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18 February 2019

Device Reforms
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via e-mail: devicereforms@tga.gov.au

Dear Sir / Madam

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

Becton Dickinson (BD) has read with great interest the above consultation document, as published by the Therapeutic Goods Administration (TGA) on 9 January 2019.

Answers to the questions posed in the document are provided below. Following this there is a section of the submission providing comments on the document in general.

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?**

  Becton Dickinson agrees there is a need to establish UDI System in Australia.

  This system should utilise the International Medical Device Regulators Forum (IMDRF) UDI Guidance when it is finalised.

  As UDI Guidance has already been published in the United States of America (USA; where it is now going through an implementation phase) and the European Union (EU; where an

implementation schedule has been announced), BD also believes it is crucially important any UDI System established in Australia should be mutually compatible, in terms of product labelling, with UDI systems already established in jurisdictions such as the USA and the EU. In addition BD proposes that special care should be taken to align the proposed AusUDID with the existing FDA GUDID attributes and the still developing EU EUDAMED data attributes to the extent possible. Global harmonisation of UDI will benefit regulators, clinicians, device manufacturers, and most importantly, the patient.

- **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?**

  BD applauds the TGA for recognising that UDI should utilise a risk-based approach and agrees that some products such as those mentioned above have a lower inherent risk and shouldn't be burdened with a significant UDI implementation expense. With that said, we should consider existing UDI precedents that have been established in the USA. For example, the USA Food and Drug Administration (FDA) provides some exemptions for not including the Production Identifier on Class 1 products including In Vitro Diagnostics. Despite the exemption, BD has voluntarily included UDI labels that exceed FDA's requirement. In this instance we elected to utilise a UDI system that provides the needed utility for the healthcare provider and provides BD with the desired tracking ability for these products. In summary, we agree that UDI requirements should be risk based and that we shouldn't have a unilateral set of rigid requirements. Since product risk classes vary by market, the Australian UDI System should also attempt to harmonise exemptions based on established global practices. BD would be happy to share additional examples if there is interest.

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

  It should be a mandatory requirement, as part of an Australian UDI System, for the TGA to accredit more than one Issuing Agency; this in order to avoid the potential of creating a monopolistic market environment where undue market power can be exercised by a sole incumbent. Further, the TGA should have the ability to stipulate to Issuing Agencies the fees

they charge for the services they deliver. TGA may want to review the various related for-profit sidelines that Issuing Agencies may have an interest in. Since the role of an Issuing Agency provides a standards organisation with unique market power, we must have safeguards applied to prevent unintended commercial for-profit motives. Regardless, the TGA should retain the statutory ability to remove the accreditation from Issuing Authorities in situations where they don't act or perform in line with the spirit of the Australian UDI System.

BD also suggests the TGA consider using the existing ISO/IEC standards for Issuing Agencies. Including:

- ISO/IEC 646 Information technology -- ISO 7-bit coded character set for information interchange
- ISO/IEC 15459-2 Information technology -- Unique identifiers -- Part 2: Registration procedures
- ISO/IEC 15459-4 Information technology -- Unique identifiers -- Part 4: Individual items
- ISO/IEC 15459-6 Information technology -- Unique identifiers -- Part 6: Unique identifier for product groupings

There are also several other ISO/IEC standards embedded into the General Specifications of GS1 and other Issuing Agencies.

- **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?**

  As is currently the case, the responsibilities held by sponsors of therapeutic goods in Australia span the breadth of their regulated portfolios, regardless of what therapeutic goods make up that portfolio. The same should be the case for any additional responsibilities that lie with sponsors as part of the Australian UDI System.

- **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?**

  Becton Dickinson is fully supportive of the TGA establishing and managing the Australian UDI Database (AusUDID). Ensuring the TGA is responsible to establish and manage the AusUDID

will ensure such responsibilities never have the ability to provide a 3rd party organisation with a powerful competitive advantage that could be used to put inappropriate pressure on users of the AusUDID; both at the Australian Sponsor level and also at the level of the users of the data within the AusUDID.

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

The fastest and most certain path to success is to align to the USA FDA GUDID data attributes to the extent possible. Since the GUDID is the most mature UDI database in the world, the data attributes are general known to device manufacturers. Millions of device records are in the system today. As a participant in the initial GUDID pilots and a current user of the GUDID, BD has participated in the evolution of the data attributes and the lessons learned. There is no need for the AusUDID to pioneer or stumble, when so much implementation experience is available. The fact that we share a common language and many of the same devices with the USA further benefits the implementation efforts.

Other benefits to aligning to the FDA GUDID include the fact that various healthcare provider IT systems, Electronic Health Records, Registries, ERP systems, and other systems are already investing to calibrate to the GUDID data attributes. This can only help Australia's implementation success. While the Australian regulatory framework does closely align with the EU, the EU has yet to fully define their EUDAMED data requirements or conduct a pilot. This compares to the USA GUDID system that has been functional since 2013.

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

The link between the Australian Register of Therapeutic Goods (ARTG) and the AusUDID would ideally be provided by the unique AUST Number allocated within the ARTG to each ARTG entry. Importantly this would need to be a one (ARTG) to many (AusUDID) relationship as multiple therapeutic goods can be covered by a single ARTG entry.

The replication of data between the two databases should be actively discouraged unless there are adequate security measures in place to ensure non-public information on the ARTG can never be accessed through the AusUDID and such replication is automated such that the same information does not need to be entered / updated in each database independently.

Given the age, architecture and limitations of the current ARTG, the TGA should also give serious consideration to the creation of a single database that serves as a modernised ARTG combined with the AusUDID. This necessarily would need to ensure users of the systems are only able to view / access parts of the combined database that were relevant to their roles and responsibilities, however, would give the TGA an ideal opportunity to modernise and future proof the existing ARTG.

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

Becton Dickinson is fully supportive of aligning the transitional arrangements with the EU transitional times, so long as there is the flexibility to address any unique Australian issues with this timeframe as we enter and move through the transition.

The one exception to the above comment is that the requirement to populate the AusUDID for each device classification should align with the implementation of the Australian UDI System at the product level (i.e. the data should only need to be populated when the product labelling is required to carry the UDI). This would be more aligned with the implementation pathway in the USA than the EU.

This comment is provided based on the assumption the data needed to be entered in the AusUDID is no more onerous than that required for the EU and that there is an appropriate mechanism to upload product data en masse with an appropriate auto-validation function that allows for the identification of errors ir the data.

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

From the perspective of an import only Australian Sponsor (i.e. no local manufacture of therapeutic goods) the impacts will primarily relate to the resource / cost associated with populating and maintaining the AusUDID. In the absence of more granular details of the AusUDID (the data elements that will need to be populated, the upload mechanism(s) and the events that will trigger a need to update entries in the AusUDID) it is though difficult to quantify this impact.

This comment is provided on the assumption there will be no new Australian specific labelling requirements at any level of packaging as a result of the introduction of an Australian UDI

System. Where possible, the legislative basis for the Australian UDI System should be written in a way that allows ongoing flexibility.

Through the Australian therapeutic goods supply chain, it is envisioned there will be multiple benefits. These benefits will though rely upon stakeholders within the supply chain adopting / embracing the AusUDID framework.

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

Australia is in a unique position to learn from the lessons learned during the USA UDI implementation, including the various corrective exemptions that have been applied in the USA after the initial release of the UDI regulation. Some of the original concepts proposed and mandated by the USA FDA turned out to be incorrect and have since evolved. The various USA "Learning Communities" and other forums continue to focus on how to optimise UDI implementation. The overarching goal should be a globally harmonised UDI system, to the extent possible, Becton Dickinson would be glad to share our lessons learned, experience, and opinions to achieve this goal.

General comments

- **Fees and charges**

The consultation document indicates funding for the maintenance of the AusUDID will be through annual charges for medical devices and IVD medical devices. At face value, this would appear to represent an increase in the existing annual charges for inclusion on the ARTG. As it is very likely most entries on the ARTG will lead to multiple entries in the AusUDID, consideration should really be given to a separate annual charge relating solely to the number of AusUDID entries an Australian sponsor maintains. In this way a true activity based costing model can be created and maintained into the future.

Becton Dickinson looks forward to continued consultations as the TGA develops their thinking around medical device cybersecurity.

Yours sincerely,