Hear now. And always

Cochlear®

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

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Submitted by:

Cochlear Limited

1 University Avenue

Macquarie University, NSW 2109

Introduction

Cochlear Limited ("Cochlear") appreciates the opportunity to make a submission to TGA's consultation regarding "*Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia"*.

Cochlear is a member of AusBiotech and also supports its submission to this consultation.

About Cochlear

Cochlear is a global leader in the manufacture of implantable hearing solutions (medical devices). Cochlear has a dedicated global team of approximately 3,000 people who deliver the gift of sound to hearing impaired people in over 100 countries. We have over 1,500 employees in Australia and most of our research and development (R&D) and manufacturing is performed in Sydney, Brisbane and Melbourne.

Cochlear's promise of "Hear now. And always" embodies the company's commitment to provide its customers with innovative products that provide the best possible hearing performance today and for the rest of their lives. For over 30 years Cochlear has helped over 450,000 people to either hear for the first time, or reconnect to the sounds of their families, friends, workplaces and communities.

Approximately 97% of Cochlear's sales are derived from exports, yet most of the company's taxes are paid in Australia. The importance of a timely, streamlined and safe, therefore globally competitive regulatory system, to Australian-based medical device manufacturers such as Cochlear, cannot be overstated. If implemented appropriately, the changes proposed in this consultation will enhance Cochlear's ability to:

- retain an Australian R&D and manufacturing base,
- continue improving products for patients,
- lead its international competitors,
- deliver continued benefits to the Australian community and economy.

Responses to Specific Questions

Question 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?

Cochlear Response:

It is always good practice to follow international guidance, such as the IMDRF UDI Guidance, as it ensures alignment and avoids unnecessary work.

Question 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?

Cochlear Response:
As a general rule, the Australian UDI database should not include device classifications until those same classes of devices are required to have UDI information provided in the European Union, as per the transition arrangements under the EU MDR. This would minimise the possibility that manufacturers would have to do something Australia-specific before it is required in a much larger jurisdiction.

Class III devices could be entered into the Australian UDID first, and then a formal review could be conducted to determine the effectiveness of the UDID before proceeding to expand it to other lower risk classes of devices.

Class I (Export Only) devices should not be required to be entered into the Australian UDID. By definition these are not supplied in Australia, and should therefore not incur costs associated with an Australian-only system.

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

Cochlear Response:
It is suggested that the TGA follows the same criteria as the FDA or the EU MDR (art 27, 2.)

Question 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?

Cochlear Response:
Since more than one Sponsor can include the same device in the ARTG, and the cost of the Australian UDID will be recovered from ARTG annual charges, then each sponsor of the device should have to enter information into the UDID.

The potential problems with this approach might include multiple sponsors entering different UDI information for what is meant to be the same device, and multiple entries being included in the AusUDID for the same products.

Question 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?

Cochlear Response:
It is preferable for the TGA to be responsible for developing and maintaining the UDI database, AusUDID, consistent with the principles outlined in the IMDRF UDI Guidance. This task is too important and should not be delegated to a non-governmental or commercial organisation.

In particular, Issuing Agencies (or their affiliates) should in no way be responsible for managing the AusUDID, as this would be a significant conflict of interest.

The main concern with TGA establishing and managing the AusUDID is the significant costs that are likely to be involved. Since TGA operates on a 100% cost-recovery basis, and is not funded by the Australian Government, this means that the cost of implementing and maintaining the AusUDID will have to be paid for by industry through annual charges.

If the additional annual charge costs are significantly more than the current values, then whether the cost-benefit of the AusUDID should be re-evaluated.

For example, it may not make sense to pursue the AusUDID if it is going to mean annual charges have to be tripled. Such costs would have to be recovered from customers (hospitals or patients), and could either lead to significant price increases, or sponsors deciding not to bring certain devices to market in Australia at all.

Question 6:
What core data elements and other relevant information should be entered into AusUDID?

Cochlear Response:
The information to be entered into the AusUDID will be dependent on the end purpose of the database and the level of resources the TGA want to invest – a full Eudamed-type solution would require a significant investment by the TGA and manufacturers, whereas a GUDID-type of solution (FDA) may be sufficient.

Despite being simpler than the proposed Eudamed, a FDA GUDID equivalent solution will also require considerable resources as is known from the FDA experience.

Generally speaking the Core data elements from the EU UDI database would be considered appropriate, although there are reservations on 2 main points:

1. Basic UDI-DI: It is not 100% clear that we need the BUDI-DI (and the concept is still not 100% clear from the European Commission).
2. Critical warnings & contra-indications: Depending on the implementation, the critical warnings and contra-indications information display may potentially be challenging and look like a "laundry list", which will not be very readable; instead, a solution similar to the FDA's *Contains Latex* and *MRI Status* fields, which are Boolean, could be sufficient to cover the needs since the patient should primarily refer to information that is supplied with the device.

Question 7:
How should we link the ARTG and the UDI database? What information should they share?

Cochlear Response:
By their nature, the ARTG and AusUDID will share some of the same information for each device. For example, the manufacturer's name, and potentially the Unique Product Identifier (UPI) would be consistent across both database.

However, the AusUDID would contain much more information than the current ARTG database.

In order to properly answer this question, one would need to know exactly who the users of the AusUDID will be, and what purpose they will be using it. At this stage, there is no indication as to who

will be accessing the UDID and for what purpose. Therefore it is difficult to know whether the ARTG should/needs to be linked to the AusUDID at all, or if so, how.

Cochlear do not support inclusion of the UDI elements into the existing ARTG database. This would likely cause significant issues with updating the UDI information, as it would necessitate submitting (and paying for) changes to the ARTG entries. This could make such a system prohibitively cumbersome & expensive, unless sponsors were able to update the UDI information as required free of charge. For example, when they need to add UDI details for new catalogue items to an existing ARTG entry for Class IIa devices.

One important question will be when will the Australian sponsor be required to input device information into the AusUDID?

- Does it have to occur at the same time as they make an ARTG application? If so, how would the AusUDID prevent that information from being displayed publically until the ARTG entry is created?
- Or will they have a time limited period after obtaining an inclusion in the ARTG to provide the UDI information in the AusUDID?
- Or will they need to input the UDI information into the AusUDID before the first time the device is imported/supplied in Australia?
- Or will the sponsor need to enter the UDI information in the AusUDID first as a prerequisite to applying for an ARTG inclusion?
  (Cochlear would not recommend this approach, as it would signal to competitors when a company was planning to include devices in the ARTG, which may never eventuate if the TGA does not include the devices in the ARTG for some reason.)

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

Cochlear Response:
Yes, there should be different transitional arrangement for different classes and categories of devices. The timeline could be based on the EU time gap between the different classes and categories. However, there are no guarantees that Eudamed will be available on time and/or in full, so it may be risky to tie the Australian implementation too tightly to the proposed dates in Europe, as they may change at short notice.

Question 9:
What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

Cochlear Response:
As both a manufacturer and sponsor of medical devices, who holds over 100 ARTG entries covering over 3,000 SKUs, we anticipate the following impacts:

- Increased cost of ARTG annual charges. Dependent on the cost of setting up and maintaining a UDID.
- Increased staff resources to submit information and maintain data in the AusUDID.

Although TGA has stated "*This paper is not intended to be a consultation on the application and use of UDI within the broader healthcare system*" one of the broader implications, which potentially can only be addressed by the TGA, is the misalignment of the GMDN codes used by global manufacturers and the GMDN codes used as an integral part of the 'kind of device' registered in Australia.

This has significant consequences particularly for devices included in the ARTG some time ago using now obsolete GMDN codes, or specifier terms which are not allowed to be used in any other jurisdiction.

Given the majority of manufacturers are based outside Australia, both Global Trade Item Numbers (GTINs), or equivalent, and UDI will be assigned by the overseas manufacturer in most cases provided to the local sponsor along with the details to be included in the AusUDI database (aligned with GUDID and EU UDI database).

If the GMDN terms between the ARTG and AusUDID do not align this may create the impression that the products are incorrectly listed in the AusUDID against a particular ARTG entry. This mismatch will also be reflected in systems like the National Product Catalogue (NPC) which includes the ARTG number and the GMDN code as identifiers along with the GTIN and other parameters.

It may be necessary to provide a mechanism to update GMDN codes on the ARTG, or at the very least, address the inconsistencies between the two databases.

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

Cochlear Response:
The FDA lessons from their UDI system implementation should be taken into consideration and the implementation should be properly planned to avoid similar issues observed by FDA, particularly as smaller companies tend to be more affected by this type of change.

A full cost-benefit analysis should be undertaken to ensure that the cost of designing, implementing and maintaining the UDI database is not going to be prohibitive. For example, if the cost of the UDI database is going to result in the annual charges for ARTG entries for medical devices needing to increase by double or triple, then it may not be a cost-effective solution, because it may result in sponsors deciding to rationalise the range of devices they are able to make available in Australia.

Depending on the increase in ARTG annual charges required to recover the costs of the AusUDID, this could create in incentive to try and minimise the number of ARTG entries that a sponsor holds. This may not be conducive to encouraging compliance.