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Submission to the TGA Consultation on:

Alignment with European medical device regulatory framework: Up-classification of surgical mesh & Patient implant cards

by Cochlear Limited

Date: 25 August 2017

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Introduction

Thank you for the opportunity to make a submission to TGA's consultation regarding "*Alignment with European medical device regulatory framework: Up-classification of surgical mesh & Patient implant cards*".

Cochlear Limited ("Cochlear") welcomes and supports the intent of the proposed changes to Australian regulations to bring them into greater alignment with those in the European Union. This has advantages for Australian patients and benefits for the wider community. Additionally, the proposed changes to labelling (patient implant cards) harmonise regulation which provide opportunities for efficiency for medical device manufacturers.

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

About Cochlear

Cochlear is a global leader in the manufacture of implantable hearing solutions. 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.

We note that around 97% of Cochlear's sales are derived from exports, yet most of the companies taxes are paid in Australia. The importance to Australian-based advanced manufacturers of medical devices such as Cochlear of a timely, streamlined and safe, therefore globally competitive regulatory system, cannot be overstated. If implemented appropriately, the regulatory changes proposed in this consultation document will enhance Cochlear's capacity to continue improving products for patients, leading its international competitors, delivering continued benefits to the Australian community and economy, whilst retaining an Australian R&D and manufacturing base.

Up-classification surgical mesh

Cochlear does not manufacture or supply any implantable surgical mesh products, and therefore we do not have any comments on the specific details of this proposal.

However, Cochlear does support the general principle of aligning the Australian classification of all medical devices with those in the European Union.

Patient implant cards

In principle, Cochlear supports the TGA's proposed adoption of the European requirements for providing information on implantable devices to patients (i.e. patient implant information card), as outlined in Article 18(1) of the new EC Medical Devices Regulations (MDR).

Cochlear will be required to meet the requirements of Article 18 when it comes to transitioning to the new MDR, so it makes sense to supply the *same information*, in the *same way*, and at the *same time*, to Australian patients and European patients alike.

Cochlear's support for this alignment will depend heavily on whether the TGA interprets the requirements for the patient implant card in the same way as the EU Notified Bodies.

Given that no EU Notified Bodies are expected to be designated to assess devices and issue certificates under the new MDR until late 2018 at the earliest, it remains to be seen how they will interpret/enforce the requirements of Article 18. Therefore, it would seem premature for the TGA to be introducing such new regulatory requirements to align with Europe, when the EU has not yet begun implementing it themselves.

There are some questions and concerns with how the TGA will incorporate certain elements of Article 18 that currently do not exist in the Australian Regulations.

For example, Article 18(1)(a) requires manufacturers to provide the Unique Device Identifier (UDI) on the patient implant card supplied with the device. The requirements of the UDI (e.g. barcode) are then separately defined in Article 27 of the MDR, and supported by the setting up of a UDI database under Article 28. Chapter III of the MDR then requires the UDI (in accordance with Article 27) to be provided on the labelling of the device.

There is currently no concept or definition of a "UDI" in the Australian medical device legislation, nor a requirement to include such a UDI on the device label. To date, there has been no proposal from the TGA to also introduce an equivalent UDI requirement for medical devices in Australia, nor the creation of a TGA UDI database to replicate the proposed EU database under Article 28.

As such, it may be premature for the TGA to require the inclusion of a UDI on the information supplied with the device or patient implant card until the requirements for a UDI are separately introduced into the Regulations.

If the TGA was to introduce a requirement for a UDI to be included on the device label and patient implant card, and the definition of the Australian UDI is *different* to the EU UDI, then this will create significant issues for manufacturers to supply this information with the device. It would mean TGA is not aligned with the EU requirements.

It is also important to recognise another element of Article 18 that seems to be necessary for the requirements in subclause (1) of Article 18 to be successfully implemented and achieve their intended goal. That is subregulation (2) of Article 18, which states:

> *"Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together* ***with the implant card, which shall bear their identity****."*

This would seem to be a critical element of Article 18 in ensuring that the information provided by the manufacturer about the implant actually finds its way to the patient. If an equivalent provision isn't also introduced into the Australian Therapeutic Goods legislation, or some other Federal or State legislation, then there is a risk that the patient implant card provided with the device by the manufacturer may not be passed on to the patient by the treating healthcare professional. Thus circumventing the requirement of the manufacturer to provide the patient implant card.

There is also some uncertainly in Europe regarding the text in Article 18(2) which states the implant card "shall bear their identity". It is not clear whether "their" refers to the patient, or the health institution, and it presumably means that manufacturer's would need to provide a space for this

information to be completed by the health institution. We believe the MedTech Europe industry association has sent a request to the European Commission to interpret this text before it is implemented by manufacturers.

Transition Arrangements

Cochlear believes the TGA's understanding of the EU MDR transition period is incorrect.

In the consultation document, the TGA suggests that:

> *"... by early-mid 2020 the manufacturers of **all** relevant medical devices will have been re-certified under the new regulatory arrangements, including this requirement."*

This is not correct. The transition provisions are provided in Article 120 of the EU MDR 2017/745. Under this Article, only **new** devices placed on the market *after* May 2020 will be required to meet the requirements of the MDR from that date, including the provision of a patient implant card under Article 18.

For devices which were placed on the market *before* May 2020, and covered by certificates issued under the previous Directives (90/385/EEC and 93/42/EEC), they "*may continue to be made available on the market or put into service until 27 May 2025*" (Article 120(4)).

CE certificates issued under the old medical device Directives prior to May 2020 will also continue to be valid until they expire (up to a maximum of 5 years), but they shall become void at the latest on 27 May 2024 (Article 120(2)).

As such, not **all** devices will have been recertified under the new EU MDR by mid-2020. There will be many devices that continue to be certified and supplied under the requirements of the old Directives until May 2024.

Therefore, in order for Australia to be aligned with the regulatory requirements in Europe (which Cochlear supports), the Australian Regulations not only need to be amended to ensure the *regulatory requirements* are aligned, but the *timing* of the enforcement of those requirements should also align with Europe.

If the TGA was to introduce the new regulatory requirements for patient implant cards in advance of the EU, this would cause misalignment and result in manufacturers needing to provide Australian-specific product information with their devices. This could result in some devices being ineligible for continued supply in Australia, even though they may continue to be legally supplied in the EU.

Cochlear would therefore recommend introduction of any new Australian regulatory requirements (such as the patient implant card) to apply from May 2020 for new devices on the market, and to allow devices included in the ARTG prior to May 2020 to be gradually brought up to the new requirements between May 2020 and May 2024 (at the same pace that their European conformity assessment certification is updated). The requirements would therefore become fully effective for all devices from around May 2024, as they will in Europe.

Publication of Information

The consultation paper appears to suggest that the information required to be provided to the patient under the equivalent of EU MDR Article 18 would also need to be published on the TGA website.

If this is the case, Cochlear does not currently support this element of the proposed changes to the Regulations for the following reasons:

1. This would be an additional requirement imposed on Australian manufacturers and/or sponsors of medical devices beyond what is required in the EU.
2. If the information provided to a patient (required by Article 18) is required to be published on the TGA website (and presumably kept up to date), this would be an unnecessary duplication of the information which would already be required to be published (and kept up to date) on the manufacturer's own website.
3. Needing to keep the information provided to patients up to date on both the manufacturer's own website and the TGA's website, would likely result in different information being available on the two websites at any point in time.
   This could occur because the manufacturer can update their own website immediately, but the TGA website will not be updated at the same time. If a patient then relies on the TGA website for accessing the relevant information instead of the manufacturer's website, they may not be aware of the most up to date safety information about their implant. This could be a potential safety risk.
4. The information required to be provided to the patient under Article 18(1) includes the serial number, lot number, and UDI of each individual implant. This level of device specific information would not be appropriate, or practical, to be published on the TGA website.

It would be preferable to have one source of truth about the implants, and this should be located on the manufacturer's own website, not through a publically accessible website which the manufacturer has no control over.

It is also unclear how the patient information published on the TGA website would be updated. Would this require an application (and fee) to be submitted to the TGA, or would it be self-managed by the Australian sponsor via the existing online TGA Business Services system?

Further details of exactly what information about an implant would be required to be published on the TGA website, and how this will be implemented, would be required before it could be supported by Cochlear.

Questions posed by TGA

Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?

Informing, training and communicating to both Health Care Professional (HCPs) and patients/ recipients on the availability and importance of the patient implant card and the product registration process with the manufacturer.

Allow alternate methods of conformance to the regulation and alternate methods of distribution of the patient implant card information:

A. Patient cards to be provided electronically to reduce the chance of patient's losing or destroying their physical paper/plastic card, or
B. Manufacturer's maintaining a registry of implants through electronic/ connected health records.

Do you have any comments or suggestions on alternative or additional strategies to promote the provision of the implant card to the patient?

Allow the information to be provided on the most appropriate format as determined by the manufacturer, rather than only allowing a physical paper or plastic card to be provided to the patient.

For example, the information could instead be supplied via electronic means, such as the patient's iPhone Wallet application. This could be particularly useful and appropriate for products such as Cochlear's implants that require the use of an external sound processor, which can be operated by a smart phone application (software).

Are there any issues or unintended consequences that may arise out of this change?

Without more details or the specific wording of the proposed regulatory requirements, it is currently difficult to identify any issues or unintended consequences that may arise from these changes.

If the TGA introduces and enforces these changes before the EU (i.e. prior to May 2020) this could increase the risk of issues arising and unintended consequences. For example, if the changes were introduced from January 2018, then this may result in some implantable devices being removed from, never introduced to, or delayed from entering, the Australian market.

If there are issues, provide suggestions for mitigating them?

If the TGA changes its device regulations at a pace which is ahead of the EU, then this increases the risk of introducing issues or unintended consequences.

One of the best ways to mitigate this would be for the TGA to wait until the new EU MDR requirements have actually been implemented by EU Notified Bodies, to ensure that the intent and interpretation of the new EU requirements are fully understood before making the equivalent changes in Australia.

In conclusion

Cochlear commends the work of the Australian Government to modernise and improve the Australian Medical Device Regulatory System.

In particular, Cochlear supports the increased alignment of Australian regulations with those in Europe. However, this should be done carefully and at the same pace as Europe to avoid any duplication of effort and misalignment of requirements. Additionally, unintended consequences of misalignment with other international regulations that negatively impact harmonisation should be assessed.

The success of these improvements will depend greatly on implementation details, and we look forward to consulting further with the TGA on these details before the changes are introduced in Australia.