



AusBiotech's response to the TGA consultation:

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

To:  
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## Executive summary

Thank you for the opportunity to make a submission to the TGA consultation regarding the *'Proposal to introduce a Unique Device Identification (UDI) system medical devices in Australia'* (**Consultation**).

In May 2018, AusBiotech, in collaboration the Medical Technology Association of Australia (**MTAA**), Australian Dental Industry Association (**ADIA**) and Pathology Technology Australia (formerly IVD Australia), published a joint policy paper titled *'UDI Implementation in Australia'* (**Policy Paper**).

AusBiotech supports the recommendations set out in the policy paper and additionally makes the following recommendations in response to the consultation below.

## Questions posed by the TGA

The TGA has sought feedback in relation to a number of questions set out on Page 16 of the consultation. Our recommendations are as follows:

- 1. 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?**

On balance, AusBiotech agrees with the principles of TGA's proposal to use the IMDRF UDI Guidance (when finalised) as the basis for informing Australia's regulatory and legislative requirements. Indeed, the majority of medical devices sold in Australia are imported from the US, Europe or Asia.

However, AusBiotech expresses significant concern if the approach taken by the TGA deviates from that in the US or Europe. Adopting a UDI system that is not globally harmonised will likely create unnecessary duplication, risk of error and increased costs within the healthcare supply chain.

- 2. 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?**

Whilst AusBiotech agrees Class 1 medical devices pose minimal risk to patients/consumers, AusBiotech considers at this stage, it is premature to consider exemptions without the IMDRF UDI Guidance being finalised. AusBiotech welcomes further consultations to discuss the topic of exemptions.

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

Australia should recognise and accept UDI's issued by all EU-designated and US-accredited UDI issuing agencies (as amended from time to time). These include:

- GS1;

- Health Industry Business Communications Council; and
- International Council for Commonality in Blood Bank Automation.

Further, any Issuing Agency accredited in Australia should be subject to the same accreditation requirements as in the US and EU. As discussed above, in the event a EU-designated and/or US-accredited UDI issuing agency is not recognised in Australia, this will significantly impede upon the cross-border supply of medical devices for a number of companies operating in Australia.

**4. 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 the proposal currently stands, AusBiotech anticipates there will be challenges where there are multiple sponsors relating to the pre-market authorisation for the device. If the AusUDID has requirements to enter in one entry for each product, then in cases where there is more than one sponsor, this may result in the duplication of inconsistent numbering of the same product.

**5. 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?**

AusBiotech agrees the TGA should establish and manage the AusUDID. We do not consider there to be any other organisations that could establish and manage the AusUDID. This is because the majority of the information relating to medical devices is currently held by the TGA (see response to question 6 below).

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

AusBiotech has considered the Core UDID data elements outlined on Pages 13 and 14 of the consultation. We note the majority of the information proposed to be uploaded to the UDI database are already contained on the ARTG.

To the extent the information is contained on the ARTG, this information need not be duplicated. Further, AusBiotech recommends the TGA utilise information from existing TGA systems and databases. These include, for example:

- (a) System for Australian Recall Actions (SARA);
- (b) Medical Device Incident Reporting & Investigation Scheme (IRIS); and
- (c) Database of Adverse Event Notifications (DAEN).

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

We refer to our response to Question 6.

AusBiotech recommends current TGA systems and databases are reviewed and upgraded to ensure ease of transferability of information on medical devices between platforms. This can be achieved by two methods:

- (a) incorporating the new UDI system into the ARTG by modifying and adapting the existing ARTG platform; or

- (b) creating a new platform for the UDI system which incorporates information from the ARTG.

A further challenge with the UDI database is that the information will be added and modified in 'real-time'. Any additional data added to the UDI database will also be required to be validated which may cause delay. We anticipate this will be quite resource intensive. On balance, we consider the better view is to consider modifying and adapting an existing database (perhaps, the ARTG) and incorporate additional fields.

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

AusBiotech has reviewed the transitional arrangements proposed by the TGA on page 15 of the consultation. Given the European Database on Medical Devices has not yet been implemented, AusBiotech considers it is premature to implement timeframes until the industry have a better understanding of what will be involved.

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

The UDI system will be very costly. AusBiotech anticipates the cost for developing the system will ultimately be passed on to manufacturers by way of increasing the annual ARTG charges.

AusBiotech seeks transparency as to the anticipated cost of developing the UDI system.

Further, we understand there will be multiple stakeholders who will benefit from the UDI system apart from the manufacturers themselves. This includes (amongst others): public and private hospitals, consumers, and the Department of Health in each state and territory. We query where the true value of the new UDI system falls and encourages the TGA to consider sharing the burden of such cost.

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

AusBiotech considers the following questions will also need to be addressed:

- (a) What will be the penalties for a sponsor who supplies a medical device without a UDI?
- (b) What will be the penalties for a sponsor and/or manufacturer who supplies a medical device with an incorrect UDI?
- (c) What will be the increase in annual charges?
- (d) What is the impact on advertising?

## Conclusion

In summary, AusBiotech supports the proposal to implement a UDI system in Australia on the proviso Australia adopts a globally harmonised UDI system consistent with that of the US and EU. This includes ensuring alignment with international coding standards of UDI issuing agencies designated in the US and accredited in the US.

We look forward to working with the TGA in relation to further consultations on the implementation of the UDI system.