

31 March 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 regulation of personalised medical devices, including 3D-printed devices.

AusBiotech is pleased to provide comment as requested by the Therapeutic Goods Administration (TGA) in relation to the TGA's proposed changes to the regulation of personalised medical devices, including 3D-printed devices.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-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 approach to the TGA's proposal has been led by the Panel and its Chair, Grant Bennett.

AusBiotech has reviewed the TGA's proposed changes to the regulation of personalised medical devices, including 3D-printed devices. It is clear that there are a variety of implications dependent on the technology being developed, and accordingly specific advice regarding implications per technology is best sought from individual sponsors. We have advised our members about this consultation and suggested to them that they may wish to review and provide submissions based on their individual needs and circumstances.

AusBiotech has recently provided a number of submissions in relation to the variety of reform proposals that the TGA is progressing regarding the regulation of medicines and medical devices in Australia. As with those proposals, there are several key principles AusBiotech would like to reiterate that are relevant to the multiple proposals currently out for consultation, including on the regulation of personalised medical devices.

Risk-based approach

An effective and efficient regulatory environment is essential for maintaining Australia's high level of quality, safety and ethical standards across the development and supply of medicines and medical devices, and the regulatory environment should deliver appropriate consumer protections. This regulatory approach should be commensurate with risk, and help ensure the availability of life-changing products is not delayed to consumers.

Global harmonisation

We operate in a global environment, and in this context ensuring harmonisation with global regulations and guidance is important. On balance, AusBiotech therefore 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.

Innovation and safety

We note the challenges of implementing regulatory changes that simultaneously allow innovation to flourish while protecting safety and delivering health outcomes. In doing so, we emphasise the importance of ensuring our regulatory framework remains relevant in an evolving regulatory landscape with rapidly changing technologies, including in personalised medical treatment. Consultation with our members has revealed three enduring reactions to such regulatory changes;

- firstly, that regulatory changes accommodate the current variety of innovative products, and be sufficiently flexible to allow for future products, such that fewer major regulatory changes are required;
- secondly, that certainty and clarity about the regulations is delivered, affording companies appropriate opportunity to be able to meet requirements; and
- thirdly, that to achieve these, the consultation process should be extensive and comprehensive to ensure unintended consequences are minimised.

Accordingly and when relevant, we 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.

Yours sincerely

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