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Therapeutics Good Administration
By email: devicereforms@tga.gov.au

Proposed application audit framework for medical devices

Cochlear is pleased to provide feedback on the proposed application audit framework and the questions outlined in the TGA consultation paper. We support the TGA's efforts to ensure regulatory effort is aligned with risk and to streamline regulatory processes to help provide Australians with timely access to new technologies shown to be safe and effective. As the proposed application framework is generally well considered and clear, our comments are focused on potential improvements and/or clarifications.

About Cochlear
Cochlear commenced operations in 1981 as part of the Nucleus group and in 1995 listed on the Australian Securities Exchange. Today, it is a Top 30 listed Australian company with a market capitalisation of over $15 billion.

Our goal is to deliver value by helping more people to hear, which contributes to building a healthier and more productive society. Our strategy is focused on improving awareness of and access to implantable hearing solutions for people indicated for our products.

We are pioneers and global leaders in the development, manufacture, and commercialisation of implantable hearing solutions, collaborating in over 100 research programs worldwide to further research into hearing loss.

We invest around 12% of sales revenue each year in research and development (R&D), with over $2.7 billion invested since listing, and we have a portfolio of more than 1,700 patent and patent applications worldwide.

Over the past 40 years we have provided more than 750,000 implant devices to people who benefit from one – or two – of our implantable solutions. And we deliver a lifetime of hearing solutions for recipients, with sound processor upgrades and services to support prior generation products.

Our global headquarters are on the campus of Macquarie University in Sydney, with regional offices in Asia Pacific, Europe, and the Americas. We have a global workforce of around 4,800 employees and a wide geographical reach, selling in over 180 countries, with employees based in over 50 countries.

Response to consultation questions

1. Is there any additional information that the TGA could publish about the new application audit framework that would help with improving the quality of applications to support more timely inclusion of devices?

In general, Cochlear finds the risk factors included in the consultation paper to be useful and clear.

Our only observation is on the risk factor categories relating to risks apparent from the quality of the clinical evidence. For the purposes of considering equivalence to a predicate device in the ARTG it would be useful to have a clear definition of what is considered a 'minor change' or a 'significant difference'.

2. Are there any concerns with limiting mandatory audits to high-risk devices only, noting that the TGA may select any device for a non-mandatory audit if required?

Cochlear has no concerns with this proposal.

3. Are there any concerns with not subjecting high risk medical devices (including IVDs) supported by US FDA PMA certification to mandatory audits, noting that the TGA could select any such device for a non-mandatory audit if required?

We support removing the mandatory audit requirement for medical devices supported by US FDA PMA certification. The way the PMA process works, is that it builds-up from the original approval, with PMA supplements. In some cases, the original PMA could be very old for a device that is no longer in the market and that could be quite dissimilar to the device under the new application. Cochlear suggests that the main consideration for decision to select the device for a non-mandatory audit should be the relevant PMA supplement that includes the device in application, instead of the original PMA.

4. What are the merits or risks of establishing a pathway for Class III medical devices based on MDSAP certification and US FDA 510(k) approval?

We support this proposal noting that the US FDA 510(k) process provides clearance rather than approval.

5. Are there any concerns with formalising the requirement for the submission of:
(a) IFU and CER for all Class III devices supported by EU MDR certification?
(b) IFU and Performance evaluation (clinical and analytical) reports for all Class 4 IVDs supported by EU IVDR certification?

Cochlear doesn't have any concern providing the information proposed. In addition, we would like to suggest that TGA is open to receiving additional information to support the decision for a medical device to be selected for non-mandatory audit. Given that the risk factors are being clarified by TGA, a manufacturer may choose to provide a summary or checklist, addressing each of the risk factors published by TGA, specific to the application, to facilitate the review and decision process.

6. Do you have feedback about further measures to improve assessment timeframes?

We support the proposed timeframes. Our only observation is that the request for information is related to the safety, quality, and effectiveness of the device. We suggest questions aimed at understanding the device, the operation of the device or the structure of the documentation, are managed directly by email or conference call with the sponsor in real time, to avoid extending the timeframe.

7. What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?

Following an Approve decision by the TGA on an application, we suggest sponsors are given the option of requesting the TGA place a temporary hold on including the device on the ARTG.

The reason for this proposal, is that the ARTG is a public database, and sponsors may not want a device to be visible to the public or competitors too early, especially when other applications for devices that work as a system with the approved device, are still under evaluation by TGA.

Giving some control to sponsors on when an approved product will be included into the ARTG, supports the aim of this question about visibility of application timeframes.

Further information and contact details

Please contact Manuel Urena, Director Regulatory Affairs APAC [redacted] or Brooke O'Rourke, Vice President Government Affairs & Sustainability [redacted] to discuss our feedback in more detail.

Yours sincerely

[redacted]

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