**Senator the Hon Fiona Nash**
Minister for Regional Development
Minister for Local Government and Territories
Minister for Regional Communications
Deputy Leader of The Nationals

13 SEP 2017

Senator the Hon Stephen Parry
President of the Senate
PO Box 1600
Senate
Parliament House
CANBERRA ACT 2600

Dear Mr President

I am writing to provide the Australian Government response to the Senate Community Affairs Reference Committee report: *Pricing regulation associated with the Prostheses List framework* for tabling in the Senate.

Please find the response enclosed.

I would like to extend my appreciation to the Community Affairs Reference Committee for conducting the inquiry, which brought together contributions from a diverse array of groups and individuals to produce a valuable report.

Yours sincerely

Fiona Nash

Encl.


**Australian Government**

Australian Government response to the

Senate Community Affairs Reference Committee report:

# Pricing regulation associated with the Prostheses List framework

September
2017

## Introduction

The Australian Government recognises the important role that medical devices play in the overall health of Australian patients and the need to maintain a stable, sustainable and innovative medical device sector. In 2016-17, 2.7 million medical devices on the Prostheses List were supplied at a cost of $2.1 billion.

The Australian Government further recognises that reform of the prostheses listing arrangements and price regulation is necessary to put downward pressure on private health insurance premiums for consumers.

In early 2016 the Government initiated an Industry Working Group (IWG) on Private Health Insurance Prostheses Reform, chaired by Emeritus Professor Lloyd Sansom AO, seeking views from stakeholders about the factors that were influencing costs of medical devices and impacting on private health insurance benefits paid for prostheses.

The Government reconstituted the Prostheses List Advisory Committee (PLAC) in October 2016 to address the issues raised in the work of the IWG, to develop detailed reform options for the Government to consider, in collaboration with stakeholders.

The Committee's Inquiry has been invaluable in drawing information and views from stakeholders, and highlighting the challenges faced by the PLAC and Government in developing and implementing reforms to prostheses price regulation. There is a high level of consistency between the Committee's findings and the PLAC's reform work plan.

In addition to reforms through the PLAC, the Australia Government has initiated new pricing reforms to reduce the cost of thousands of medical devices to take pressure off private health insurance premiums for Australians.

In a first tranche of cost reductions passed onto 13.5 million Australians with private health insurance, the government reduced the cost of medical devices as set by the Prostheses List by 10 per cent for cardiac devices and intraocular lenses and 7.5 per cent for hip and knee replacements from 1 February 2017. This reduced costs for private health insurance members by an estimated $86 million in the first year, and a further estimated $500 million over the next six years.

The Government has asked the Independent Hospital Pricing Authority to provide data in relation to average public sector prostheses costs, average public sector private insurance payments for prostheses and average private sector prostheses costs.

The data shows differences in the prices of prostheses related procedures between private and public sectors. Government is consulting with the medical device sector on a second tranche of cost savings to be delivered from 2018 to further improve the cost of private health insurance and deliver pricing stability for the sector.

The Australian Government welcomes the report, has carefully considered the recommendations and provides the following responses.

## Recommendation 1

**The committee recommends that the Prostheses List Advisory Committee, in consultation with stakeholders, develop and publish a formal work plan with defined agreed targets, activities, timeframes, indicators and outcomes to assist stakeholders to better understand and participate in the reform process; and**

**Recommendation 5**

**The committee recommends that the Prostheses List Advisory Committee continue to consult with stakeholders regarding reform of the Prostheses List to ensure transparency of the reform process.**

**Response:** The Australian Government agrees that the reform work undertaken by the Prostheses List Advisory Committee (PLAC) should be transparent to all stakeholders.

The PLAC is taking a collaborative approach to prostheses reform, and has published a workplan on its website. The PLAC has committed to keeping stakeholders informed, engaged and consulted throughout the reform process through a range of mechanisms, including releasing communiques after each meeting.

The PLAC will develop a communication strategy with input invited from all stakeholders to guide future engagement.

The Department is regularly updating the PLAC website to provide more information about PLAC activities and timeframes as these are developed and agreed, and has established a consultation "hub", which enables stakeholders to participate in reforms by accessing consultation papers and providing views.

**Recommendation 2**

**The committee recommends that the department immediately implement better and more robust coordination between the Therapeutic Goods Administration and the Prostheses List Advisory Committee, including implementing appropriate coordination of health technology assessment processes to ensure that applications to list on the Prostheses List as a minimum have a concurrent application for listing on the Australian Register of Therapeutic Goods.**

**Response:** The Government notes this recommendation. Parallel processing of applications to register new medical devices on the Australian Register of Therapeutic Goods (ARTG) and list on the Prostheses List is an important part of the existing health technology assessment processes, and assists with earlier patient access to important new technologies.

The form to apply to list a new device on the Prostheses List for reimbursement includes a checkbox for applicants to confirm that an application has been made to the Therapeutic Goods Administration (TGA) for registration.

The Government supports better and more efficient coordination of health technology assessment between the PLAC and the TGA.

The PLAC's reform workplan includes "Minimising duplication and improving the listing process", and the PLAC has commenced identifying opportunities for aligning and streamlining processes with those of the TGA.

The TGA assesses safety and performance for the device's intended purpose, and the PLAC assesses comparative clinical effectiveness and cost relative to comparators. However, there are features that are common to both assessment processes. Mapping of processes to find opportunities for alignment and to reduce duplication is underway, and the PLAC membership includes an advisor from the TGA.

The PLAC Chair hosted a Health Technology Assessment Roundtable on 9 June 2017. Expert members of the PLAC, Chairs of the Clinical Advisory Groups (CAGs), members of the Panel of

Clinical Experts (the Panel), members of the TGA's Advisory Committee on Medical Devices (ACMD) and the Chair of the Medical Services Advisory Committee (MSAC) participated in discussion about the health technology assessment processes of each committee and how the combined clinical expertise and health economics expertise could be used to achieve better outcomes.

The outcomes of the Roundtable were published on the PLAC's website and are being translated into action plans for developing processes and protocols for sharing resources in application assessment and post market surveillance.

The Medical Technology Association of Australia has also agreed to assist in developing Questions and Answers that will help medical device sponsors to better understand the parallel processing pathway.

In addition the Government is consulting with the MTAA and other stakeholders on enhanced reforms that could be introduced to minimise the time taken for approvals to ensure that patients being treated in the private sector are able to access safe, effective and cost effective medical devices available in the public sector.

**Recommendation 3**

**The committee recommends that clinical input through Clinical Advisory Groups remain an integral part of the Prostheses List Advisory Committee and the Prostheses List decision making process to ensure that safety and effectiveness of medical devices remains a primary consideration in decisions about inclusion on the Prostheses List.**

**Response:** The Government agrees to this recommendation. Clinician input is and will remain an integral part of Prostheses List decision making.

The PLAC has recently updated the Terms of Reference and Operational Guidelines for the Clinical Advisory Groups and Panel of Clinical Experts to reflect their roles in providing expert clinical advice.

The revenue received from Prostheses List cost recovery is primarily used for supporting clinician input into the application and listing processes.

**Recommendation 4**

**The committee recommends that the Government assess the resources needed to develop and implement reforms within an agreed timeframe and provide any further resources to the Prostheses List Advisory Committee and the Department of Health.**

**Response:** The Government notes this recommendation.

The Department and the PLAC are currently reviewing the cost recovery arrangements that fund the operations of the Prostheses List, and will consider the resources required to support the implementation of agreed reforms as they are developed.

**Recommendation 6**

**The committee recommends that where the Commonwealth decides that a prostheses registry is needed, the Parliament should ensure that the registry is legislated for and collection of data is made compulsory.**

**Response:** The Australian Government notes this recommendation.

There are already a number of Commonwealth government and industry funded devices registries (including the National Joint Replacement Registry). The Commonwealth is working with state and territory health department representatives to develop a national policy and funding framework for clinical quality registries, which will include consideration of other prostheses registries and mandatory collection of data.

**Recommendation 7**

**The committee recommends that the Government legislate for the compulsory provision of private hospital and day surgery data to the Independent Hospital Pricing Authority.**

**Response:** The Government notes this recommendation.

The *National Health Reform Act 2011* specifies that the provision of costing information in relation to the calculation of an efficient price (by the Independent Hospital Pricing Authority (IHPA) is only applied to public hospital services in Australia. Cost information from the private sector is provided to the IHPA on a voluntary basis. The IHPA currently reports on this information through the *National Hospital Cost Data Collection, Private Sector Cost Report* for each year.

The Government will continue to encourage the provision of data by all relevant stakeholders to inform improved policy and planning processes.

**Recommendation 8**

**The committee recommends that action is needed to reduce the prostheses costs and that savings should be delivered as soon as possible and have an evidence base.**

**Response:** The Government agrees in principle, and recognises the need to work with medical device sponsors, health providers, private hospitals, day hospitals and private health insurers to identify ways to reduce prostheses costs without reducing patient outcomes, or reducing the value of private health insurance to Australian consumers.

Data provided by the Independent Hospital Pricing Authority (IHPA) on prostheses pricing in public and private hospitals has identified price differences, which are now the subject of consultation with stakeholders and consideration of a further tranche of price reforms in 2018. Along with data and information from stakeholders, and the PLAC's advice on the outcomes of targeted reviews, this will assist the Government to identify potential changes to prostheses benefits.

**Recommendation 9**

**The committee recommends that guidelines for targeted prostheses reviews be finalised at the earliest opportunity and published with a schedule of proposed targeted reviews to enable stakeholders sufficient time to prepare for the reviews.**

**Response:** The Government agrees in principle to this recommendation. The PLAC has commenced targeted reviews of prostheses listings in the hip, knee, cardiac and spinal categories to inform options to improve arrangements and identify potential reductions in private health insurance expenditure. These reviews are being conducted in collaboration with stakeholders, including medical device sponsors, private hospitals, day hospitals and private health insurers, as well as consumers.

The PLAC has published its draft *Approach for Targeted Prostheses Reviews* on the department's website and invited feedback from stakeholders. The department received eleven responses, and this feedback is assisting in scoping and planning targeted reviews.

The PLAC has committed to publishing the plan for each review so that stakeholders can prepare and provide input. This includes setting out a consultation strategy to seek the views of stakeholders on options, impacts and implementation considerations.

**Recommendation 10**

**The committee recommends that the Department of Health undertake further analysis and consultation, including with consumers, to determine the most appropriate benefit setting model or models, and that this analysis include investigation of the introduction of outcomes based categorisation of items on the Prostheses List, and the option of the government purchasing devices directly.**

**Response:** The Government notes this recommendation, and recognises the need for further work on a future benefit-setting framework.

The Department of Health commissioned preliminary research from the Centre for Health Policy at University of Melbourne on possible pricing models for medical devices and how they could be applied to the prostheses listing arrangements. Input from stakeholders was taken into consideration to ensure a broad understanding of potential impacts. The final report on this research is available on the Department of Health website.

Further work to develop an evidence-based benefit-setting framework for prostheses will occur in consultation with stakeholders.

**Recommendation 11**

**The committee recommends that the Prostheses List Advisory Committee be required to review the group prices for prostheses when applications for new comparable devices are received which request listing at a lower price than the existing benefit level for that group of devices.**

**Response:** The Government notes this recommendation.

It is intended that the PLAC will develop an approach to reviewing the benefits for prostheses as part of building the evidence-based benefit-setting framework for prostheses. As part of this work, the PLAC will consider appropriate triggers to initiate reviews and provide advice on options to the Government.

In the interim, the category-based targeted reviews will consider the current benefits for prostheses with reference to available data on pricing.

**Recommendation 12**

**The committee recommends that the Minister for Health release new Independent Hospital Pricing Authority data on the differences between prostheses prices in private and public hospitals and investigate whether this could be used to adjust Prostheses List Advisory Committee prostheses prices as soon as possible.**

**Response:** The Government agrees to this recommendation. The Minister for Health has consulted with stakeholders on prostheses cost data as supplied to the Independent Hospital Pricing Authority (IHPA) with a view to using this information to assist with developing reforms to

prostheses listing arrangements. The IHPA data shows that prostheses costs in the public sector are, on average, lower than in the private sector for comparable patient types, classified by Diagnosis Related Group. However these data do not fully take into account differences in the type and use of prostheses in the private and public sectors. The Government will seek further advice from the Medical Technologies Association of Australia and other parties on additional data sources.

**Recommendation 13**

**The committee recommends that the Prostheses List Advisory Committee further investigate rationalisation of the Prostheses List to reduce its size as an important element in reviewing and reforming the benefit setting process.**

**Response:** The Government agrees to this recommendation. The PLAC has commenced reviewing the criteria for listing devices on the Prostheses List. In addition, the PLAC is reviewing devices that are currently listed on the Prostheses List to consider any opportunities for lower cost and/or high volume devices to be reimbursed more efficiently through other mechanisms.

The targeted reviews of prostheses will also consider the current grouping schemes for prostheses and seek opportunities for reducing their complexity. This work will contribute to streamlining the Prostheses List.

The work to review the listing criteria and streamline the grouping schemes will be undertaken in consultation with stakeholders, to provide advice to Government on options.

**Recommendation 14**

**The committee recommends that the department investigate the impact of the 25 per cent market share requirement and its role in distorting the market.**

**Response:** The 25 per cent market share guide is not a requirement for setting benefits on the Prostheses List. It was an historical guide to establish single benefits for groups of devices on the Prostheses List in the absence of pricing data being available.

The PLAC will develop options for an evidence-based benefit-setting framework for the future, in consultation with stakeholders, to inform advice to the Government.

**Recommendation 15**

**The committee recommends that the Prostheses List Advisory Committee investigate a mechanism for the reimbursement of medical devices not currently eligible for inclusion on the Prostheses List, including non-implantable devices and implantable devices not requiring hospital admission.**

**Response:** The Government notes this recommendation, and the need to balance the objectives of keeping private health insurance affordable, and ensuring that insurance policies provide cover for appropriate health care to meet the needs of policy holders.

The PLAC has commenced reviewing the criteria for listing devices on the Prostheses List, which will include discussion of devices that do not meet the current listing criteria, such as cardiac pressure wires, drug eluting balloon catheters and cardiac ablation catheters. In this review process, the PLAC will also have regard to other reimbursement options, such as theatre banding and case-based payments. The PLAC will consult with stakeholders in developing options for Government on possible revisions to the listing criteria.

**Recommendation 16**

**The committee recommends that the nature and cost of services associated with a medical device on the Prostheses List be disclosed separately to the cost of the device.**

**Response:** The Government agrees to this recommendation. The PLAC is working to develop an evidence-based benefit-setting framework for prostheses for the future.

In this context, the PLAC will consider the costs of medically relevant services and other cost factors in supplying prostheses to patients, and how these costs are identified and reported.