Australian Government

Prostheses List Advisory Committee

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

Dear Secretary

Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

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

The Therapeutic Goods Administration (TGA) and PLAC both assess medical devices but for two distinctly different purposes – the TGA for regulation of the supply of medical devices in Australia and the PLAC for reimbursement for medical devices for privately insured Australians. A successful application to the TGA will result in a medical device being included on the Australian Register of Therapeutic Goods (ARTG) and a successful application to the PLAC will result in listing on the Prostheses List.

The focus of the assessments is also distinctly different – the TGA assesses the safety, quality and performance of individual devices for fitness for lawful supply in Australia and the PLAC assesses clinical effectiveness and cost effectiveness compared with other medical devices and other treatment options, to determine reimbursement levels.

The medical devices considered by the PLAC – surgically implanted prostheses, devices that are integral to implanting surgically implanted prostheses or are essential to the functioning of surgically implanted prostheses, human tissue items and other specific devices - are a subset of the medical devices assessed by the TGA for inclusion on the ARTG.

Safety and performance are essential contributing factors to clinical and cost effectiveness of medical devices on the Prostheses List. Inclusion on the ARTG demonstrates that a medical device has satisfied these threshold assessments so this is one of the criteria for listing on the Prostheses List.

Under the current prostheses listing arrangements:

- a medical device sponsor can apply to list a prosthesis on the Prostheses List at the same time as applying to include it on the ARTG;
- a medical device sponsor may apply to list a prosthesis on the Prostheses List when it is already included on the ARTG or an application for inclusion is in progress;
- the assessment processes can run concurrently but separately as in many cases the requirements for supporting evidence and information are different;

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- the PLAC may assess that a medical device satisfies the other criteria for listing and will delay making a recommendation to the Minister on granting the application until it is included on the ARTG;
- there is a process in place for clinicians to raise issues of concern regarding the safety of medical devices with the TGA, either directly or through the PLAC; and
- there is a process in place for the TGA to liaise with the PLAC when issues around safety and/or performance are raised in relation to medical devices on the Prostheses List.

With a few exceptions, the prostheses listed on the Prostheses List are risk classified by the TGA as Class IIb, Class III or Active Implantable Medical Devices. These classifications are based on the manufacturer's intended use of the device; the level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm); the degree of invasiveness in the human body and the duration of use. The way in which medical devices are assessed for safety, quality and performance by the TGA differs according to the classification.

Concerns have been raised about medical devices that the PLAC has assessed as not sufficiently demonstrating comparative clinical effectiveness but have been deemed by the TGA to be safe and performing satisfactorily for the indications set out by the manufacturer.

Whilst recognising that the requirements for supporting evidence and information required by PLAC and the TGA are different, the PLAC has been particularly concerned about the standard of evidence for those devices already approved in Europe following an assessment by a European Notified Body. The TGA has taken measures to overcome these problems. As an example, in the last few years, the TGA has changed the classification of hip, knee and shoulder joint replacement prostheses from Class IIb to Class III, meaning that these devices undergo mandatory audit of the evidence to support the manufacturers' claims of safety and performance. The PLAC has taken some comfort from these devices undergoing more rigorous pre-market assessment, particularly of use in the clinical setting. Recent work underway in Europe to strengthen the quality of the work carried out by the European Notified bodies will assist the TGA given that the current TGA legislation permits, and the majority of industry sponsors indeed use, European Notified bodies conformity assessment certification to demonstrate compliance with safety and performance requirements.

As the TGA assessments are integral to the work of the PLAC it is essential that there is confidence that any change to the conformity assessment processes by setting up Australian Notified Bodies to carry out the assessment of medical devices maintain high levels of safety and performance. The PLAC notes that the TGA will continue to maintain capacity to carry out conformity assessments for medical devices in addition to any work by an Australian Notified Body.

The PLAC would welcome changes to regulatory requirements and assessment processes that are sufficiently flexible and consider robust enough evidence to support breakthrough new technologies that address urgent and unmet clinical needs.

The 2016 Industry Working Group on Private Health Insurance Prostheses Reform (IWG), chaired by Emeritus Professor Lloyd Sansom AO, who also led the 2015 Review of Medicines and Medical Device Regulation, noted that there are opportunities for enhanced cooperation between the PLAC and the TGA to ensure that assessment activities are not inappropriately duplicated. Further, the IWG recommended that there should be a formalised process of post-market review of medical devices listed on the Prostheses List, and the PLAC should work with the TGA to develop processes

for post-market assessment with a view to removing underperforming devices from the Prostheses List.

The PLAC work plan aligns to the findings of the IWG. As part of its work plan to improve the Prostheses List assessment and listing processes, the PLAC is working with the TGA to identify areas of duplication in process and evidence requirements and opportunities for alignment of medical device assessment, with a view to reducing unnecessary regulation and red tape for medical device sponsors and suppliers, and to promote timely access to devices for patients.

The PLAC has nine Clinical Advisory Groups and a Panel of Clinical Experts that undertake and advise on the assessment of comparative clinical assessment of medical devices. The PLAC is also working with the TGA to identify opportunities to share knowledge and expertise between these subcommittees and the TGA's Advisory Committee on Medical Devices.

Thank you for the opportunity to offer comment to inform your inquiry.

Yours sincerely

Professor Terry Campbell AM
Chair
Prostheses List Advisory Committee

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