Response to the TGA Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Background:

The stakeholders to this submission are pleased to have the opportunity to provide a response to this consultation regarding the feasibility of introducing a 'UDI System' in Australia.

We welcome the approach being undertaken by the Therapeutic Good Administration, and see this consultation is a significant step towards Australia joining with many other countries around the world in implementing changes to improve the management of medical devices. Alignment and harmonisation where possible are welcomed by the users of GS1 global standards.

We have endeavoured to provide responses to the specific questions raised within the consultation, reflecting both global and Australian based user communities. In addition, we have also provided some comments where GS1 has experience from working with other global regulators in the hope that this may help to guide your process.

We look forward to providing continued support throughout the process the complete this review.

Executive approval of this submission:

GS1 Australia

GS1 Global Office

Contacts:

Primary contacts and for additional information relating to this submission please contact:

About the respondents:

About GS1

GS1 is a neutral, not-for-profit organisation that develops and maintains the most widely used global standards for efficient business communication.

We are best known for the barcode, named by the BBC as one of "the 50 things that made the world economy". GS1 standards improve the efficiency, safety and visibility of supply chains across physical and digital channels in 25 sectors. Our scale and reach – local Member Organisations in 112 countries, 1.5 million user companies and 6 billion transactions every day – help ensure that GS1 standards create a common language that supports systems and processes across the globe.

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare members include more than 100 leading healthcare organisations worldwide.

About GS1 Australia

GS1 Australia works in Healthcare to support adoption and implementation of interoperable GS1 standards within the Australian healthcare industry to enhance patient safety, and operational and supply chain efficiencies.

Our local community is guided by leading healthcare stakeholders and experts in our Healthcare User Group to ensure we effectively represent Australia in the development on our global standards and guidelines and that we also have a program that supports the implementation of our standards accordance with local needs. Our diverse stakeholders in our local healthcare community include pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, trade associations, clinicians, supply chain professionals and most importantly patients and consumers of healthcare.

Stakeholders

GS1 Australia has coordinated this submission on behalf of our healthcare user community. This response has also been approved by the broader global GS1 Healthcare community to ensure it is consistent with similar global requirements. The Stakeholders to this submission are very pleased to have the opportunity to respond to this consultation and remain keen to support the TGA throughout the decision-making process.

Responses to consultation questions:

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?***

Yes, our stakeholder communities support the establishment of a UDI system in Australia.

We also support the suggestion that where possible Australia will be informed by and harmonise with the IMDRF UDI Guidance within our regulatory and legislative requirements.

We would include support for the consideration of all of the elements suggested by the IMDRF guidance as benefits of introducing such a system, so that we ensure that we deliver the most benefit for all Australians as a result of any changes to the system and processes.

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 do not have any proposals for exemptions.

Feedback from our stakeholder community is that it is important to ensure that we balance the timeframes to meet the complexity of identification requirements and the need to ensure accuracy and traceability of all medical devices. Patient records need accuracy but the challenge to implement 'UDI' for some devices is great in many instances.

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

We recommend the alignment with the IMDRF Guidance with regard to accreditation of Issuing Agencies.

Refer: http://www.imdrf.org/consultations/cons-udi-system-180712.asp

(Additional feedback: Note 2)

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?

It will be important to ensure that the legislative amendments safeguard against duplication of multiple sponsors attempting to enter the same AusUDID information.

Similar challenges have been faced in other countries or markets, so where possible we suggest Australia is consistent or harmonises to ensure quality processes and data. Consideration should be given to whether the manufacturer of the product should be given the opportunity to provide the data within the AusUDID even where they are not the sponsor.

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 strongly support the establishment of an 'AusUDID' and note from our experience the role of the TGA in strategic leadership and governance of the AusUDID will be of critical importance.

GS1 in Australia and globally has over 15 years developing global standards for data synchronisation to support machine to machine technology platforms for data synchronisation. We understand through our ongoing work with industry of the need to balance the burden on industry in providing and exchanging data but more importantly the significant benefits to the health system when it is structured in a way that supports interoperability.

Through leadership from Government and our ongoing collaboration with industry GS1 has developed a number of machine to machine platforms in Australia that enable the synchronisation of product data (product description, codes, digital assets). This included development of a robust data quality engine to review and report back to suppliers on the quality of their data.

We are passionately supportive of continuing to work with Government on the development of the AusUDID given our global experience in data synchronisation standards. We also believe there is a significant opportunity for the Government to leverage the work undertaken to date on existing machine to machine technology platforms that should accelerate the development of AusUDID, reduce duplication to industry and improve on the overall quality of data held within it.

Strategically the development of AusUDID provides an opportunity to review the duplication of information held (including effort to provide and maintain) and work towards an interoperable solution where we have a single source of the truth providing information to the many systems across Government that require it.

This is a view that through the consultation period has been reinforced to us by our stakeholder community.

(Additional feedback: Note 3)

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

We suggest that the AusUDID align to the IMDRF guidance where possible, allowing for the addition of specific Australian data requirements if needed.

Refer: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf

---

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

Where possible we suggest that the ARTG and the UDI databases are linked as this may help to eliminate the need to duplicate registries, eliminating some of the potential for errors and misalignment.

Where linkage to the ARTG or other databases would help to eliminate duplication of data management processes this would be of great benefit to the industry in ensuring accuracy and consistency of data.

We recommend that the linkage between the databases should be made using globally unique identification.

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

Transitional implementation timelines for different classes and categories has been a successful approach within other similar regulatory change processes. Feedback from our stakeholders is that this would be a recommended approach for Australia.

Allowing for separate identification/database timelines and physical marking timelines has also been proven to be a successful and manageable approach.

Alignment to the EU transitional times is appropriate and enables manufacturers to work to a common timeline across markets.

Sufficient transition times will be necessary to ensure effective management and successful implementation for all stakeholders and eliminate the need for potential deadline extensions.

(Additional feedback: Note 4 & 5)

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

In order to meet the merging requirements globally the GS1 organisations have developed effective frameworks and policies to ensure that the users of our standards are well supported. We would leverage our experience to support our stakeholder community in any UDI system implementation in Australia. Consistent with the broader impact to industry of the implementation of a large change, GS1 Australia would expect we will need to provide additional support to stakeholders through both the design and implementation period.

Our manufacturer stakeholders' primary impact will be if the requirements in Australia differ greatly from those of other countries, thus as previously highlighted support for alignment to the IMDRF Guidance. Regardless of whether some will have already met the timelines for other markets and regulations, the most important feedback from this stakeholder group is that the requirements need to be clear and the timelines must be realistic to ensure that not only compliance but also accuracy can be assured. This is especially so for smaller medical device companies.

Our Distributor/Sponsors stakeholders' primary impact will be to ensure that they can source any authorities and data required to be able to comply as sponsors of products within the Australian market. This has been proven to be challenging in other areas in the past, especially where products are imported from less regulated markets. As much of the Australian medical device market is dominated by smaller organisations clarity of responsibilities between the sponsor (market authorisation holder), manufacturer, labeller and other parties within the product origination and distribution process will be an important factor in success of a UDI system.

Our Health Provider stakeholders' primary impacts are several. Many have expressed positivity that they will have less resistance when sourcing products and asking that they are uniquely identified (data and physical marking). They have also expressed positivity at their potential improved ability to manage their supply chains, not only the management of inventories, but also in their improved ability to link products to patients within the clinical setting. Better inventory management means that they will have improved capability to manage waste and enact product recalls in their supply chains. Improved linkage of product to patient has two primary benefits a positive impact to their accuracy in cost/billing but most importantly also enables improved accuracy of patient records, which has obvious flow on effects post procedure.

All stakeholders mentioned above, will have some challenges related to the solutions they use to manage medical devices (or medical devices data) within their organisations (whether manual or technology based). In many instances significant investment will be needed in order to be able to meet the requirements that come with a comprehensive UDI system. Having a defined regulatory requirement will assist in their specifying the requirements of any systems as they move through adoptions phases.

Many of our Solution Provider (ICT) stakeholders welcome the clarity that will come with a UDI regulation within Australia as this will ensure that whether local or international, the solutions that they need to deliver must adhere to specific sets of standards. Though this may mean significant investment for some solutions, the clarity will ensure that all systems across the supply chain and clinical interactions will have consistency of data, ultimately supporting greatly traceability within the industry.

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

We would like to take the opportunity to emphasise the importance of global alignment in order to facilitate successful implementation of TGA's UDI requirements and ensure the competitiveness of the local medical devices industry within and outside of Australia.

We recommend TGA to align with the IMDRF Unique Device identification of Medical Devices Guidance. In particular, we invite the TGA to consider accrediting issuing agencies responsible for the issuance of unique identifier according to international standards.

Most fundamentally this will impact how products are regulated into the Australian market, however we encourage the consideration of the end-to-end process for managing medical devices and the associated use cases as a part of this consultation process. This will not only require engagement with external stakeholders but may also mean engagement with other Federal Health agencies where their activities will be able to leverage such a system. Two examples of this are Private Health Insurance Branch and the potential to leverage UDI within its context and the second is the My Health Record managed by the Australian Digital Health Agency where UDI will have impact on the capability to capture items such as implantable medical devices within this centralised record.

Additional Feedback:

Note 1 **Basic UDI-DI Definition**

Though we understand that the definition in the document is represented as being unique to the EU Regulations, if this concept is being considered for inclusion within the Australian regulations as a core data element, our recommendations would be to create a definition that is consistent with EU but relevant to the Australian context.

Note also that the EU definition for the Basic UDI-DI will be reviewed as it is currently inconsistent (i.e. 'model' assigned at the 'unit of use')

Note 2 **Issuing Agencies/Entities**

The U.S. FDA's UDI Rule permits accreditation of multiple Issuing Agencies (IA) and provides a process through which an applicant can seek FDA accreditation as an IA. U.S. FDA has accredited GS1, HIBCC, and ICCBBA.

Pending the European Commission's decision on designation, GS1, HIBCC and ICCBBA are deemed the designated Issuing Entities in Europe. This process is currently underway.

Both processes have been based upon the IMDRF Guidance

Note 3 **Providing data to AusUDID**

As mentioned in response to the proposed establishment of the AusUDID above, our stakeholder community are keen to emphasise the potential of machine to machine technologies as an efficient and accurate method of providing and maintaining quality data.

Global Data Synchronisation (GDSN) which is one of the GS1 Global standards developed with our international user community, is being used by our stakeholders today as one of the methods of providing data to other countries UDI databases. As this is a globally defined, structured, validated and automated mechanism to manage and share product data, our stakeholders ask that this be considered within the process of further developing this data repository.

The potential to use this standard would also leverage some of the existing local infrastructure developed and in use to support Australian healthcare industry data needs.

The details of how GDSN can be implemented to provided structured data to the US FDA GUDID has been documents within the GS1 GDSN GUDID Implementation Guide.
https://www.gs1.org/docs/gdsn/guidelines/GS1_GDSN_GUDID_Implementation_Guide.pdf

A detailed review and similar guidance document could be developed to support the AusUDID data requirements and Australian context if required.

Note 4 Transitional requirements

Some of our stakeholders have raised that they are already requiring and utilising available 'UDI' within their data and physical product management processes (e.g. procurement, inventory management, patient records) and are concerned that the transitional requirements and timelines will slow their progress to improve downstream processes.

As indicated in the areas of benefits suggested by the IMDRF, supporting the meaningful use of the 'UDI' in other parts of the 'supply chain' will be an important part of creating an effective UDI framework for Australia.

Note 5 **Use cases for 'UDI'**

Work carried out in partnership between the GS1 community and Australian Digital Health Agency related to data quality resulted in a simplified document that outlines some of the use cases of data (including Unique Device Identification) within Australia's healthcare context. Though this document was intended as a reference for users of the National Product Catalogue to help the understand the data elements it contains, the basic definitions may be useful in the process of assessing potential impacts and touchpoints for the UDI framework.

https://www.gs1au.org/download/GS1au-use-cases-product-data-standard.pdf/file

---