Hear now. And always

Cochlear®

Submission to the TGA Consultation on: *"Proposed changes to the medical device Essential Principles for safety and performance"*

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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 "*Proposed changes to the medical device Essential Principles for safety and performance"*.

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

About Cochlear Limited (ASX: COH)

Cochlear is the global leader in implantable hearing solutions with products including cochlear implants, bone conduction implants and acoustic implants. Cochlear commenced operations in 1981 as part of the Nucleus group and in 1995 listed on the Australian Securities Exchange (ASX). Today, Cochlear is a Top 50 ASX-listed company with annual global revenues exceeding AUD$1 billion.

Cochlear aims to support cochlear implantation becoming the standard of care for people with severe to profound hearing loss. Cochlear also provides bone conduction implants for people with conductive hearing loss, mixed hearing loss and single sided deafness.

Cochlear has provided more than 550,000 implantable devices, helping people of all ages to hear. Whether these hearing solutions were implanted today or many years ago, Cochlear strives to continuously develop new technologies and innovations for all recipients. Cochlear invests more than AUD$180 million each year in research and development and currently participates in over 100 collaborative research programs worldwide. Our promise is to help people "Hear now. And always" – aiming to provide them with a lifetime of hearing through the best possible support.

Cochlear's global headquarters are on the campus of Macquarie University in Sydney, Australia with regional headquarters in Asia Pacific, Europe and the Americas. Cochlear has a significant international footprint, selling in over 100 countries, and a global workforce of more than 4,000 employees.

With manufacturing and R&D occurring at Macquarie University, and further manufacturing facilities at Lane Cove and Brisbane, Cochlear invested more than $700 million dollars into the Australian economy in FY18/19, including:

- more than $345m in payments to Australian suppliers
- $194m in wages to more than 1700 employees
- $72.6m in corporate tax and $12m in payroll tax
- Over $100 million in R&D investment

In the last financial year, Cochlear manufactured more than 85% of our products and conducted around 66% of our R&D in Australia. We also paid more than 80% of our corporate tax in Australia while earning more than 95% of our revenue from sales outside Australia.

Executive Summary

Cochlear generally supports moves to align the Australian medical device regulatory requirements with those of other major markets such as the European Union (EU), and where the changes are necessary to improve or protect patient safety.

In relation to the proposals in this consultation paper, Cochlear supports changes to the Australian Essential principles which align with the requirements of other major markets, such as the EU Medical Device Regulation (MDR) 2017/745 General Safety & Performance Requirements (GSPR).

However, Cochlear does not support elements of the proposal which would introduce unique Australian-only requirements, such as:

- incorporating the Essential Principles from the IMDRF guidance document which no other major market has also adopted, and
- the requirement to include the ARTG number in medical device software (or on labelling for any other medical device).

Australia is a relatively small commercial market and introducing requirements (such as the IMDRF aspirational requirements) which are unique and not required by any other major market (e.g. EU or USA), could result in manufacturers making commercial decisions not to supply certain medical devices in Australia or delay their introduction to Australia. The additional cost and resource investment required to make devices available in Australia could also contribute to them becoming more expensive in Australia. None of these outcomes would be beneficial to Australian patients or the broader Australian healthcare system.

Responses to Specific Questions

Question 1:

"Do you agree with the proposal to update the Australian Essential Principles to:

a) align with the IMDRF Essential Principles and Labelling documents?

b) include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations?"

Cochlear Response:

Cochlear does not agree with the proposal to update the Australian Essential Principles to align with the IMDRF Essential Principles and Labelling document, where those requirements are not also aligned with the existing Australian Essential principles or the EU MDR GSPRs.

The IMDRF Essential Principles are over-complicated, and do not bring any additional assurance of safety or performance when compared to the EU MDR GSPRs. They are relatively difficult to understand and therefore would be more difficult to demonstrate compliance with.

Adopting IMDRF Essential Principles which also appear in the EU MDR GSPRs makes sense; however, it is premature and impractical to implement the labelling requirements specified in Appendix 3 of the consultation paper, which go above and beyond the requirements of the EU MDR and have not been adopted by any major market.

Incorporating requirements which are not yet implemented in other jurisdictions (such as IMDRF-only requirements), would increase the overall regulatory compliance burden (time and cost) of medical device manufacturers, which seems to go against the "benefits of proposed changes" listed by the TGA in its consultation paper.

However, Cochlear does agree with the proposal to update the Australian Essential principles to align with the relevant GSPRs in the EU MDR, provided they are not enforced in Australia before they are enforced in the EU for the same devices (i.e. the Australian transition provisions should not require earlier compliance than those in the EU).

As noted in the TGA proposal, most medical devices are included in the ARTG based on CE marking, so it is practical and appropriate to adopt the EU MDR GSPRs into the Australian Regulations, where relevant.

When updating the Australian Regulations to align with the EU MDR GSPRs, the intent or wording of these requirements should not be altered. For example, including a requirement to include a "summary of safety and clinical performance" (SSCP) in the IFU of all devices (as per Appendix 1, page 16 of the TGA proposal), whereas the EU MDR only requires that the IFU include "***where applicable, links*** to the summary of safety and clinical performance referred to in Article 32". This means that the EU MDR only requires a link to a copy of the SSCP (for example to the copy in the Eudamed database), and only if the device is of a kind that requires an SSCP to be created as per Article 32 (i.e. only for implantable and Class III devices).

This proposal also suggests that the TGA will need to introduce a new concept or requirement for a "summary of safety and clinical performance" to be aligned with EU MDR Article 32, which does not appear to be part of this proposal (because the SSCP itself is a not a requirement specified in the GSPRs). It is unclear whether the TGA intends on introducing an Australian-only version of the SSCP, or whether referring to the EU SSCP would suffice.

Question 2:
"Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?"

Cochlear Response:
Cochlear does not oppose the provision of additional clarity regarding expectations for compliance with the Essential principles. However, because the details of this 'clarity' are not provided in the consultation paper, it is not possible to comment on whether we agree with the content or intent of that additional clarity.

It is also not clear how this additional clarity would be accommodated. For example, would the additional clarity be included in the Regulations themselves? Cochlear would suggest that any additional clarity regarding expectations for compliance with the Essential principles can and should be provided in the form of Guidance materials, rather than being 'hard-wired' into the Regulations or other legislative instrument.

Such additional clarity should be subject to additional consultation with relevant stakeholders before being formally adopted or enforced and should also be consistent with any guidance endorsed by the European Commission regarding compliance with the EU MDR GSPRs.

Question 3:
"Do you agree with the proposal to restructure the Essential Principles and Labelling requirements for clarity and readability?"

Cochlear Response:
Yes. Improving the clarity and readability at the same time as introducing new Essential Principles would be efficient.

Question 4:
"Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label? Are there other devices where the ARTG number should be provided?"

Cochlear Response:
Cochlear strongly disagrees with this proposal.

The TGA has not presented any justification or suggested any benefit for this proposal.

This proposal would introduce a unique Australian-only regulatory requirement for no apparent benefit to any stakeholder. Therefore, the cost and ability for manufacturers to comply with this proposed requirement cannot be assessed against any potential benefit.

The perceived need behind requiring inclusion of the ARTG number within software medical devices, when there is no similar requirement for any other type of physical medical device, is not clear.

It is worth considering some of the implications this proposal would have on manufacturers of medical devices. For example, given the ARTG number is related to a particular sponsor, how would a

manufacturer of a device incorporate an ARTG number in the labelling (or in medical device software) if there are multiple Australian sponsors of the same device? Would they be required to list all ARTG entries belonging to all Australian Sponsors of the device?

Given the ARTG entries effectively belong to Australian Sponsors rather than device manufacturers, it would not make sense to impose a requirement on manufacturers to include the ARTG number on any information they provide with their medical devices, because this number is not known at the time of manufacture, and there could be multiple ARTG numbers for exactly the same device if it is supplied by multiple Australian Sponsors.

Question 5:
"What financial or other effects—including any that are unintended—do you anticipate the changes to the Essential Principles may have for yourself, your business, and other stakeholders (such as consumers, healthcare professionals, health organisations, industry, etc.)?"

Cochlear Response:
There will be some cost to manufacturers associated with updating the Australian Essential Principles Checklists for their full range of products, particularly if the Australian EPs are aligned (but still slightly different) to the EU MDR GSPRs.

There would be considerable cost and effort required to manufacturers if the proposal to include ARTG numbers on any medical devices was implemented.

Question 6:
"Do you have any comments regarding the transitional arrangements proposed in this paper?"

Cochlear Response:
The proposed transitional provisions would seem to be reasonable, but the suggested 4-year transition period for devices already included in the ARTG should not result in needing to comply with the new Essential Principles until 26 May 2024 (i.e. they should not come into effect earlier than the latest date of the EU MDR transition period).

However, it should be noted, there may be delays in introducing new products onto the Australian market where the products are already on the market in other regions. Manufacturers will only align with the new Australian EPs as they align with the EU MDR GSPRs.

Question 7:
"Are there any further issues, questions, or requirements we should consider when implementing this change (including areas that can/should be clarified in our guidance)?"

Cochlear Response:
The exact wording of any proposed changes to the Regulations should be consulted on separately as an exposure draft before being finalised.

The general proposals outlined in this consultation paper may seem reasonable, however without the exact details and wording of the proposed changes, it is not possible to provide a complete commentary or analysis of the likely effects of those changes. See example above in response to Question 1.