Committee Secretary
Senate Standing Committee on Community Affairs

PO Box 6100
Parliament House
CANBERRA ACT 2600
AUSTRALIA

Submission from Australian Medical Device Manufacturers and Distributors to the Senate Community Affairs Legislative Inquiry into *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016*

3 March 2017

Dear Committee Chair,

This is a joint submission written collaboratively by a group of four Australian-owned SMEs who develop, manufacture and distribute medical devices in Australia and abroad. We are:

- **Global Orthopaedic Technology** (NSW)
    - The largest Australian-owned orthopaedic implant designer and manufacturer.
- **Prism Surgical** (QLD)
    - An Australian designer, developer, manufacturer and supplier of innovative and novel spinal implant technologies.
- **LifeHealthcare** (NSW)
    - Australia's leading publicly listed medical device distributor.
- **Device Technologies Australia** (NSW)
    - One of Australia's leading providers of medical devices, services, equipment and hospital consumables.

Together, we employ over 1,000 Australian personnel in sales and technical roles such as clinical service, education and training, clinical sales, research and development (R&D), quality, regulatory, engineering and production. The medical products we design, manufacture and distribute are subject to assessment and approval by the Therapeutic Goods Administration (TGA) and as such, we are key stakeholders for policy and regulatory changes in these areas.

We make this submission in support of the Medical Technology Association of Australia (MTAA) submission and as we believe it is vital to voice our support for the Government's moves to improve and streamline the approval process of medical devices in Australia.

Further, we seek to highlight to the committee the unique challenges faced by Australian SMEs in our industry and ways in which the Government can foster growth and strengthen Australian SME competitiveness into the future.

Australia has a strong reputation for the quality of its scientific and medical research and is home to some of the world's best researchers. Over 1,000 companies are in the pharmaceutical, biotechnology and medical device sectors, employing over 70,000 highly-skilled Australians. These companies generate more than $5 billion a year in exports for Australia. Clearly, a sustainable Australian industry has huge benefits to the economy but more importantly to the community by driving research, education and training, providing Australians with high-skilled jobs and better and faster access to potentially lifesaving medical care.

We support the provisions of this Bill that enable the making of regulations to establish new priority pathways for faster approval of medicines, medical devices, biologicals and conformity assessment certificates in Australia. We further support the provisions that will enable the making of regulations to designate Australian notified bodies that would be able to appraise the suitability of the manufacturing process for medical devices manufactured in Australia and to consider whether such medical devices meet relevant minimum standards for safety and performance, as an alternative to the TGA undertaking such assessments.

Though this legislation is welcomed it is our hope that the Government continue to further support innovation and science by backing the Australian industry and making TGA processes simpler, faster and more certain for users into the future. There are several areas that we believe need greater consideration by the Government including the speed of clinical approvals, the significant costs associated with getting a medical device onto the Australian market, and the related matter, that after TGA approval is granted, the large wait times and increased evidence required for product inclusion on the Prostheses List which forms a large market for medical devices in Australia.

To highlight these issues, attached at Appendix 1 is a real-life example of the approval pathway for one of our companies in launching an Australian designed and manufactured hip both in Australia and internationally.

Further, we hope the findings from this inquiry are considered in concert with the broader business environment in which Australian companies operate. Australia is a high cost operating environment but we are also an increasingly significant player on the world stage when it comes to research, advanced manufacturing and innovation.

The Government must ensure that Australian advanced manufacturing and innovation prospers. Manufacturing in Australia is entering a new phase marked by innovation and specialisation and in fast changing industries. As such the design of medical device approval regulation must reflect this. The innovative pharmaceuticals, biotechnology and medical devices sector is one of Australia's strongest prospects in manufacturing.

The government has made clear that the Australian manufacturing sector has a strong future but needs to transition to higher value added, export oriented production. Our companies have a long-standing and substantial commitment to our communities and country and expect our revenue and employment to continue to grow over the comings years. Such a commitment is optimised where Government legislation, regulation and policy creates a positive investment environment and the long-term certainty and stability that industry requires.

It is through our pursuit of innovative medical device and clinical support ideas that we create business growth, employ more Australians, improve patient outcomes and take our IP and technologies to the world. With the correct settings we can support and attract huge investment into the industry which will facilitate innovation, R&D, clinical support and services, education and training, local investment, taxes and jobs.

We encourage the Committee to consider the issues we have raised.

Sincerely,

Andrew Fox-Smith
CEO - Global Orthopaedic Technology

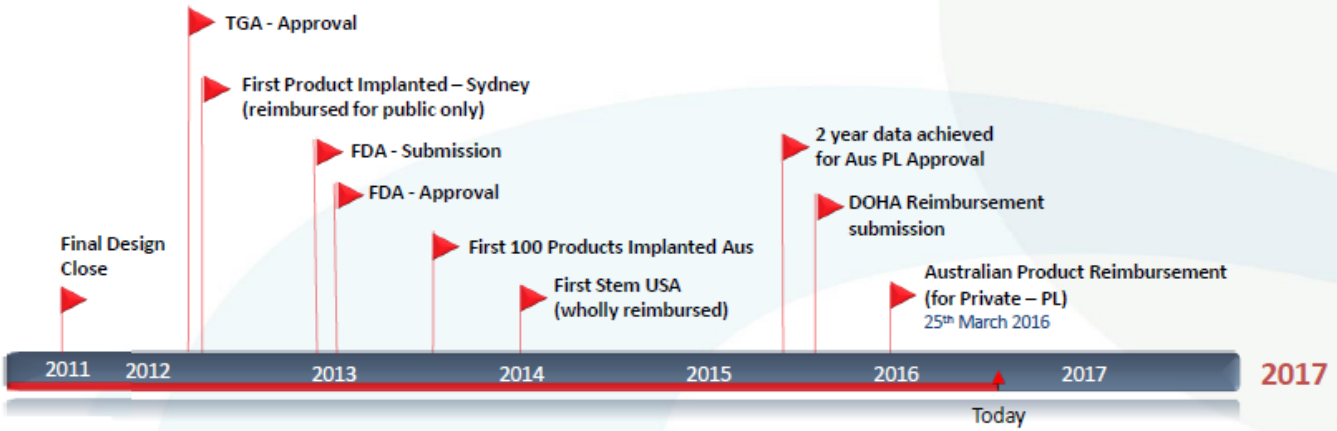
Brett Spence
Managing Director - Prism Surgical

Matt Muscio
CEO - LifeHealthcare

Mick Trevaskis
CEO - Device Technologies

Appendix 1

Hip Product Launch Timeline



1. $5 million R&D investment in Australia for hip product development and commercialisation.
2. Full reimbursement for USA market achieved over 2 years prior to full Australian reimbursement.