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Submission to the TGA Consultation on: *"Potential reclassification of active medical devices for diagnosis and patient therapy"*

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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 "*Potential reclassification of active medical devices for diagnosis and patient therapy"*.

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.

General Comments

New Classification Rule

TGA have proposed that a new classification rule be included in the Australian medical device Regulations, to align with Rule 22 of the EU Medical Devices Regulations (EU MDR).

However, the rule proposed by the TGA goes beyond Rule 22 of the EU MDR, and would appear to capture additional active medical devices that are not subject to Rule 22 in the EU.

The TGA may have misinterpreted Rule 22 of the EU MDR as being applicable to ***all*** active medical devices, when in fact it only relates to the subgroup of active medical devices known as '*active therapeutic devices*'.

The EU MDR includes three definitions for different types of active medical devices:

1. '*Active device*' (defined in Article 2)
2. '*Active therapeutic device*' (defined in Annex VIII, cl.2.4)
3. '*Active device intended for diagnosis and monitoring*' (defined in Annex VIII, cl.2.5)

Rule 22 of the EU MDR states:

- ***Active therapeutic devices*** *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.*

It is clear that EU MDR Rule 22 only applies to those active devices which are also defined as '*active therapeutic devices*'. **It does not apply to all '*active devices*', nor does it apply to an '*active device intended for diagnosis and monitoring*'**.

However, the classification rule the TGA is proposing to be added to the Australian medical device Regulations sates:

- ***Active medical devices*** *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (such as closed loop systems or automated external defibrillators) are classified as Class III.*

This is not aligned with EU MDR Rule 22, as it applies to ***all*** active medical devices, not just those that are equivalent to the EU MDR definition of '*active therapeutic devices*', which under the Australian definitions would be '*active medical devices for therapy*'.

This would result in misalignment with the classification of other active devices, including active devices for diagnosis, between Australia and the EU.

Therefore, in order to remain aligned with EU MDR Rule 22, the proposed Australian classification rule should be worded as follows (emphasis added):

> ***Active medical devices for therapy*** *with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.*

Cochlear would support the above classification rule being added to the Australian Regulations as it would be aligned with EU MDR Rule 22.

Alignment of Definitions

The TGA has proposed:

a) The Australian definition of '**active medical device**' be changed to align with the EU MDR definition of 'active device', specifically to clarify that software is also defined as an active medical device.

b) The Australian definition of '**active medical device for diagnosis**' remain the same, as it is already considered to be aligned with the EU MDR definition of 'Active device intended for diagnosis and monitoring'.

c) The Australian definition of '**active medical device for therapy**' remain the same, as it is already considered to be aligned with the EU MDR definition of 'Active therapeutic device'.

Cochlear agrees with the above proposals to ensure the relevant definitions are aligned with those in the EU.

Responses to Specific Questions

Question 1:

What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

Cochlear Response:

If the classification rule was implemented as proposed, there would likely be active medical devices which would become Class III in Australia, but remain at lower classifications in the EU. If this was to occur, then it would increase the chances of companies being unable to register those active medical devices in Australia, due to lacking sufficient conformity assessment evidence from Europe.

Question 2:

Are there any further issues and questions we should consider when implementing this change (i.e. areas that need to be clarified in our guidance)?

Cochlear Response:

Any future guidance related to this proposed classification rule should expand on what constitutes "significantly determines the patient management". It is likely this will be a source of contention, i.e. at what level is determining patient management considered significant versus non-significant.

Question 3:

Other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include:

- *external pacemakers*
- *continuous positive airway pressure (CPAP) devices*
- *intravascular heating/cooling system control units*
- *hyperthermia systems, temperature mapping units*
- *intraperitoneal-circulation hypothermia system control units*
- *mechanical bloodstream indicator injectors.*

We seek your feedback whether reclassification of any or all of these devices in Australia to Class III is appropriate.

Cochlear Response:

It is not clear where or how the TGA determined that the above list of medical devices would be captured by EU MDR Rule 22, or the proposed Australian classification rule.

EU MDR Rule 22 only specifies Automated External Defibrillators (AEDs) and closed loop systems as examples of active therapeutic devices which are Class III under that classification rule.

TGA should consider waiting for EU classification guidance to be published before suggesting what devices (other than AEDs and closed loop systems) are captured by this classification rule. Otherwise, there is a risk that TGA will classify some of these devices as Class III, when they may remain lower than Class III in the EU. This could create a situation where it is not possible or feasible to register such devices in Australia, due to the lack of suitable conformity assessment evidence in the EU.

Question 4:
Are there any other groups of devices that we have not considered which might fall within the scope of this proposed change?

Cochlear Response:
EU MDR Rule 22 is intended to capture active devices which both apply therapy to a patient, **and** incorporate a diagnostic function which determines patient management without the intervention of a health professional to make the decision to change the therapy.

It seems reasonable that such devices (e.g. AEDs) are classified as Class III.

However, the proposed Australian classification rule would potentially capture other types of active devices as being Class III, and this would not necessarily be an appropriate risk classification.

For example, if software (which is an active medical device) incorporated a diagnostic function which significantly determines the patient management, but it did not directly apply therapy to the patient itself based on that diagnostic result, but instead a health professional used that information to make their own decision about the therapy required, then this software may become Class III under the proposed Australian classification rule. We do not believe EU MDR Rule 22 was intended to classify such devices as Class III.

For the reasons described above in the General Comments section of this response, in order to ensure alignment with the EU MDR, the Australian classification rule should be limited to active medical devices ***for therapy***, not all active medical devices.

Question 5:
Do you have any comments regarding the transitional arrangements proposed in this paper?

Cochlear Response:
The proposed transitional arrangements would appear to be largely consistent with the EU MDR grace period. This would be appropriate.