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Cochlear®

Submission to the TGA Consultation on: *"Proposed changes to the classification of active implantable medical devices and their accessories"*

Date:

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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 classification of active implantable medical devices and their accessories"*.

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$160 million each year in research and development and currently participates in over 100 collaborative research programs worldwide.

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 3,500 employees.

Cochlear's promise is to help people "Hear now. And always" – aiming to provide them with a lifetime of hearing through the best possible support.

Cochlear invested more than half a billion dollars into the Australian economy in FY17/18:

- Global HQ, manufacturing and R&D at Macquarie University with further manufacturing facilities at Lane Cove and in Brisbane
- ✓ **Suppliers:** more than $200M in payments
- ✓ **Employment & wages**: around 1600 FTE; with $190M in wages
- ✓ **Corporate Income Tax:** $84M
- ✓ **Payroll Tax:** approx. $11M
- ✓ **R&D spend**: $100+ million

In the last financial year, Cochlear manufactured more than 85% of our products and conducted around 70% of our R&D in Australia. We also paid more than 80% of our corporate tax in Australia while earning 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.

However, Cochlear *strongly opposes* the proposals in this consultation paper, particularly regarding the reclassification of non-invasive active implantable medical device (AIMD) system accessories to become Class III medical devices. The primary reasons for the opposition to this proposal include:

1) **Changes are unnecessary because Australian regulations are already consistent with new EU MDR rules related to active implantable devices and their accessories.**
    a. We believe Australia's current classification rules are already consistent with the classification rules in the EU Medical Device Regulation (MDR) related to active implantable devices (and their accessories), and therefore there is no need for change classification in relation to these types of devices.
    b. We disagree with the TGA's interpretation of the EU MDR Classification Rule 8, which we understand only applies to ***long-term invasive*** accessories to AIMD, and does not apply to non-invasive accessories to AIMD. The proposed changes would therefore mean the Australian regulations would not be aligned with the EU MDR.

2) **Even if changes were needed, the cochlear implant system accessory examples provided should not be affected.**
    a. Many of the cochlear implant system component examples provided in Appendix B, which are proposed to become Class III devices, are actually accessories to the external Class III sound processor, and ***not*** accessories to the AIMD cochlear implant. Many of the examples therefore appear not to be relevant to the proposed classification rule changes.

3) **There is no evidence to suggest re-classifying the cochlear implant system accessories is necessary to protect or improve patient safety.**
    a. The TGA has not provided any evidence that would suggest up-classifying non-invasive cochlear implant system accessories from Class I to Class III is necessary to protect patient safety, or would improve patient safety. Cochlear has been supplying these non-invasive accessories for many years as Class I devices in Australia, and there has been no post-market evidence provided which suggests these products are causing any safety concerns, or are otherwise inadequately regulated.

4) **The proposed changes would result in a significant increase to initial and ongoing regulatory costs incurred by manufacturers/sponsors, with no added benefit to patient safety.**
    a. This may affect a sponsor's or manufacturer's ability to register some (or all) cochlear implant systems in Australia, and therefore reduce the choice of systems available to Australians.
    b. Requiring sponsors to apply for Class AIMD devices to be re-entered in the ARTG as Class III devices, simply to ensure consistency of nomenclature between EU and Australian regulations, adds no value either in safety or regulatory oversight.
    c. Class AIMD is already defined as being equal to Class III under the current Australian legislation and must meet exactly the same requirements as Class III devices.

d. If the proposal was to go ahead, TGA should amend the current ARTG entries from Class AIMD to Class III without the sponsor needing to re-apply or pay any additional costs.

5) **Given the absence of patient safety issues, the significant cost and potential impact on product availability, the TGA has not demonstrated the need to implement the proposed changes ahead of the EU, generating unnecessary complexity for no appreciable gain.**

a. The EU MDR not yet implemented in the EU, which has contributed to uncertainty about application/interpretation etc.

b. These decisions should be deferred until further implementation is carried out in the EU.

General Comments

Australian classification rules for AIMD and their accessories are already aligned to the EU MDR

Cochlear believes that the existing Australian classification rules are already aligned with those of the EU MDR as they relate to active implantable medical devices and their accessories.

Australian Class AIMD versus EU MDR Class III

The TGA consultation paper suggests that it is necessary or preferable to change Class AIMD to Class III in order to be consistent with the EU MDR.

However, Cochlear believe that this is unnecessary and would result in additional work and costs, for no benefit in either regulatory oversight or safety to the patient. This is supported by the fact that the Australian Regulations already define Class AIMD to be equal to Class III (Regulation 3.1(2)(c)):

> ***3.1 Medical device classifications (Act s 41DB)***
> *(1) For section 41DB of the Act, the following table specifies the medical device classifications.*

Item	***Medical device***	***Class***	***Class***	***Class***	***Class***	***Class***
1	*Medical devices other than IVD medical devices*	*I*	*IIa*	*IIb*	*III*	*AIMD*
2	*IVD medical devices and in-house IVD medical devices*	*1*	*2*	*3*	*4*	

> *(2) In the table:*
> *(a) the lowest level of medical device classification is specified in column 3; and*
> *(b) successively higher levels of classification are specified in columns 4 to 6; and*
> *(**c) **columns 6 and 7 are of equal classification**; and*
> *(d) a device specified in a column has the same level of classification as any other device specified in that column.*

Comparison between Australian and EU MDR classification of active implantable devices and accessories

Appendix A of the TGA paper compares the current Australian and EU MDR classification rules and other relevant legislative provisions. However, the table appears to be inaccurate in some instances. In relation to the relevant EU MDR classification rules directly related to active implantable devices, the following table shows that the current Australian classification rules *are already aligned*, and therefore do not require any further changes to be consistent with the EU MDR:

EU MDR Classification Rule	**Equivalent Australian MD Regulations**	**Comments**
ANNEX VIII **5. INVASIVE DEVICES** **5.4 Rule 8** All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: *(6th dot point)*	**Schedule 2** **Part 5—Special rules for particular kinds of medical devices** **5.7 Active implantable medical devices** (1) An active implantable medical device is classified as Class AIMD.	**In relation to active implantable medical devices:** Class AIMD in Australia is already equal to Class III because of Regulation 3.3(2)(c) which declares them to be equal. Therefore no change to the Australian classification of active implantable devices is required in order to be aligned

EU MDR Classification Rule	Equivalent Australian MD Regulations	Comments
• are active implantable devices or their accessories, in which cases they are classified as class III;	(2) An implantable accessory to an active implantable medical device is classified as Class III.	with the risk level for the same devices in the EU MDR. **In relation to accessories to active implantable devices:** Both the EU MDR Rule 8 dot point 6, and Australian Rule 5.7(2), only apply to implantable accessories. See previous section of this response explaining the applicability of EU MDR Rule 8 to only implantable and long-term invasive devices (and accessories). If TGA wishes to *strictly* align with the EU MDR, then the only change required would be to change Rule 5.7(2) to read: *(2) An implantable or long-term surgically invasive accessory to an active implantable medical device is classified as Class III.*
ANNEX VIII **6. ACTIVE DEVICES** **6.1. Rule 9** *(4th paragraph)* All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.	**Schedule 2** **Part 5—Special rules for particular kinds of medical devices** **5.7 Active implantable medical devices** (3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.	As indicated by the TGA in Appendix A, the classification of active devices intended to control, monitor or directly influence an AIMD are already Class III in Australia, and this is consistent with EU MDR Rule 9. Cochlear agrees that no change is necessary for these devices.

In row 4 of the table in Appendix A, it suggests that the Australian Regulations do not have an equivalent implementing rule as the following EU MDR implementing rule in section 3.3 of Annex VIII:

- *Software, which drives a device or influences the use of a device, shall fall within the same class as the device.*
  If the software is independent of any other device, it shall be classified in its own right.

However, the Australian Regulations do already have an equivalent classification implementing rule for software, in Regulation 3.3(5) it states:

- *If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.*

Cochlear disagrees with TGA's interpretation of EU MDR Rule 8

Cochlear has reviewed the medical device classification rules set out in EU Medical Device Regulation (MDR) 2017/745.

Cochlear's current portfolio of medical devices is certified under the Active Implantable Medical Device (AIMD) Directive 90/385/EEC, which does not include any risk-based classification system.

However, when considering the transition to the new EU MDR, Cochlear is now required to classify its devices according to the classification rules set out in Article 51 and Annex VIII of the EU MDR.

Cochlear understands that classification Rule 8 of the EU MDR is intended to capture only those accessories to active implantable devices that are themselves implantable or long-term surgically invasive. So for example:

- A cochlear implant is Class III under Rule 8, as it is implantable and is also an active implantable device.
- An accessory to the cochlear implant would only be Class III under Rule 8 if it was *also* implantable or long-term surgically invasive. For example:
    - a replacement implantable magnet would be classified as Class III under Rule 8, because it is a long-term surgically invasive accessory to the cochlear implant.

Cochlear's interpretation is based on a number of factors:

- Along with Rules 5, 6 and 7, Rule 8 sits under the general heading of Section 5 *Invasive Devices*. This indicates that the rules covered by sections 5.1-5.4 of Annex VIII are **only applicable to invasive devices** (or accessories, since they are classified in their own right).
- When written as a complete sentence, Rule 8 (including sub dot point 6) reads as follows:
    - ***All implantable devices and long-term surgically invasive devices are classified as Class IIb, unless they are active implantable devices or their accessories, in which case they are classified as Class III.***
- Due to the "*unless they*" statement, each of the sub points that follow are not applicable unless the device or accessory in question is itself implantable or long-term surgically invasive. The word "they" can be replaced with the type of device being referred to, which would allow the statement to be re-written as follows:
    - All implantable devices and long-term surgically invasive devices are classified as Class IIb, unless the implantable devices and long-term surgically invasive devices are active implantable devices or their accessories, in which case they are classified as Class III.

As highlighted in the TGA paper, the EU MDR states in section (58) of the Preface that:

- *It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body, should take into account the potential risks associated with the technical design and manufacture of the devices. To maintain the same level of safety as provided by Directive 90/385/EEC,* ***active implantable devices should be in the highest risk class****.*

However, this statement only refers to ‘active implantable devices’. Many of the TGA’s examples of non-invasive accessories to active implantable devices (such as ear hooks for cochlear implant sound processors) are themselves neither active nor implantable, and therefore this statement does not indicate that such accessories were ever intended to be placed in the highest risk class (Class III).

It is not saying that ***all*** devices covered by Directive 90/385/EEC should be in the highest risk class, it is only saying that *active implantable devices* should be in the highest risk class.

The AIMD Directive 90/385/EEC does not have any classification system, and some devices which were subject to this Directive were not active or implantable, despite the name of the Directive.

The Australian medical device regulations already took these products into account when it was introduced in 2002, and it incorporated the products covered by both the AIMDD 90/385/EEC and MDD 93/42/EEC into one risk-based classification system, which is what the EU MDR is doing now for the European Union.

Status of cochlear implant system components & accessories

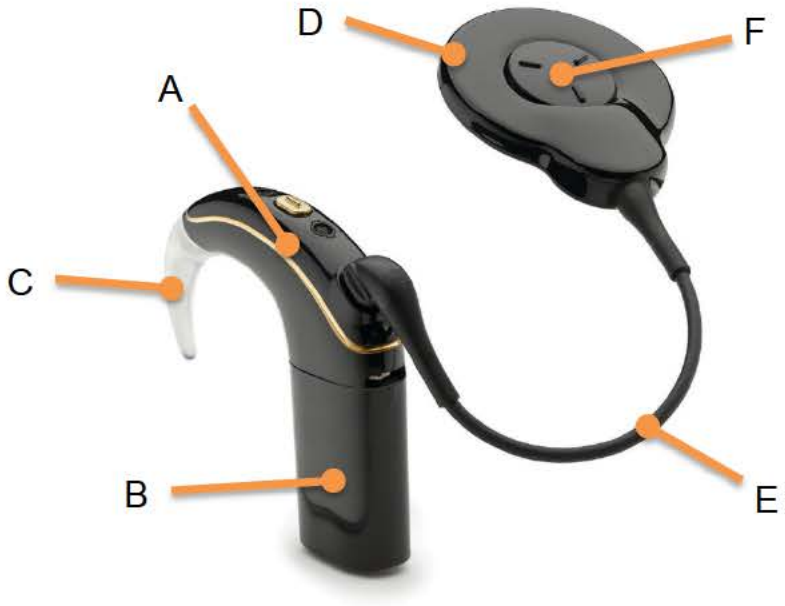
A cochlear implant system is currently generally considered to be made up of several components, including:

- A cochlear implant (with no energy source)
- An external sound processor system (incorporating the energy source and firmware)
- External programming hardware and associated software

However, the external sound processor system is subsequently composed of a number of sub-components, including:

A. Sound Processing Unit, including firmware – currently Class III in Australia
B. Battery module – currently Class I in Australia
C. Ear hook (or other retention aid) – currently Class I in Australia
D. RF Coil (with or without an integrated cable) – currently Class IIa in Australia
E. Coil cable (where RF Coil does not have an integrated cable) – currently Class I in Australia
F. External coil magnet – currently Class I in Australia

These components are identified in the representative diagram below:



Although this complete 'system' may be supplied together as a collection of devices to the patient when they first receive the sound processor, each of the individual components identified above may also be supplied individually at any point in time. For example, a patient may require a different strength coil magnet, or they may wish to have a more compact battery module.

For the purposes of classifying the sound processor system, Cochlear has applied the following interpretation:

- The Sound Processing Unit (A) is considered to be the 'main' medical device of the Sound Processor system.

- Each of the attached sub-system components (B-F) are considered 'accessories' to the main medical device. i.e. they do not perform any therapeutic function themselves, but they do assist the sound processor unit to perform it's therapeutic functions.
- The Sound Processing Unit (A) is considered a medical device in its own right (as it has a therapeutic function) and is not considered an accessory to a cochlear implant.
- The sound processor components (B-F) are not considered accessories to the cochlear implant (an AIMD), but rather accessories to the external Sound Processing Unit (A) (an active, non-invasive Class III device).

Some of the examples of accessories to cochlear implants provided in Appendix B of the TGA paper are not valid examples of accessories to an active implantable device, but are instead accessories to an active non-invasive device (i.e. the sound processing unit).

For example, the sound processor ear hooks which have been identified as being Class I and are proposed to become Class III, are actually accessories to the Class III Sound Processor. They are not accessories to an active implantable medical device (e.g. the Class AIMD cochlear implant). This is because they do not assist the cochlear implant to achieve its intended purpose.

The sound processor ear hooks are non-active, non-invasive products. If the ear hooks fail to perform their function (to hold the sound processor onto the ear), this will have no safety impact to the operation of the cochlear implant. If the sound processor becomes disconnected from the head, then the implant stops working until the sound processor can be reconnected.

Regardless of whether individual components are deemed medical devices, or accessories to a medical device, Cochlear believes this would have no impact on the final classification of each component of the system.

This is because implementing Rule 3.2 of Annex VIII of the EU MDR indicates that:

- *If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.*
- *Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.*

The Australian Therapeutic Goods (Medical Devices) Regulations 2002 already include equivalent principles for applying the classification rules (see Regulation 3.3).

Proposed changes are premature in light of EU MDR implementation status

Regardless of the interpretation of the EU MDR classification rules, Cochlear believes it is premature for TGA to change the Australian legislation in an attempt to align with the EU MDR. Until such time as sufficient knowledge and clarity exists on how the new EU MDR rules will actually be implemented there is a risk of misalignment with the European classification of the affected devices.

As it stands today:

- There has been no guidance published by the European Commission regarding clarification or interpretation of any of the classification rules under the EU MDR.
- Only one Notified Body has been designated under the EU MDR (BSI UK) and they have not started to accept any applications from manufacturers to have their QMS or products assessed under the EU MDR.
- No Notified Bodies have issued an MDR conformity assessment certificate, and therefore no Notified Bodies or Competent Authorities have made any final decisions regarding the correct classification of any devices under the EU MDR.
- Equally, manufacturers have not had the ability to confirm the classification of their devices with their EU Notified Body, nor dispute the Notified Bodies' classification determinations with their Competent Authority, as allowed for under EU MDR Article 51.

Therefore, until the new EU MDR system has been put into practice, it is not possible to categorically know how some of the classification rules will be implemented.

To change the Australian legislation now, only to find that it is not consistent with the actual implementation in Europe, would result in significant and unnecessary complications here in Australia.

Cochlear strongly suggests that any proposed changes to the Australian medical device classification rules are not proposed or implemented until such time as sufficient knowledge and experience can be gained from the practical implementation of the new EU MDR in Europe.

Absence of patient safety concerns

There are a number of non-invasive cochlear implant system accessories that TGA have identified in Appendix B of the paper that would be reclassified from Class I to Class III under this proposal, including:

- Connectors (e.g. cables connecting the processing unit to the RF coil)
- External magnets (which holds the external coil in place on the head)
- Ear hooks (used to hold behind-the-ear sound processors on the ear)
- Waterproof case (to allow sound processors to be worn in the shower or while swimming)

There is an absence of identified safety concerns in the TGA consultation paper regarding the use of any these types of products with cochlear implant systems.

Without sufficient post-market evidence indicating that there are safety issues which would benefit from reclassifying these products as Class III, Cochlear believes there is no justification on safety grounds to regulate these types of products as Class III medical devices.

To do so would be incompatible with the rules-based & risk-based classification system employed in the Australian legislation and other IMDRF partner jurisdictions, including the new EU MDR.

Cost implications of the proposal to manufacturers & sponsors

Cochlear, and other suppliers of cochlear implant systems, would be significantly impacted from a financial perspective by the proposed change in classification to non-invasive accessories to cochlear implant systems.

This additional significant cost is likely to result in either increased costs to patients or health payers, or decisions to reduce the range of products made available to Australian patients, as Australia is a relatively low-volume market for these types of devices.

The following table summarises the current Cochlear ARTG entries lower than Class III for cochlear implant system components or accessories:

Classification	# of ARTG Entries (approx.)	Current Annual Charges
Class I	41	$3,690
Class IIa	12	$10,800
Class IIb	4	$3,600
Total < Class III	**57**	**$18,090**

It is difficult to accurately determine how many Class III ARTG entries would be required to cover all of these products due to unknown interpretations of allowable variants.

However, if one assumes that we would need a separate Class III ARTG entry for each 'kind of device' which relates to each sound processor (we have 6 Class III sound processors in the ARTG), then it is estimated we would need to replace the above 57 ARTG entries with approximately 340 Class III ARTG entries (6 x 57).

Based on current TGA fees and charges, the following **additional** costs would be expected to be incurred by Cochlear in order to re-submit our existing lower class devices as Class III devices:

Cost Item	Cost calculation	Total Initial Additional Cost
Initial Design Examination Application Fees	57 x $1,000*	$57,000
Initial Design Examination Assessment Fees	57 x $58,300*	$3,323,100
ARTG Application Fees	340 x $1,310	$445,400
ARTG Annual Charges	340 x $1,160	$394,400
Current ARTG Annual Charges for same devices	See table above	-$18,090
Total		**$4,201,810**

** It is acknowledged that the full Design Exam assessment fee of $58,300 is unlikely to be applied to each of the 340 Class III devices, however we have assumed for this estimate that the full fee is likely to be applied to each of the 57 different 'kinds of devices' that are subject to reclassification.*

It should be noted that Cochlear have assumed that obtaining TGA conformity assessment design examination certificates for these products would be the only option to support the Class III ARTG entries. This is because Cochlear do not anticipate being able to obtain the equivalent EU Design

Exam certificate under the MDR, as the products are not expected to be Class III in the EU (see previous section on interpretation of MDR classification rules).

Based on the above assumptions and calculations:

- Cochlear would experience additional direct TGA costs of approximately **$4.2 million** to simply re-register existing lower classification devices as Class III.
- The additional workload would also require Cochlear to employ additional regulatory staff (at additional cost) to manage these submissions, as well as undertake annual reporting for the first 3 years for all 340 devices now classified as Class III.
- Ongoing ARTG annual charges would result in an increase of around **$376,000 each year** compared to our current annual charge levels (at current rates of annual charges).

This represents a significant increase to Cochlear's regulatory costs and is considered disproportionate to the actual risks posed by the affected products, most of which are not active, non-invasive, have little or no contact with the patient's body, and have no safety impact on the operation of the cochlear implant.

Responses to Specific Questions

Question 1:
"What impacts—including any that are unintended—do you anticipate the proposed amendments may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?"

Cochlear Response:
As described in the body of this submission, Cochlear believes the following unintended impacts may occur as a result of the proposed changes being implemented:

- Classifying non-active and non-invasive accessories of a cochlear implant system as Class III, when they are considered lower classification under the EU MDR, could result in manufacturers being unable to support ARTG registration of those products in Australia due to the lack of suitable conformity assessment evidence for Class III devices.
  - This could result in a significant reduction in products made available to Australian patients, or in the worst case, the complete withdrawal of cochlear implant systems from the Australian market.
  - For manufacturers based in Australia, such as Cochlear, this would also result in being unable to supply the affected devices to other export markets where country-of-origin approval is required as a pre-requisite for registration, for example China, India and Thailand. This would make Australia a less attractive place for manufacturers to be based.
- For devices that are able to be included in the ARTG as Class III, it is likely to result in a significant cost increase to payers (health insurers and/or patients) due to the increase in upfront regulatory costs associated with TGA design examination of Class III devices, and the ongoing cost of Class III ARTG entries. This would particularly be the case for items such as the sound processor ear hooks which are by their nature relatively low-cost and low-volume product lines.
- If the TGA adopt similar post-market requirements to the EU MDR for providing annual post-market surveillance update reports (PSUR) for Class III devices, this would have a significant impost on Cochlear due to the expected increase in Class III ARTG entries as a result of this proposal. There is a question on the value of having to provide annual reports to the TGA on all non-invasive accessories, such as the ear hooks.

Question 2:
"Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?"

Cochlear Response:
The following should also be considered:

- What is the actual safety risk that the TGA is trying to address by reclassifying non-active, non-invasive components of a cochlear implant system to Class III?
- Why can the TGA not wait for official guidance or decisions on classification to be released by the European Commission or Medical Devices Coordination Group before proposing to implement legislative changes in Australia?
- Can the TGA's resources cope with the expected significant increase in volume of devices being re-classified as Class III, including review of potential annual reports of all such devices?

Question 3:
"Do you have any comments/views regarding all or some of non-implantable accessories to AIMD that are proposed to be reclassified to Class III? Is reclassification of these devices in Australia to Class III appropriate?"

Cochlear Response:
Classifying non-implantable accessories to an active implantable medical device to Class III **is not appropriate** for the reasons outlined in the body of this submission. The existing Australian classification rules adequately classify the vast range of different non-implantable accessories to cochlear implant systems.

Many of the examples provided in Appendix B of the TGA paper have no impact on the safety of the cochlear implant itself. In the worst-case scenario where the accessory fails and the external sound processor becomes damaged or non-operational, the implant stops applying therapy to the patient. Therapy can be resumed by replacing the failed accessory, with no direct injury or lasting effect on the patient.

Question 4:
"Do you have any comments regarding the transitional arrangements proposed in this paper?"

Cochlear Response:
The transitional arrangements would appear to be satisfactory, however we believe that the current classification rules do not need to be changed in order to be aligned with the EU MDR, and therefore transition arrangements would not be necessary.