

5 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 a number of definitions and the scope of the medical device regulatory framework in Australia.

AusBiotech is pleased to provide comments to the Therapeutic Goods Administration (TGA) in response to its proposed changes to definitions and Australia's medical device regulatory framework.

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, [REDACTED]

AusBiotech agrees with the TGA's approach and suggested amendments, which will facilitate greater harmonisation with global regulations.

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

[REDACTED]
[REDACTED]
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AusBiotech Ltd