Australian Government

Prostheses List Advisory Committee

Committee Secretary
Senate Community Affairs Legislation Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Committee

Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017

Thank you for your invitation to make a submission, as Chair of the Prostheses List Advisory Committee (PLAC), to this Inquiry into this proposed legislation.

The provisions in the *Therapeutic Goods (Charges) Amendment Bill 2017* do not impact on the work of the PLAC, so I will not provide comment on this Bill.

I made a submission to the Inquiry into the *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.* The submission included explanation of the different roles of the Therapeutic Goods Administration (TGA) and the PLAC in assessment of medical devices, so I have attached it for information.

The *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017* (the TGA Measures Bill) contains provisions that will effectively reduce the administrative burden for sponsors of some medical devices and reduce the time taken to assess medical devices for regulation. These objectives are consistent with the Government's direction for reforms of the prostheses listing arrangements.

On 13 October 2017, the Minister for Health, the Hon Greg Hunt MP, announced that the Government has entered into an Agreement with the Medical Technology Association of Australia (MTAA) to promote the sustainability of privately insured healthcare and support a viable, innovative and diverse medical technology sector in Australia.

The Agreement includes commitments to reduce the time to market for medical devices by:

- ceasing duplicative safety and efficacy assessment by the PLAC of devices that have been approved by the TGA, by 1 February 2018; and
- the Minister asking the Secretary of the Department of Health to advise on options for improved expedited pathways for listing appropriate applications with approval for safety and efficacy by the TGA, within six months of the commencement of the Agreement.

The Department, the TGA and the PLAC have commenced work to compare and contrast assessment processes and evidence requirements to find opportunities for concurrent assessment of applications for inclusion on the Australian Register of Therapeutic Goods (ARTG) and listing on

the Prostheses List for medical devices. The outcomes of this work will potentially support reduced times taken to assess devices for regulation and reimbursement and more timely access to new healthcare technologies for patients.

The PLAC would welcome changes to regulatory processes and requirements by the TGA that can potentially strengthen health technology assessment processes in Australia.

Yours sincerely

Emeritus Professor Terry Campbell AM
Chair
Prostheses List Advisory Committee

9 January 2017

(authorised for electronic transmission)