

29 April 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
devicereforms@health.gov.au

Dear Medical Devices Branch

Re: AusBiotech's response to the TGA's proposal to make changes to the classification of active implantable medical devices and their accessories.

AusBiotech is pleased to provide comments to the Therapeutic Goods Administration (TGA) in response to its proposed changes to the classification of active implantable medical devices and their accessories (AIMD).

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bi-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. Within AusBiotech, the medical device and diagnostic industries are represented by AusMedtech, an industry group dedicated to the development, growth and prosperity of the Australian medical technology industry.

The AusMedtech Regulatory Affairs Expert Panel is a subcommittee of AusMedtech, providing expert advice on operational and policy-related regulatory matters. This response has been led by the Panel and its Chair, Grant Bennett.

Response to proposal

AusBiotech is supportive of measures which further enhance patient safety. We therefore support the TGA's implementation of its suite of reforms to enact Australia's response to the Review of Medicines and Medical Devices Regulation. However, we believe two issues warrant further consideration by the TGA in relation to the proposed changes to AIMD regulation (and their non-invasive accessories).

1. Alignment with international regulations

The EU Regulation on Medical Devices (EU MDR) takes effect in 2020 and there has not yet been authoritative decisions and regulatory guidance released by the European regulatory authority that give confidence that an agreed, definitive interpretation of the proposed rules in the EU MDR have been finalised. Until this occurs, aligning Australian regulations with the incoming EU MDR is challenging.

In regard to AIMD regulation, there is currently sufficient ambiguity to question whether these regulatory changes in Australia could be occurring too soon.

The life sciences industry operates in a global environment, and in this context ensuring harmonisation with global regulations and guidance is important. On balance, AusBiotech agrees that relevant EU and US regulations and guidance (when finalised) should be used as the basis for informing Australia's regulatory and legislative requirements. Indeed, the majority of medical devices sold in Australia are imported from the US, Europe or Asia.

However, if the approach taken by the TGA deviates from that in the US or Europe or outpaces those international reforms, then unnecessary duplication, risk of error and increased costs within the healthcare supply chain could result.

In the absence of specific guidance by the EU, AusBiotech recommends that the TGA awaits implementation of the new requirements in the EU, which will ensure that the underlying interpretations of the EU MDR are and will be consistent with those to be implemented in Europe.

2. Possible unintended adverse consequences of the proposed changes

AusBiotech is concerned by the blanket approach to the risk reclassification of *all* AIMD non-invasive accessories (as per currently accepted definitions) from Class I to Class III and associated lack of evidence for each accessory's reclassification.

The only safety-related rationale provided in the consultation paper is the following generic statement (p.11), which does not have adequate regard for differences across non-invasive accessories:

- "AIMD have high risks associated with its [sic] use due to many different factors, including the combination of implantation and the use of energy sources inside the body, seriousness of medical indications for which these devices are used, the high requirements for maintenance and calibration, etc. Therefore, any accessory (both implantable and non-implantable) intended to be used together with an AIMD to specifically enable the AIMD to be used in accordance with its/their intended purpose(s) or to assist the functionality of the AIMD, also potentially presents a high risk if they do not perform as intended. The proposed change to the classification of all AIMD accessories (both implantable and non-implantable) to Class III ensures that appropriate assessment is undertaken commensurate with the level of risks of the device."

There is no attempt in this rationale or elsewhere to account for differences across accessories. Similarly, the classification for pacemaker system analysers is currently dependent on the composition of the device, which reflects that composition can influence risk, but the proposal will make *all* these devices Class III regardless of their composition.

This lack of specificity also means there is a lack of evidence provided in the proposal to demonstrate the risk to patient safety that different AIMD accessories pose, and therefore to support their near-universal higher risk reclassification.

For example, it is not clear from the above rationale how an ear hook for the cochlear implant would pose a 'high risk' to a patient, yet the paper explicitly identifies it as an example of an accessory that would be reclassified from Class I to the 'high risk' Class III classification. Cochlear implants make significant contributions to the quality of life of many Australians, and it is not evident that all its associated accessories pose an adequately significant threat to public safety such that the public and industry would be best-served by imposing restrictive regulation on these products. While the TGA may have appropriate evidence and a clear safety-related rationale for proposing the reclassification of these accessories, this has not been articulated in the consultation document.

Raising the risk level to Class III will have a series of potentially profound impacts that ultimately will affect patients. It will have a significant impact on manufacturers by increasing the regulatory costs associated with manufacturing these products. Undertaking a Class III conformity assessment is expensive (around \$70K), while costs and risks for sponsors will also increase. Measures that affect manufacturers will ultimately impact the recipients of these devices, such as the products that are available, and cost. This will also hamper efforts made by emerging companies to enter the market, and offer alternative AIMD treatments, by raising the capital

required to secure regulatory approvals. Therefore, although unintended, there is a risk to product and treatment innovations for patient benefit as a result of these proposals.

AusBiotech is supportive of appropriate and sensible regulation commensurate with risk. The regulatory environment should deliver appropriate consumer protections and ensure the availability of life-changing products is not delayed to consumers. The consultation paper proposes regulatory changes “to reflect high-risks associated with the use of AIMD and their accessories” but does not make a compelling case that articulates why all non-invasive accessories are high risk. Ironically, this risks affecting patient wellbeing by potentially driving up the cost of some devices and reducing the number available, even if there is no evidence to suggest they are unsafe.

AusBiotech therefore believes further investigation and evidence is needed on the risks to patient safety posed by these accessories before it can support this measure. We also recommend the TGA explore options for differentiating between non-invasive accessories.

When relevant, the industry would appreciate advance notice of implementation of the changes and the opportunity to comment on any subsequent amendments proposed. We look forward to working with the TGA on behalf of our members in relation to further consultations on possible changes to Australia’s medical device regulatory framework.