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3rd March 2017

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Email: community.affairs.sen@aph.gov.au

Dear Secretary

Submission into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

On behalf of BIOTRONIK AUSTRALIA Pty Ltd I am writing in support of the Medical Technology Association of Australia (MTAA) submission to the Senate Community Affairs Committee into the above Bill.

BIOTRONIK AUSTRALIA Pty Ltd is supportive of this Bill as it proposes to implement key recommendations from the Expert Panel Review of Medicines and Medical Devices Regulations *(recommendations 15, 24 and 27)* undertaken by Emeritus Professor Lloyd Sansom AO, Mr. Will Delaat AM and Professor John Horvath AO.

These include:

- Introducing an expedited approval pathway to accelerate the development, assessment and review process for novel medical devices using priority review *(recommendation 15);*
- Having third-party Conformity Assessment Bodies (CAB) authorised to issue conformity assessment certificates in Australia required before including medical devices in the Australian Register of Therapeutic Goods *(recommendations 24)* and
- Changes around the "more comprehensive post-market monitoring scheme" *(recommendation 27).*

The aim of the Bill is to:

- Address unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods

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Medical devices allow patients to lead longer and more productive lives and to spend less time in hospitals. Medical devices also experience innovation at a high pace due to new materials and technologies becoming available which improve on existing devices. However, patients miss out if they cannot get access to the latest technology due to outdated and slow regulatory processes. On the other hand, it needs to be ascertained that any new technology entering the Australian market is safe and does not put patients at risk. It is our view that this Bill achieves both by keeping up the strict regulatory framework but spreading the load onto more shoulders by allowing third party CABs to conduct those reviews as well. We are working with some of those third party CABs in other jurisdictions already (TÜV Süd, BSI) and found them to be thorough notified bodies which have vast experience with the devices at hand in particular Active Implantable Medical Devices and Class III devices. Introducing them to Australia would be a gain as they bring know-how which will ultimately benefit the Australian patient.

Additionally, at a time when the Government has committed to an innovation agenda it is important that an innovative industry like the medical device industry has certainty around its policy and operating environment and that it receives ongoing support.

BIOTRONIK AUSTRALIA Pty Ltd fully supports this agenda and therefore aligns with the MTAA Senate submission.

Yours Sincerely,

[redacted]

Falko Thiele
Director Clinical and Regulatory Affairs

[redacted]

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