Hear now. And always

Cochlear®

Submission to the TGA Consultation on: *"Scope of regulated software-based products"*

Date:

13 May 2020

Submitted by:

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Summary

Cochlear Limited ("Cochlear") appreciates the opportunity to make a submission to TGA's consultation regarding "*Scope of regulated software-based products"*.

Cochlear believes it is important for the TGA to continually review the medical device regulatory framework in Australia to ensure it remains contemporary and consistent with other leading regulators in major world markets.

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

Cochlear supports the TGA's proposal to better regulate software and to clarify the boundary for software-based products which could potentially be exempt or excluded, to ensure that sponsors and manufacturers are not subject to unnecessary regulatory burden.

In particular, Cochlear believes that it would be appropriate to exclude Clinical Decision Support Software (CDSS) from the medical device framework in Australia, as adequate alternative mechanisms of oversight exist within the healthcare system.

It may also be appropriate to exempt all medical device software that is purchased directly by the patient/consumer for their own individual (or 'personal') use.

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$1.4 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 600,000 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.

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 180 countries, and a global workforce of more than 4,000 employees.

Cochlear strives 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 $600 million into the Australian economy in FY18/19:

- Global HQ, manufacturing and R&D at Macquarie University with further manufacturing facilities at Lane Cove and in Brisbane

- ✓ **Suppliers:** more than $345M in payments
- ✓ **Employment & wages**: more than 1700 FTE; with $194M in wages
- ✓ **Corporate Income Tax:** $72.6M or 80% of global corporate tax
- ✓ **Payroll Tax:** approx. $12M
- ✓ **R&D spend**: $100+ million more than 2/3 of total global spend.

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.

Responses to Specific Questions

Question 1:
"What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

Cochlear Response:
Software-based products listed below should be exempted from inclusion in the ARTG:

- Software that poses no potential for significant harm to a patient
- Software-based products for Individual use
- Custom-made Software-based products

If it can be demonstrated that Software-based products pose no potential for significant harm to a patient/user, risks associated with the use and performance can be properly mitigated.

It may also be appropriate to exempt all medical device software that is purchased directly by the patient/consumer for their own individual (or 'personal') use. For example, *any* smartphone app (that is also a medical device) that is downloaded by an individual consumer for their own personal use.

Currently, the exemptions listed in Schedule 4, Part 1, Item 1.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* only exempt devices for personal use if they are 'imported' by an individual for use on themselves or an immediate family member.

It is not clear whether this existing exemption covers smartphone apps downloaded from an app store, and if so, if the app store has to be based overseas for the downloading of the app to be considered 'imported'.

Cochlear would suggest that this exemption be expanded to specifically cover software downloaded by Australians for use by themselves or their immediate family, regardless of whether the app is downloaded from an overseas or Australian-based app store or website.

For example, software which is used by an individual to check or test their own hearing performance (for example., with or without with hearing aids), so that they are aware when their hearing drops below a certain threshold, and they can decide to visit their hearing healthcare professional for a more thorough assessment.

Question 2:
"What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?"

Cochlear Response:
When there is an alternative mechanism of oversight in place, software-based products should be excluded from regulation by the TGA as there are already other methods or information to support a clinical diagnosis or treatment decision. This can reduce the associated risk of taking a decision.

One example of the type of software that may fit into this category is Clinical Decision Support Software (CDSS).

As proposed in the TGA consultation paper, CDSS may be suitable to be excluded (or alternatively exempted, but preferably excluded) from regulation when:

- it is **not** intended to acquire, process, or analyse a medical image or a signal from a hardware medical device or an in vitro diagnostic device, and
- it is intended for the purpose of:
  - displaying, analysing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines), and
  - supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition, and
  - enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

This would appear to be consistent with the US FDA's recent guidelines regarding CDSS, and Cochlear believes the reasons provided by the US FDA would also support the TGA to exclude (or exempt) CDSS from the normal medical device regulatory requirements for the same reasons that other oversight mechanisms already exist.

Question 3:
"Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?"

Cochlear Response:
Cochlear supports the TGA using the US FDA's recent draft guidance regarding Clinical Decision Support Software (CDSS) to inform the Australian approach to regulation of these kinds of medical devices.