to end supply chain management and traceability.

The management and responsibilities for the registration UDIs from separate sponsors for the same product and how that is accommodated with the Australian Register of Therapeutic Goods (ARTG) and AusUDID will required addressing in any legislation supporting this initiative. This will be a matter for the TGA and the sponsors/manufacturers to resolve with supply chain stakeholder review.

### 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 support the proposal for the TGA to be responsible for the establishment of the register noting that AusUDID and ARTG Data and associated metadata would need to be confirmed in the National Product Catalogue as GS1. There would be broad benefits if TGA leveraged existing industry expertise and capabilities to streamline deployment and information capture. The established GS1 processes currently being used for product recalls (that already support GS1, HIBCC and International Society of Blood Transfusion (ISBT) identification standards) would minimise change impact within public and private health providers consuming these services.

Note: This is not suggesting the TGA reuse one of the exiting GS1 platforms, but rather engage GS1 to develop the AusUDID with native seamless interoperability with the NPC, RecallHealth, and supporting the required links to the ARTG.

### What core data elements and other relevant information should be entered into AusUDID?

The core set of data element documented by the IMDRF appears to be sufficient for ACT Heath, noting that the NPC contains additional product data supporting product safety and use.

### How should we link the ARTG and the UDI database? What information should they share?

Ideally product/medical device master data would only need to be entered once by the manufacturer/sponsor. This will reduce the burden and cost of compliance, and risk of inconsistent device information/data entry.

The AusUDID database needs to reference the ARTG at the product level. This may require additional data items in the ARTG unless accommodated in the AusUDID appropriately. Wherever possible, device data should be synchronised automatically between the GDSN/NPC and the AusUDID and the ARTG. The UDI-DI (e.g. GS1 GTIN) is globally unique and would be the logical key to link the records for synchronisation.

### Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?

Differential transition arrangements need to be in place to accommodate different phases of international progress on UID. There is no benefit, and possible increased risk, in prioritising alignment to one jurisdiction over another as, all should be accommodated.

## What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

Positive Impact

- Better patient outcomes through reduced risk of incorrect or expired/recalled devices being consumed.
- Reduction in healthcare spending associated with medical device related issues that impact patients.
- Optimised device rebate spending/revenue.
- Consistency across processes for managing product and medical device recalls.
- Increased use of EDI in device procurement and associated transactional efficiency cost savings.
- Transparency in product tracking across the breadth of the medical device supply chain.

Negative Impact

- Possible increase in device costs to fund compliance requirements
- Potential reduction in device options available due to non-compliance
- Increased demand on compliant vendors may result in short term supply shortages
- Increase in internal hospital manufactured device compliance effort and cost.

While there are obvious cost implications for this work the costs need to be offset by the benefits.

## Are there any other issues and questions we need to consider when implementing this change?

The management of provenance from manufacture to usage is a key capability arising through this initiative and supports counterfeit detection and sets a key to support blockchain implementation and the virtual replication of the supply chain. Many of the standards and metadata required to accompany the UID is contained in the NPC and this places Australia in a good place at this time.