Hear now. And always

Cochlear®

Submission to the TGA Consultation on: *"Changes to a number of definitions and the scope of the medical device regulatory framework in Australia"*

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Submitted by:

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Introduction

Cochlear Limited ("Cochlear") appreciates the opportunity to make a submission to TGA's consultation regarding "*Changes to a number of definitions and the scope of the medical device regulatory framework in Australia"*.

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

Cochlear is only providing feedback on the proposals related to aligning definitions with the EU MDR.

Cochlear is not providing feedback to the proposals related to regulating products without a medical purpose as medical devices, as we have no business, or planned business, related to these types of products.

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.

General Comments: Definitions

As a general principle, Cochlear supports the alignment of Australian legislative definitions for medical devices with those contained within the current European Union legislation (EU MDR), where applicable and appropriate.

However, given that the EU MDR is not yet in full force, and there is a lack of any guidance documents published by the European Commission outlining its interpretation of the EU MDR definitions & scope, there is a risk that if the TGA changes the Australian medical device Regulations to align with the EU MDR *before* those interpretative guidance materials are released, it could inadvertently lead to the changed Australian definitions being misaligned with the eventual interpretations adopted in the EU.

Responses to Specific Questions: Definitions

Question 1:

Do you have comments about the proposed changes to the definitions (refer Appendix A)?

Cochlear Response:

The proposed changes specified in Appendix A, Tables A1 and A2 would appear to be appropriate and would assist with aligning the Australian definitions with those of a major international jurisdiction, which would enhance harmonisation efforts.

The terms identified in Table A3 as definitions that are **not** proposed to be aligned with the EU MDR, are for the most part also considered appropriate not to align with.

However, the terms related to post-market activities would be beneficial to align with (e.g. recall, adverse event, serious adverse event etc.). This is because using different terminology for these activities to those used in the majority of other larger jurisdictions can be confusing for overseas manufacturers, or Australian manufacturers operating in Europe.

Although the Post Market Requirements terms are identified as being subject to a separate future consultation process (Table A4), it does not seem to make sense to consult on some post-market terms in this consultation document, and others in a separate consultation document.

Question 2:

Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?

Cochlear Response:

Cochlear is a manufacturer and sponsor of active implantable medical devices & systems in Australia, and internationally.

Question 3:

Will you be affected by the proposed definition changes? If yes, how?

Cochlear Response:

We are unlikely to be affected by the proposed changes to definitions, as the majority are not changing the currently understood meaning of the Australian definitions, they are simply providing clarity and consistency.

Question 4:

What benefits or disadvantages might be there for patient, consumer or public health and safety in these proposed definition changes?

Cochlear Response:

We do not believe there would be any benefit, or disadvantages, for patients or consumers as a result of the proposed definition changes.

However, by not aligning the post market and recall activity definitions may cause additional confusion for patients and consumers, since post-market actions will be reported differently in Australia

compared to Europe. For example, an action may be referred to as a “recall” in Australia, but may be reported in Europe as a “Field Safety Corrective Action”. This may cause unnecessary alarm or confusion if these terms are not clearly understood.

Question 5:

If you are an Australian business, please provide information on potential impacts relating to these changes including:

- *the number of products affected*
- *benefits or disadvantages related to the safety and performance of your products*
- *changes to administrative or regulatory obligations of sponsors*
- *any operational impacts on your business*
- *costs that these changes may impose on your operations.*

Cochlear Response:

We are not aware of any potential impacts the proposed definition changes would have on our business.