The Senate

Community Affairs References Committee

Price regulation associated with the Prostheses List Framework

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45th Parliament

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ABBREVIATIONS

AH	Australian Hearing
AMA	Australian Medical Association
AOA	Australian Orthopaedic Association
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
ARTG	Australian Register of Therapeutic Goods
CAG	Clinical Advisory Group
CHA	Catholic Health Australia
Department	Department of Health
Doyle Review	Review of the Prostheses Listing Arrangements
DRG	Diagnosis Related Group
DVA	Department of Veterans' Affairs
FTE	Full Time Equivalent
HESC	Health Economics Sub Committee (of the PLAC)
hirmaa	Health Insurance Restricted Membership Association of Australia
HTA	Health Technology Assessment
HTA Review	Review of Health Technology Assessment in Australia
IHPA	Independent Hospital Pricing Authority
IWG	Industry Working Group on Private Health Insurance Prostheses Reform
MMDR	Medicines and Medical Devices Review
MSAC	Medical Services Advisory Committee
MTAA	Medical Technology Association of Australia
NDIS	National Disability Insurance Scheme

NHCDC	National Hospital Cost Data Collection
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PHA	Private Healthcare Australia
PHI Act	*Private Health Insurance Act 2007*
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
SME	Small and medium sized enterprise
TGA	Therapeutic Goods Administration

LIST OF RECOMMENDATIONS

Recommendation 1

5.4 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.

Recommendation 2

5.5 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.

Recommendation 3

5.6 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.

Recommendation 4

5.7 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 that are required to achieve this.

Recommendation 5

5.8 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.

Recommendation 6

5.11 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.

Recommendation 7

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

Recommendation 8

5.18 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.

Recommendation 9

5.19 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.

Recommendation 10

5.26 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.

Recommendation 11

5.27 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.

Recommendation 12

5.28 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.

Recommendation 13

5.29 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.

Recommendation 14

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

Recommendation 15

5.32 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.

Recommendation 16

5.35 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.

Chapter 1
Introduction

> The Prostheses List was introduced as measure to stabilise uncontrolled and uncontained growth in the private sector, however it resulted in a system that is complicated and not well understood.[1]

1.1 The Australian healthcare system operates under a mixed model of private and public health and hospital services. Australians with private health insurance who are recipients of prostheses may choose to receive treatment as private patients in either private or public hospitals.

1.2 Where prostheses are provided to private patients in either a private or public hospital, the price paid for the prostheses by private health insurers is set by the Prostheses List (PL). The PL is regulated by the Australian government and requires that private patients have no out-of-pocket expenses for prostheses.

1.3 Private health insurance premiums have increased by approximately 5.6 per cent each year in the last ten years leading to concerns about private health insurance becoming increasingly unaffordable.[2] For the first time since the government introduced measures to encourage the uptake of private health insurance, participation rates are decreasing.[3]

1.4 The price of prostheses on the PL has been identified by the Government and private health insurers as a factor in the rising price of health insurance premiums.[4] In October 2016 the Government announced a number of changes to the PL in an effort to ease pressure on private health insurance premiums.[5] The response to these changes has been mixed with private health insurers claiming they do not go far enough and manufacturers raising concerns about the lack of evidence for the changes and the impact on the prostheses industry.[6]

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1 Australian Medical Association, *Submission 40*, p. 2.

2 Medibank Private, *Submission 14*, p. 3.

3 Mr Matthew Koce, Chief Executive Officer, hirmaa, *Committee Hansard*, 16 March 2017, p. 18.

4 See, for example: Private Healthcare Australia, *Submission* 7; Medibank, *Submission 14*; BIB, *Submission 16*; HBF, *Submission 27*; HCF, *Submission 28*; Bupa, *Submission 31*; The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

5 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

6 See, for example: Medical Technology Association of Australia, *Submission 2*; CONMED Linvatec Australia, *Submission* 5; Private Healthcare Australia, *Submission* 7; HBF, *Submission 27*; Joint submission from four Australian medical device manufacturers and distributors, *Submission 39*.

1.5 Rising health insurance premiums, coupled with an ageing population and an increase in hospital admissions has sparked concerns that the public health system will be under even greater pressure in the future.

Conduct of the inquiry

1.6 This inquiry was referred by the Senate for inquiry on 21 November 2016, with a reporting date of 30 March 2017.[7] On 23 March 2017, the committee received an extension of time to report until 10 May 2017,[8] and on 10 May 2017, the committee received a further extension to 11 May 2017.[9] Details of the inquiry are available on the committee's website.[10]

1.7 The terms of reference for this inquiry are:

Price regulation associated with the Prostheses List Framework, with particular reference to:

(a) the operation of relevant legislative and regulatory instruments;

(b) opportunities for creating a more competitive basis for the purchase and reimbursement of prostheses;

(c) the role and function of the Prostheses List Advisory Committee and its subcommittees;

(d) the cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries;

(e) the impact the current Prostheses List Framework has on the affordability of private health insurance in Australia;

(f) the benefits of reforming the reference pricing system with Australian and international benchmarks;

(g) the benefits of any other pricing mechanism arrangements, including but not limited to those adopted by the Pharmaceutical Benefits Scheme, such as:

(i) mandatory price disclosure,

(ii) value-based pricing, and

(iii) reference pricing;

(h) price data and analytics to reveal the extent of, and where costs are being generated within, the supply chain, with a particular focus on the device

7 *Journals of the Senate*, No. 16, 21 November 2016, pp. 497-497.

8 *Journals of the Senate*, No. 34, 23 March 2017, p. 1150.

9 *Journals of the Senate*, No. 40, 10 May 2017, p. 1325.

10 See: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework.

categories of cardiac, Intra Ocular Lens Systems, hips, knees, spine and trauma;

(i) any interactions between Government decision-making and device manufacturers or stakeholders and their lobbyists;

(j) any implications for prostheses recipients of the National Disability Insurance Scheme transition period; and

(k) other related matters.[11]

1.8 The committee received 45 submissions from a range of individuals and organisations including medical device manufacturers, private health insurers, private hospitals, practitioners, consumer groups and government departments.

1.9 The committee acknowledges those who contributed to the inquiry through submissions or as witnesses. A list of the individuals and organisations who provided submissions to the inquiry is available at Appendix 1.

1.10 Three public hearings were held in Canberra on 15, 16 and 31 March 2017. Transcripts of these hearings are available on the committee's website and a list of witnesses who gave evidence at the public hearings is provided at Appendix 2.

Structure of the report

1.11 This report is divided into five chapters:

- **Chapter 1** provides a background to the committee's inquiry and an overview of the operation of the PL Framework.
- **Chapter 2** examines past reform of the PL, issues and relationships between stakeholders and the effect of the current PL Framework.
- **Chapter 3** examines the current reforms under way.
- **Chapter 4** examines alternative models and opportunities for reform.
- **Chapter 5** concludes the committee's consideration and makes recommendations for further consideration.

Operation of the Prostheses List Framework

What is the Prostheses List

1.12 The PL was introduced by the Australian government in 1985 to regulate the price of prostheses paid by patients with private health insurance and reduce public hospital waiting lists for procedures involving prostheses.[12]

1.13 For the purposes of the PL, a prosthesis is defined as a surgically implantable device such as a cardiac pacemaker, intraocular lenses used in cataract surgery and hip

11 *Journals of the Senate*, No. 16, 21 November 2016, pp. 497-497; See also: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework.

12 Department of Health, *Submission 38*, p. 8.

or knee joints used in replacement surgeries. The PL does not included external devices such as hearing aids or prosthetic limbs. [13]

1.14 The PL enables surgeons to have access to and chose the optimal prostheses for patients covered by private health insurance. Private hospitals purchase prostheses directly from device manufacturers and often receive rebates or other incentives from manufacturers for buying in bulk or achieving certain volume amounts, commonly referred to as volume discounts. Where a private patient receives treatment in a public hospital, the public hospital is able to access prostheses at a much lower price and invoice the private health insurer for the higher minimum benefit amount on the PL.

1.15 A patient's private health insurer is required by law to pay the minimum benefit amount for any prostheses included on the PL, regardless of the price paid by the hospital for the device. The price of prostheses are passed on to consumers through health insurance premiums and indirectly to government through the private health insurance rebate.

Regulation of the Prostheses List

1.16 Division 72 of the *Private Health Insurance Act 2007* (PHI Act) sets out the PL Framework and provides that private health insurance policies must cover the benefit amount of a prosthesis included on the PL.[14] The Private Health Insurance (Prostheses) Rules set out the listing criteria which must be satisfied in order for a prosthesis to be included on the PL.[15]

1.17 The PL is divided into three parts which are outlined below:

- Part A includes surgically implantable devices and integral single-use aids used to implant the device.
- Part B includes human tissue-based products that are regulated by the Therapeutic Goods Administration (TGA) as 'biologicals'.
- Part C includes devices which do not meet the criteria for Parts A or B and are determined at the Minister's discretion. Currently Part C is limited to insulin infusion pumps, implantable cardiac event recorders and cardiac home/remote monitoring systems.[16]

1.18 As at 1 December 2016, 10 718 individual prostheses were listed on the PL.[17]

1.19 Prostheses included in Parts A and C can be divided into four different tiers: categories, subcategories, groups and subgroups. [18] Firstly, prostheses are organised in a hierarchical structure into the following categories:

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13 Department of Health, *Submission 38*, p. 2.

14 *Private Health Insurance Act 2007*, https://www.legislation.gov.au/Details/C2016C00911 (accessed 3 May 2017).

15 Private Health Insurance (Prostheses) Rules 2017 (No. 1), https://www.legislation.gov.au/Details/F2017C00240 (accessed 3 May 2017).

16 Department of Health, *Submission 38*, pp. 2, 4.

17 Department of Health, *Submission 38*, p. 2.

- Cardiac
- Cardiothoracic
- Ear Nose and Throat
- General Miscellaneous
- Hip
- Knee
- Neurosurgical
- Ophthalmic
- Plastic and reconstructive
- Specialist Orthopaedic
- Spinal
- Urogenital
- Vascular.

1.20 Prostheses are then divided into subcategories based on the essential function of the prosthesis. The devices are subsequently allocated into groups which reflect their specific function and may be further divided into sub groups to differentiate them on the basis of performance.[19]

1.21 Following the *Review of Health Technology Assessment in Australia 2009* (HTA Review) (discussed further in Chapter 3), each grouping of prostheses on the PL has a single minimum benefit level.[20] That is, the amount paid by private health insurers for a particular prostheses is the same amount for each prostheses listed in that group.

New prostheses

1.22 In order for a prosthesis to be included on the PL an application must be made, usually by a medical device sponsor or supplier (i.e. the device manufacturer), which outlines how the device meets the listing criteria for Part A or C and the comparative clinical effectiveness of the device.[21]

1.23 Applications are considered by the Prostheses List Advisory Committee (PLAC) which is made up of experts in clinical practice, health economics, health technology assessment and health consumerism as well as representatives of the Department of Veteran Affairs, the TGA and major stakeholder organisations.[22]

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18 Department of Health, *Submission 38*, p. 4.

19 Department of Health, *Submission 38*, pp. 4-5.

20 Department of Health, *Submission 38*, pp. 4, 10.

21 Department of Health, *Submission 38*, p. 5.

22 Department of Health, *Submission 38*, p. 7.

The PLAC is supported by Clinical Advisory Groups (CAGs), a Panel of Clinical Experts and the Health Economics Sub-Committee (HESC).[23]

1.24 All applications for new prostheses are subject to an administrative assessment by the Department of Health (the department) to ensure that sufficient information has been provided.[24] Applications are also subject to a clinical assessment by appropriate experts who are members of a CAG or Panel of Clinical Experts and provide advice on whether the device satisfies the listing criteria and can demonstrate comparative clinical effectiveness.[25]

1.25 If the prosthesis is a new device and the sponsor proposes that it be included in a new grouping, subgroup or suffix on the PL, the HESC assesses the sponsor's application to determine if the recommended benefit is reasonable and that the proposed benefit amount reflects the demonstrated difference in clinical outcomes between the new prostheses and existing prostheses included on the PL.[26] The HESC also considers advice from clinicians on the comparative clinical effectiveness of the new device and provides their assessment to the PLAC for consideration.[27]

1.26 The PLAC provides advice to the Minister of Health (or the Minister's delegate) who ultimately decides whether a device should be included on the PL.

Administration of the Prostheses List

1.27 The PLAC and the administration of the PL is supported by a secretariat within the Department which includes 12 full time equivalents (FTE's).[28]

1.28 The cost of processing and maintaining the PL is recovered by the department through the payment of fees. Medical device sponsors and suppliers are required to pay a fee to apply for a new listing and to maintain devices on the PL as outlined below:

- $600 to make an application for a new item to be included on the PL;
- $200 to initially list a new prosthesis; and
- $200 payable twice per year to maintain a prosthesis on the PL.[29]

1.29 Currently the department receives approximately $4.4 million per annum in fees.[30]

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23 Department of Health, *Submission 38*, pp. 5-6.

24 Department of Health, *Submission 38*, p. 6.

25 Department of Health, *Submission 38*, p. 6.

26 Department of Health, answers to written questions on notice (received 26 April 2017).

27 Department of Health, *Submission 38*, p. 6.

28 Department of Health, answers to written questions on notice (received 26 April 2017).

29 Department of Health, *Submission 38*, p. 2; Private Health Insurance (Prostheses Application and Listing Fee) Rules 2008 (No. 1).

30 Department of Health, *Submission 38*, p. 2.

Size of the industry

1.30 In 2015-16 the private health insurance industry provided $18.9 billion in health insurance benefits, increasing 5.1 per cent from 2014-15.[31] Medibank, Australia's largest private health insurer, spent $5.1 billion on their customer's health care last financial year. Of this, $540 million was on prosthetic devices alone.[32]

1.31 Private health insurance plays a significant role in Australia's healthcare system. As at 30 September 2016, 46.8 per cent of Australians were covered by hospital treatment policies and 55.6 per cent had a form of general treatment cover.[33] Two in every five hospital admissions are funded by private health insurance representing 33 per cent of all days of hospitalisation in Australia.[34] In addition, approximately two thirds of elective surgeries are performed in private hospitals which reduce waiting times for elective surgeries in public hospitals.[35]

1.32 While private health insurance reduces pressure on the public hospital system, the industry is also subsidised by the Australian government through the income-tested Private Health Insurance Rebate. The rebate is expected to cost the Government $6.4 billion in 2017-18.[36]

1.33 The committee heard throughout the inquiry that is not only the cost of prostheses which places pressure on private health insurance premiums but also the increase in utilisation of prostheses, hospital admissions and Australia's ageing population. While these other factors are important considerations for the future of Australia's healthcare policy, the focus of this inquiry is on the PL Framework.

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31 Department of Health, *Submission 38,* p. 2.

32 Medibank, *Submission 14*, p. 3.

33 Department of Health, *Submission 38,* p. 2.

34 Medibank, *Submission 14*, p. 3.

35 Medibank, *Submission 14*, p. 3.

36 Department of Health, *Submission 38,* p. 1.

Chapter 2

The Prostheses List in Practice

Introduction

2.1 The Prostheses List Framework has been subject to a number of reviews since its introduction in 1985. Successive reviews have consistently raised similar issues suggesting that there are a number of challenges to reform. However, while the inquiry has shown that there is general support for reform, there is little agreement on the areas which require reform and how this should be achieved.

2.2 The absence of agreement may be a symptom of both a segregated system where stakeholders have limited interaction with each other and a system which lacks transparency.

2.3 This chapter provides an outline of previous attempts at reform in this area, the roles and relationships of each stakeholder and the impact of the Prostheses List (PL) on stakeholders, private health insurance premiums and consumers.

History of reform

Introduction of the Prostheses List

2.4 The PL was introduced in 1985 with a view to reduce hospital waiting list for procedures involving surgically implanted prostheses. The government passed legislation to require private health insurers to pay a benefit equal to the amount determined by the Minister, or the price of the prosthesis if it was less than the amount determined by the Minister.[1]

Deregulation

2.5 In 1999 PL benefit amounts were deregulated in response to concerns raised by the private health insurance industry about the rate of increase of benefits.[2]

2.6 However, under the period of deregulation, private health insurers negotiated the benefit amount directly with device manufacturers on the condition that there would be no gap payment for patients. This condition undermined the private health insurers' ability to negotiate benefit amounts and prostheses benefits almost doubled between 2000-01 and 2002-3.[3]

Reregulation

2.7 The Government announced new arrangements in April 2003 in response to concerns about the rapid increase in prostheses benefits during deregulation.[4] The new

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1 Department of Health, *Submission 38,* p. 8.

2 Department of Health, *Submission 38,* p. 8.

3 Department of Health, *Submission 38,* p. 9.

4 Department of Health, *Submission 38,* p. 9.

arrangements were developed in consultation with private health insurers, private hospitals, clinicians, sponsors of prostheses devices and consumers.[5]

2.8 The new arrangements came in to effect on 31 October 2005 and ensured that independent clinical advice was integral to determining the clinical effectiveness of a device. The department advised the process for determining the benefit levels:

> Prostheses for use in hip and knee replacement surgery, intraocular lenses and cardiac defibrillators, pacemakers and stents were clinically assessed and their benefit amounts negotiated with their respective sponsors.
>
> Benefits for the remaining prostheses were determined by applying the weighted average benefit calculated using benefit levels and utilisation data on individual prostheses from each insurer that had an agreement in place with the sponsor as at 31 October 2004.[6]

2.9 Under the new arrangements, benefit levels for new prostheses were negotiated by the Prostheses and Devices Negotiating Group, acting on behalf of the Prostheses and Devices Committee (precursor to the Prostheses List Advisory Committee (PLAC)), who undertook commercial-in-confidence negotiations directly with medical device sponsors.[7]

Doyle Review

2.10 In accordance with section 12 of the *National Health Amendment (Prostheses) Act 2005*, The Honourable Robert Doyle undertook an independent review of the prostheses arrangements in October 2007 entitled the *Review of the Prostheses Listing Arrangements* (Doyle Review).[8]

2.11 The Doyle Review made 15 recommendations for structural, operational and administrative changes. However, few of these recommendations were adopted and most were deferred until completion of the *Review of Health Technology Assessment in Australia* (HTA Review).[9]

Review of Health Technology Assessment

2.12 The HTA Review was released two years later in 2009 and highlighted that the process to establish consistent groupings of prostheses with similar clinical effectiveness had been slow.[10]

2.13 The HTA review recommended that the process to establish consistent groupings be completed by a dedicated resource within the Department of Health (department) and that negotiations of benefits for individual prostheses should cease

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5 Department of Health, *Submission 38*, p. 9.

6 Department of Health, *Submission 38*, p. 9.

7 Department of Health, *Submission 38*, p. 9.

8 Department of Health, *Submission 38*, pp. 9-10.

9 Department of Health, *Submission 38*, p. 10.

10 Department of Health, *Submission 38*, p. 10.

and that a single benefit level should be established for all prostheses in each particular group.[11]

2.14 This lead to a decision that in order to expedite the grouping process, a 25 per cent utilisation benchmark would be used to determine the minimum benefit amount for prostheses in each group.[12] The committee heard that this process entrenched benefit levels which had been negotiated in the preceding years when prices were high and negotiations lacked transparency.[13]

2.15 Submitters raised concerns during the inquiry that the 25 per cent utilisation rule was anti-competitive and did not provide an incentive for device sponsors to lower their prices.[14] The department explained that the PLAC has moved away from that rule and is looking to at better ways to arrive at pricing, but clarified that prostheses are still added to groups on the PL which were subject to the 25 per cent utilisation rule.[15]

Industry Working Group on Private Health Insurance Prostheses Reform

2.16 The Industry Working Group on Private Health Insurance Prostheses Reform (IWG) is the most recent body to consider reform of the PL. The IWG operated between January and March 2016 and was established to examine opportunities for reform of the arrangements governing prostheses and pricing in the private health insurance sector.[16]

2.17 The IWG's report was the impetus for the Government's decision in October 2016 to reduce the minimum benefit amount for cardiac devices and intraocular lenses by 10 per cent, and reduce hip and knee replacement joints by 7.5 per cent. These reforms came into effect on 20 February 2017.[17]

2.18 At the same time the Government also announced the reconstituted PLAC, investigating a more robust and transparent price disclosure model and considering a transparent way to reimburse hospitals for the costs of maintaining inventory of medical devices.[18] The IWG's final report and its recommendations will be discussed further in Chapter 3.

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11 Department of Health, *Submission 38,* p. 10.

12 Department of Health, *Submission 38,* p. 10.

13 hirmaa, *Submission 12*, pp. 2-3, 5.

14 See, for example: Applied Medical, *Submission 41*; Private Healthcare Australia, *Submission 7*.

15 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard,* 16 March 2017, p. 62.

16 Department of Health, *Submission 38,* Attachment A.

17 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

18 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

Effect of the Prostheses List Framework

2.19 The PL has been described as being left on 'set and forget mode' with almost half of all items on the list priced at the same benefit level in 2016 as they were in 2011.[19]

2.20 In any other market this would indicate that prices have not risen with inflation and were therefore below what they should be. In fact prostheses prices have not risen in real terms in the past seven years.[20] However, some submitters argued that prices were initially set artificially high and this cost is being passed on to consumers.[21]

2.21 An area of key concern is that '[t]he high price of prostheses impacts on health insurance premiums, and therefore contributes to concerns about the affordability of private health insurance.'[22]

Private health insurance premiums

2.22 Private Healthcare Australia (PHA) submitted that price sensitivity modelling indicates that private health insurance premiums will become unaffordable for at least one-fifth of current customers in five to six years.[23]

2.23 Already private health insurers are reporting that their members are decreasing their level of cover in an effort to reduce the premium paid.[24] New private health insurance customers are also choosing to take out less comprehensive policies with a higher excess amount in order to pay a lower premium. For example, HBF noted that '[i]n 2010, 32% of people taking out hospital cover with HBF chose "top hospital" or the equivalent but by 2016 this had fallen to just 13%.'[25] In 2013-14, 69 per cent of HBF hospital cover policies had zero excess but this declined to 54 per cent in 2015-16.

2.24 The committee heard that in the quarter ending September 2016, 14 per cent of private health insurers' hospital cover reimbursements were for prostheses. Medical benefits consisted of 16 per cent, whereas private hospital costs such as accommodation, theatre fees and nursing care accounted for 70 per cent of total reimbursements paid.[26] The Medical Technology Association of Australia (MTAA) therefore considered that a review of private hospital costs was more likely to result in

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19 Private Healthcare Australia, *Submission 7*, [p. 8].

20 Mr Gavin Fox-Smith, Managing Director, Johnson & Johnson Medical Devices ANZ, *Committee Hansard*, 15 March 2017, p. 10.

21 See, for example: Private Healthcare Australia, *Submission 7*; [pp. 6-7]; Bupa, *Submission 31*, pp. 6-7; Applied Medical, *Submission 41*, Attachment 1, pp. 4-5.

22 Bupa, *Submission 31*, p. 6.

23 Private Healthcare Australia, *Submission 7*, p. [3].

24 HBF, *Submission 27*, [p. 3]; See also, Australian Medical Association, *Submission 40*, p. 1.

25 HBF, *Submission 27*, [p. 3].

26 MTAA, *Submission 2*, p. 12.

substantial savings, rather than reforming or decreasing the minimum benefit amounts of the PL.[27]

2.25 Device manufacturers also noted that private health insurance premiums have increased by 40 per cent in the past seven years in contrast to PL benefits which have not increased in real terms over the same period.[28] Mr Fox-Smith of Johnson & Johnson Medical Devices ANZ pointed to an increase in utilisation of private health care in Australia as contributing to an increase in costs for private health insurers rather than the price of prostheses.

2.26 This view was supported by information provided by HBF. In their submission, HBF stated that in 2014 an average of 3.3 prostheses were used per procedure and that this number has increased to 3.6 prostheses per procedure in 2016. HBF attributed the increase in utilisation to changing technique, industry behaviour and the addition of new devices to the PL.[29]

2.27 Medibank Private also noted that since 2011 the number of hospital admissions per customer has increased by 19 per cent and the average amount paid by Medibank Private per admission has increased 10 per cent.[30]

2.28 It is estimated that the PL reforms announced in October 2016 will reduce costs for private health insurers by $86 million in the first year.[31] Medibank Private advised that this would result in a reduction of between $22 million and $24 million for their company and a 0.35 per cent reduction in fees for their customers.[32] Both Medibank Private and Bupa, Australia's largest private health insurers, have provided assurances that any savings will be directly passed on to customers through lower premiums.[33]

2.29 While hospital admissions and utilisation of prostheses has increased in recent years, the evidence heard by the committee does suggest there is a direct relationship between PL minimum benefit amounts and private health insurance premiums.

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27 MTAA, *Submission 2*, p. 3.

28 Mr Gavin Fox-Smith, Managing Director, Johnson & Johnson Medical Devices ANZ, *Committee Hansard*, 15 March 2017, p. 10.

29 HBF, *Submission 27*, [p. 4].

30 Medibank Private, *Submission 14*, p. 3.

31 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

32 Mr Craig Drummond, Chief Executive Officer, Medibank Private, *Committee Hansard*, 31 March 2017, p. 2.

33 Medibank Private, *Submission 14*, p. 4; Bupa, *Submission 31*, p. 3.

Price differences

2.30 A number of submitters described the price of prostheses in the private hospital system as 'inflated' or 'high', particularly in comparison to the prices paid by public hospitals for the same device.[34]

2.31 This view is supported by a 2009 Productivity Commission report on the performance of public and private hospital systems which suggested that 'the cost of prostheses in public hospitals is considerably lower than in private hospitals.'[35]

2.32 The Independent Hospital Pricing Authority (IHPA), an independent agency established under the *National Health Reform Act 2011* to contribute to reforms to Australian public hospitals, provided data to the committee on the number of episodes and cost of prostheses for intraocular lenses, cardiac, hip, knee and spinal prostheses. The tables below provide data for public hospitals in 2014-15 and for private hospitals in 2013-14. The IHPA urges caution in comparing the data given it was collected for different years, and was collected using different standards and different collection methods.

Table 2.1: Number of episodes and cost of prostheses provided to public hospital patients in 2014-15

Description	Episodes	Average Prosthesis Cost
Lens Procedures	59,087	$282
Implantation and Replacement of Implantable Cardioverter-Defibrillator, Total System	2,465	$18,923
Implantation and Replacement of Pacemaker, Total System	5,988	$4,776
Insertion and Replacement of Pacemaker Generator	1,433	$4,324
Hip Replacement	14,374	$6,299
Knee Replacement	13,442	$6,788
Other Hip and Femur Procedures	11,623	$1,604
Spinal Fusion	2,502	$10,963

Source: Independent Hospital Pricing Authority, *Submission 37*, [p. 2.]

34 Private Healthcare Australia, *Submission 7*; [pp. 6-7]; Bupa, *Submission 31*, pp. 6-7; Applied Medical, *Submission 41*, Attachment 3, p. 3; Department of Health, *Submission* 38, Attachment E, Industry Working Group on Private Health Insurance Prostheses Reform - Final report, p. 7.

35 Productivity Commission, *Performance of Public and Private Hospital Systems Research Report*, 10 December 2009, http://www.pc.gov.au/inquiries/completed/hospitals/report (accessed 1 May 2017).

Table 2.2: Number of episodes and cost of prostheses in private hospitals 2013-14

Description (Adjacent DRG)	Episodes	Average Prosthesis Cost ($)
Lens Procedures	26,042	556
Implantation or Replacement of AICD, Total System	1,709	46,877
Implantation or Replacement of Pacemaker, Total System	4,645	12,014
Insertion or Replacement of Pacemaker Generator	1,402	10,797
Hip Replacement	12,982	9,626
Knee Replacement	17,766	7,496
Other Hip and Femur Procedures	2,864	2,210
Spinal Fusion	6,797	12,554

Source: Independent Hospital Pricing Authority, answers to questions on notice, 15 March 2017, (received 3 April 2017).

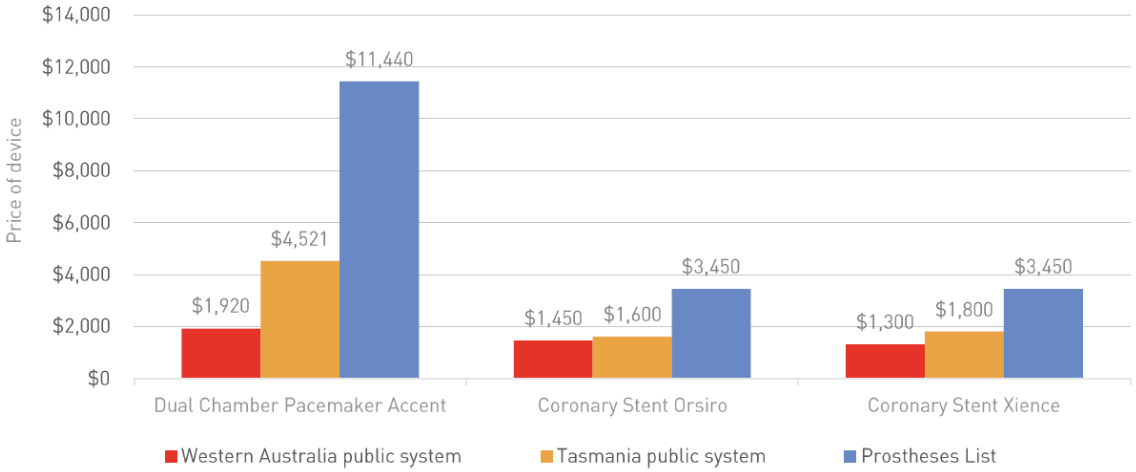
2.33 In its submission, Bupa cited the following examples which demonstrated the price difference between private and public hospitals:

- a standard branded ceramic hip is purchased by the Prince of Wales Public Hospital in Sydney for $4,900 while a private patient in the hospital next door pays $11,000;
- an uncemented Zimmer Trilogy cup cost Western Australia Health $1939, which is just under $1000 less than the listed benefit on the Australian Prostheses List of $2,900;
- an implantable cardiac defibrillator cost Western Australia Health $19,000 while the current listed benefit on the Prostheses List is $52,000 - $33,000 more expensive.[36]

2.34 Medibank Private also provided examples of prostheses which it had funded at the PL minimum benefit amount and the price paid for the same device in the Western Australian and Tasmanian public health systems. Figure 2.1 below demonstrates the price difference paid.

36 Bupa, *Submission 31*, pp. 6-7 (footnotes omitted).

Figure 2.1: Examples of differences in pricing between the Prostheses List Minimum Benefit amount and public sector pricing



Source: Medibank Private, *Submission 14*, p. 5.

2.35 Medibank Private submitted that in the 2015 calendar year it had funded the Dual Chamber Pacemaker Accent 328 times and paid up to $3.12 million more for the same device compared to a Western Australian public hospital.

2.36 Price information released by WA Health for cardiac, ophthalmic and orthopaedic prostheses showed that on average, public hospitals in Western Australia pay approximately 45% less than the price set by the PL.[37] This is consistent with the Doyle Review which found that 'some sponsors were willing to provide prostheses to public hospitals at 30 to 40 per cent less than the PL minimum benefit.'[38]

2.37 Similarly, submitters noted that Australian private patients pay significantly more for the same device compared to international markets. For example:

- A Consulta CRT-P model C3TR01 triple-chamber pacemaker costs €4000 in France (approximately $5 840 AUD) compared to $13 520 on the PL.[39]
- A St Jude Medical pacemaker costs £16 448 (approximately $27 000 AUD) in the United Kingdom compared to $52 000 on the PL.[40]

37 HBF, *Submission 27*, [p. 2].

38 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, p. 94 https://www.health.gov.au/internet/main/publishing.nsf/Content/AF68234CE9EB8A78CA257BF00018CBEB/$File/hta-review-report.pdf (accessed 3 May 2017).

39 Private Healthcare Australia, *Costing an arm and a leg*, October 2015, p. 6, http://www.privatehealthcareaustralia.org.au/wp-content/uploads/PHA-Report-Costing-an-arm-and-a-leg-Oct-2015.pdf (accessed 1 May 2017).

40 Bupa, *Submission 31*, p. 8.

2.38 Private health insurance companies submitted that these price differences are contributing to the rising cost of private health insurance premiums.[41] However, the MTAA who represents prostheses manufacturers disagrees with this view and noted that since December 2009 medical device inflation has increased by only 2.3 per cent, compared to medical and hospital services which have increased by 55.1 per cent in the same period.[42]

Committee view

2.39 The committee recognises that in many instances the minimum benefit amount of a prosthesis listed on the PL and paid by private health insurers is significantly greater than the price paid by public hospitals for the same device and internationally.

2.40 The committee notes that the cost of prostheses is one aspect which influences the cost of private health insurance premiums, however, utilisations rates are also a factor. The committee is concerned that the rising cost of private health insurance premiums may make health insurance unaffordable in the future and therefore place greater pressure on the public health system.

2.41 The committee notes there is a wide range of views on the reasons for the price difference between public and private patients and overseas markets and that there is little consensus between stakeholders as to how this may be addressed. This will be explored further in Chapter 4.

Relationships between stakeholders

2.42 The framework within which benefits for prostheses paid for through private health insurance are set is complex, opaque and involves multiple stakeholders. Privately insured patients in public or private hospital settings are provided with prostheses that are:

- chosen by their surgeon or other relevant specialist;
- purchased by the hospital in which they are being treated; and
- paid for by a private health insurer at benefit levels recommended by a committee appointed by the Minister for Health.

2.43 The majority of benefit levels were set some years ago in an opaque process when prostheses prices had inflated substantially over a short period of time and seem, at least in some cases, to have been set at levels far in excess of what is paid in the public sector domestically or in comparable countries internationally.

2.44 At the heart of this inquiry are the consumers, affected by rising private health insurance premiums, and taxpayers, who subsidise a significant proportion of private health insurance premium payments.

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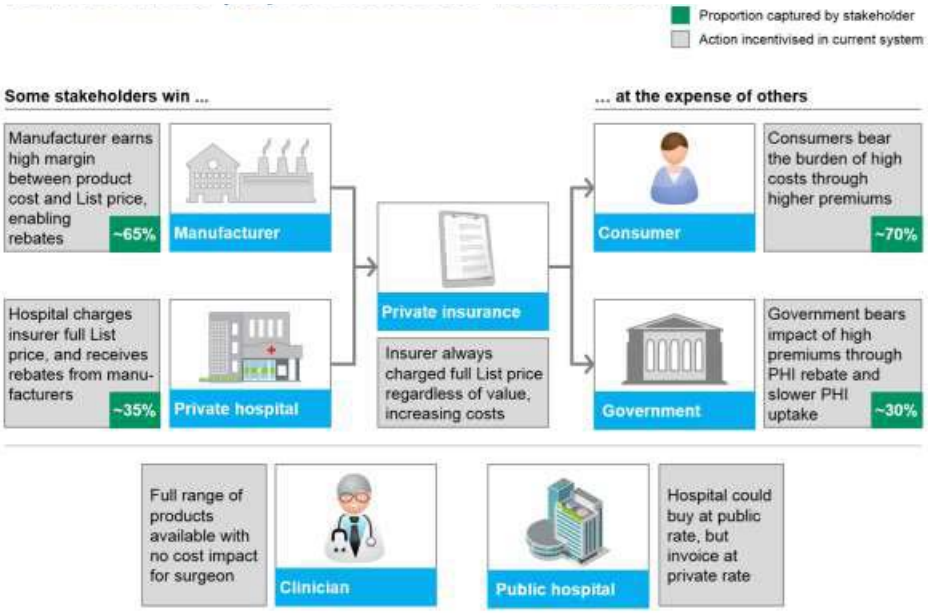
41 See, for example: Private Healthcare Australia, *Submission* 7; Medibank Private, *Submission 14*; BIB, *Submission 16*; HBF, *Submission 27*; HCF, *Submission 28*; Bupa, *Submission 31*.

42 Mr Ian Burgess, Chief Executive Officer, Medical Technology Association of Australia, *Committee Hansard*, 15 March 2017, p. 1.

2.45 The committee heard that the relationships between stakeholders with a vested interest in the PL are not transparent and siloed which means each stakeholder has a limited understanding of the practices of other stakeholders and their relationships with each other. Figure 2.2 below outlines the interaction of stakeholders in the operation of the PL.

Figure 2.2: Prostheses value chain



Source: Private Healthcare Australia, *Submission 7*, [p. 15].

Private hospitals and doctors

2.46 The MTAA submitted that the PL enables patients in private hospitals to access a greater range of prostheses and more complex technologies than public patients as a patient's surgeon is able to choose the prostheses which best meets their patient's circumstances.[43]

2.47 A surgeon simply advises the hospital of the prostheses required and the private hospital will acquire the prosthesis requested.[44] While some submitters raised concerns that this freedom of choice may lead to perceived conflicts of interest, the Australian Orthopaedic Association (AOA) told the committee that they recommend any surgeon 'involved in the manufacture, promotion or study of a device or is on a recommendation board'[45] disclose this information to their patient if they are using that prosthesis.

43 Medical Technology Association Australia (MTAA), *Submission 2*, p. 7.

44 Mr Michael Roff, Chief Executive Officer, Australian Private Hospital Association, *Committee Hansard*, 16 March 2017, p. 35.

45 Dr Peter Lewis, Deputy Director, Australian Orthopaedic Association, *Committee Hansard*, 16 March 2017, p. 53.

2.48 The AOA Code of Conduct also states that members 'must declare any conflicts of interest, in particular, financial relationships with prosthetic companies or hospitals and other corporate entities or persons.'[46] However, as there is limited development of prostheses in Australia it is unlikely for a need for disclosure to arise.[47]

2.49 It is also important to note that surgeons do not work for the hospital in the same sense that doctors in the public sector work for a public hospital.

Manufacturers and private hospitals

2.50 The committee repeatedly heard that information around the price of prostheses paid by private hospitals to manufacturers was not available due to the commercial-in-confidence nature of the contracts between private hospitals and manufacturers regarding the purchasing of prostheses and other medical devices.[48]

2.51 A representative of Catholic Health Australia told the committee that '[t]he commercial arrangements between vendors and hospitals are complex, opaque and vary in their structure.'[49]

2.52 A further issue is the value of rebates which private hospitals receive for purchasing a number of medical devices from one manufacturer. An orthopaedic surgeon told the committee that at the hospital they performed procedures in, these rebates were referred to as Stryker dollars, Zimmer dollars and J&J dollars, and that these could be used to purchase other consumable products from the manufacturers.[50]

2.53 The Australian Private Hospital Association explained how the rebates operate:

> Those who are a bit larger and in a stronger negotiating position have arrangements, I am advised, that are typically on two bases. There is a volume basis. So, if you hit a particular target for a whole-of-business spend, for example, you spend X million dollars or X hundred million dollars a year—and that is not necessarily just on prostheses but also on

46 Australian Orthopaedic Association Code of Conduct for Members 2010, p. 8, https://www.aoa.org.au/docs/default-source/ecm-files/codeofconduct2010_240910_pdf.pdf?sfvrsn=2 (accessed 1 May 2017).

47 Dr Peter Lewis, Deputy Director, Australian Orthopaedic Association, *Committee Hansard*, 16 March 2017, p. 52.

48 Biotronik Australia Pty Ltd, *Submission 22.1*, [p. 2]; Australian Medical Association, *Submission 40*, p. 3; Mr Maurice Ben-Mayor, Managing Director, Stryker Australia, *Committee Hansard*, 15 March 2017, pp. 16-17; Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 30; Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 70; Mr Michael Craig Sammells, Chief Financial Officer, Healthscope Ltd, *Committee Hansard*, 31 March 2017, p. 7.

49 Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 30.

50 Name withheld, *Submission 34*, [p. 3].

> consumables, theatre equipment or whatever that particular company supplies—then a rebate regime will kick in.[51]

2.54 This practice nets Ramsay Health Care, Australia's largest private hospital company, rebates of between five and seven per cent of the $700 million Ramsay spent on 650 000 individual prostheses last financial year, equating to between $35 million and $40 million.[52]

2.55 PHA described the practice as 'price shielding' and suggested that the practice provides an incentive to choose devices on the PL with a higher minimum benefit amount to maximise the level of rebate paid, as private health insurers are required to pay the minimum benefit amount, regardless of the amount paid by the hospital for the device.[53]

2.56 Some submitters argued that one third of the price difference between prostheses in public and private hospitals goes to the private hospital and the remaining two thirds to the manufacturers of prostheses.[54] However the opaque and confidential nature of the contracts which contain these rebates means it is difficult to quantify this amount.

Private hospitals and private health insurers

2.57 Private health insurers are required to pay the minimum benefit amount listed on the PL for a prosthesis received by one of their customers.

2.58 Dr Andrew Wilson of Medibank Private described private health insurers as merely bill payers who have no visibility of the relationship between private hospitals and manufacturers.[55]

2.59 As outlined above, there is no transparency regarding the price actually paid by the private hospitals for a particular prosthesis compared to the amount paid by the private health insurer, as required by the PL.

2.60 Last financial year Medibank Private (including AHM) spent $540 million on prostheses devices as part of the total $5.1 billion spent on healthcare.[56] Excluding AHM, Medibank alone spent $485 million on prostheses in the 2015-16 financial

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51 Mr Michael Roff, Chief Executive Officer, Australian Private Hospital Association, *Committee Hansard*, 16 March 2017, pp. 34-35.

52 Mr Christopher Rex, Chief Executive Officer, Ramsay Health Care, *Committee Hansard*, 31 March 2017, pp. 13-14.

53 Private Healthcare Australia, *Submission 7*, [p. 9].

54 Applied Medical, *Submission 41*, Attachment A, pp. 6-7; Applied Medical, *Submission 41.1*, p. 18; Dr Rachel David, Chief Executive Officer, Private Healthcare Australia, *Committee Hansard*, 16 March 2017, p. 25.

55 Dr Andrew Wilson, Group Executive, Healthcare Strategy, Medibank Private, *Committee Hansard*, 31 March 2017, p. 4.

56 Medibank Private, *Submission 14*, p. 2.

year. This is in addition to $904 million for hospital benefits and $204 million on medical benefits associated with the cost of prostheses.[57]

Private health insurers and consumers

2.61 An advantage of the PL for consumers is that it offers certainty for consumers that any prostheses which they receive from the PL will be covered in full by their private health insurer.[58] However, private health insurers then pass the cost of prostheses onto their customers through the price of health insurance premiums. PHA estimated that this adds $150 per year to each private health insurance premium.[59]

2.62 Consumers are required to place a significant amount of trust in the information provided to them by their surgeon. The committee heard that consumers are often unaware of the costs or rebates associated with the device chosen for them by their surgeon.[60]

2.63 Applied Medical observed that consumers are the only advocates for lower prices in the current system. Only one of the twenty-one members of the PLAC represents consumers.[61] Consumers are at a further disadvantage as they are under resourced and are not commercial entities so do not have the required knowledge or influence to negotiate within a complex system.[62]

The role of government

2.64 The government is both the regulator of the PL as well as a purchaser/funder of medical devices in the public and private sectors. The government regulates private health insurance through a range of legislative instruments, including the *Private Health Insurance Act 2007* and, of particular interest to this inquiry, through the Private Health Insurance (Prostheses List) Rules.[63]

2.65 The government is also a significant purchaser or funder of medical devices through its support for veterans, administered by the Department of Veterans' Affairs (DVA). In 2015-16 DVA provided access to a range of health services for approximately 200 000 veterans, war widows and dependants. Expenditure for

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57 Mr Craig Drummond, Chief Executive Officer, Medibank Private, answers to questions on notice, 31 March 2017 (received 11 April 2017).

58 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 16 March 2017, p. 8.

59 Private Healthcare Australia, *Submission 7*, [p. 5].

60 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 16 March 2017, p. 8.

61 Department of Health, Prostheses List Advisory Committee, Committee Members, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-PLAC (accessed 4 May 2017).

62 Mr Nicolas Taylor, Regulatory Consultant, Applied Medical, *Committee Hansard*, 16 March 2017, p. 6.

63 Department of Health, *Submission 38*, p. 3.

hospital services over this period was $1.6 billion, with $853 million in the private sector and $743 million in the public sector.[64]

2.66 DVA private hospital contracts use the PL as the basis for funding medical devices for veterans. The table below shows DVA's expenditure on medical devices in private hospitals over five years to 2015-16.[65]

Table 2.3: DVA expenditure on medical devices in private hospitals

	2011-12	**2012-13**	**2013-14**	**2014-15**	**2015-16**
Expenditure	$110 473 079	$105 748 801	$107 026 717	$103 962 144	$101 284 452
Items	116 580	111 352	110 274	103 276	101 769
Average cost	$948	$950	$971	$1007	$995

Source: Department of Veterans' Affairs, *Submission 20*, p. 3.

2.67 DVA estimated that its public hospital expenditure for medical devices was $9.6 million in 2015-16. DVA stated the difference in funding between the two sectors can be attributed to a number of things, including 'the expected economies of scale that can be realised by the public hospital system through purchasing arrangements.'[66]

2.68 While the government regulates the PL, the Australian Medical Association (AMA) submitted that 'the current construct of the reimbursement system is currently swayed towards industry, ultimately at the expense of consumers and the Government.'[67]

2.69 The department is similarly segregated from other stakeholders stating that 'there are financial transactions going on between private hospitals, prosthesis makers and private health insurers which are, at some level, opaque to the public and the department.'[68] This is a concern as the government is a key stakeholder, as the regulator of the PL, yet does not have full visibility of the system and how it operates in practice.

64 Department of Veterans' Affairs, *Submission 20*, p. 2.

65 Department of Veterans' Affairs, *Submission 20*, p. 3.

66 Department of Veterans' Affairs, *Submission 20*, p. 3.

67 Australian Medical Association, *Submission 40*, p. 3.

68 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, pp. 69-70.

2.70 The complex nature of stakeholder relationships and the operation of the PL was reinforced by the department who noted that 'no-one has a complete understanding, and no-one has a complete dataset.'[69]

Committee view

2.71 The committee notes that through the operation of the PL, the relationships between stakeholders are complex and not transparent and has resulted in some stakeholders having limited interaction with each other.

2.72 The committee believes that the complex relationships and competing interest of stakeholders has made past reform challenging. The committee is concerned that the lack of transparency has reinforced the operation of the existing PL Framework and contributed to the slow rate of reform.

2.73 The committee notes the role of the government as a significant funder/purchaser of medical devices on the PL and considers that government could achieve significantly cheaper prices if it purchased devices directly.

Issues identified by submitters

2.74 Submitters raised a number of issues during the inquiry which have been the identified by previous reviews of the PL and the subject of past attempts at reform. These issues are outlined below and will be further discussed in Chapter 4.

Lack of transparency

2.75 In addition to concerns around the transparency of relationships between stakeholders as discussed above, the committee heard that many aspects of the PL lack transparency including the benefit setting process.

2.76 Mr Glenn Cross of AusBiotech Ltd noted that the '[c]urrent benefit setting processes are opaque.'[70] This view has been consistently expressed throughout reform of the PL. For example, hirmaa submitted that in 2005 when the PL was reregulated, '[t]he underlying basis upon which benefit amounts were negotiated and determined is unknown.'[71]

2.77 Concerns were also raised by the AMA that the scope and methods which PLAC used to set prostheses benefits was unclear. The AMA pointed out that 'under "commercial in confidence" protection, the PLAC does not have access to all commercial and industry data to make an assessment on appropriate prostheses pricing.'[72]

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69 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 69.

70 Mr Glenn Cross, Chief Executive Officer, AusBiotech Ltd, *Committee Hansard*, 16 March 2017, p. 41.

71 hirmaa, *Submission 12*, p. 2.

72 Australian Medical Association, *Submission 40*, p. 3.

2.78 The department suggested that further reform was necessary to achieve transparency commenting that 'in order to get greater transparency, we need to change arrangements.'[73]

Reducing duplication and redundancies

2.79 Submitters also identified areas of the PL Framework which should be reformed with a view to reducing duplication of processes between the PLAC and the TGA, for the PLAC to operate more efficiently and reduce the number of items included on the PL.

2.80 Ausbiotech observed that '[a] big opportunity for cost-saving is in reducing red tape and redundancy across the application and evaluation process of the prosthesis list.'[74] The MTAA shared this view and suggested that devices already approved by the TGA could be added to an existing group on the PL without review by the PLAC in order to improve the efficiency of the Health Technology Assessment process.[75]

2.81 However, the benefits of the clinical advisory groups in providing advice on safety and effectiveness were affirmed through, for example, detection of safety concerns in relation to the 'VAIOS' prosthesis.[76]

2.82 Bupa identified that reviewing the number of items on the PL and removing those which are not clinically effective or are rarely used would enhance the operation of the PLAC. Since 2008, 2,746 items from the current PL have never been used, accounting for 26 per cent of items on the list.[77]

2.83 Minimising duplication and improving the listing process forms part of the PLAC's work program following the final report of the IWG.[78] The PLAC's work plan also includes undertaking a number of targeted category and benefit reviews such as low cost high volume items which could be rationalised.[79]

International price benchmarking

2.84 As discussed earlier in this chapter, private health insurers identified a significant difference between the price paid by Australian consumers compared to

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73 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 70.

74 Mr Glenn Cross, Chief Executive Officer, AusBiotech Ltd, *Committee Hansard*, 16 March 2017, p. 41.

75 MTAA, *Submission 2*, p. 5.

76 For information in relation to the VAIOS case, see: *Orthotech Pty Ltd v Minister for Health* [2013] FCA 230, http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2013/2013fca0230 (accessed 11 May 2017).

77 Bupa, *Submission 31*, p. 10.

78 Department of Health, *Submission 38*, Attachment F.

79 Department of Health, answers to written questions on notice (received 26 April 2017).

international markets. A number of submitters suggested that reform to the PL should include international price benchmarking.[80] However, a number of device manufacturers cautioned against this approach:

> …we find that comparing prices in Australia's private and public healthcare systems or benchmarking to international healthcare systems is an incredibly simplistic notion—one which demonstrates no understanding of the reality or the complexity of the environment or why it is unworkable to directly compare without taking into consideration other factors.[81]

2.85 Medtronic agreed that an effective international price benchmarking system would be difficult to establish stating that:

> An international referencing system would be extremely complex and fail to consider the varying factors impacting supply and purchase of medical devices in the Australian healthcare system:
>
> - It does not take into account differences in healthcare market structures, local costs of doing business, market size, economies of scale, service provision and delivery models, currency volatility;
> - Many types of products – not just medical devices – exhibit a range of price variation for a range of reasons both within and between countries for the same product; and,
> - To our knowledge, no other Government price disclosure process, including for the PBS, uses international referencing.[82]

Potential savings

2.86 PHA reported that a 45 per cent decrease in the private prostheses expenditure would amount to approximately $800 million in savings.[83] However, this figure is disputed by a number of stakeholders on the grounds that it was based on flawed methodology and data.[84]

2.87 For example, the MTAA argued that the calculation was made on a very small sample of only 41 of the approximately 10 400 devices of the PL. These devices were also from a narrow range of categories on the PL and were devices that were more likely to included additional services and ancillary support.[85]

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80 Private Healthcare Australia, *Submission 7*, p. 10; Bupa, *Submission 31*, p. 3.

81 Mr Glenn Cross, Chief Executive Officer, AusBiotech Ltd, *Committee Hansard*, 16 March 2017, p. 41.

82 Medtronic, *Submission 36*, p. 15.

83 Private Healthcare Australia, *Costing an arm and a leg*, October 2015, p. 6, http://www.privatehealthcareaustralia.org.au/wp-content/uploads/PHA-Report-Costing-an-arm-and-a-leg-Oct-2015.pdf (accessed 1 May 2017).

84 Mr Ian Burgess, Chief Executive Officer, Medical Technology Association of Australia, *Committee Hansard*, 15 March 2017, p. 2.

85 Mr Ian Burgess, Chief Executive Officer, Medical Technology Association of Australia, *Committee Hansard*, 15 March 2017, p. 2.

2.88 The department was also unable to verify the accuracy of the $800 million savings figure .[86]

Committee view

2.89 The committee acknowledges the concerns of stakeholders regarding the veracity of the $800 million in potential savings from reforming the PL. However, the committee believes that there is significant scope for reform and savings in this area.

2.90 The committee notes that stakeholders identified a number areas in the PL Framework which would benefit from reform. The committee considers the lack of transparency in the PL framework to be a barrier to further reform and consideration of alternative models such as price benchmarking an reducing redundancies.

86 Mr Martin Bowles PSM, Secretary, and Mr Andrew Stuart, Deputy Secretary, Health Benefits Group, Department of Health, *Committee Hansard*, 19 October 2016, pp. 97-98; Mr Andrew Stuart, Deputy Secretary, Health Benefits Group, Department of Health, *Committee Hansard*, 16 March 2017, p. 69.

Chapter 3

Prostheses List reforms

> …the differing benefit setting arrangements for prostheses between the public and private hospitals sectors result in private health insurers having to reimburse prostheses at much higher levels in the private hospital sector where clinicians are not required or encouraged to consider cost effectiveness. While some differences reflect the level of training and product support between public and private hospitals, benchmarking indicates variation that exceeds this justification.[1]

3.1 The previous chapters have outlined the Prostheses List (PL) framework, and the history behind the current issues that this inquiry seeks to address.

3.2 This chapter will examine the review of the PL framework undertaken in 2016 and the reforms announced by the government.

3.3 Chapter 4 will canvas the issues raised in relation to the review and reforms that have been undertaken and those that are proposed to be undertaken.

3.4 The key issues which arise again and again in relation to prostheses pricing and the administration of the system are the lack of transparency in how decisions are made, and limited integration between health technology assessment (HTA) systems and processes. These issues persist despite a number of reviews, over an extensive period which have recommended greater transparency and better coordination and integration of HTA systems.

Industry Working Group on Private Health Insurance Prostheses Reform

3.5 The government established the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) to assess the current PL system, in the context of a broader review of private health insurance regulation.[2]

3.6 The IWG, chaired by Emeritus Professor Lloyd Sansom AO,[3] was established by the Department of Health (department) in February 2016 and included representatives from the medical devices industry, private for-profit and not-for-profit

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1 Senate Community Affairs References Committee, *Inquiry into The Regulatory Standards for the Approval of Medical Devices*, November 2011, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/medicaldevices/report/index (accessed 28 April 2017), p. 91.

2 Department of Health, *Submission 38*, Attachment E.

3 Emeritus Professor Lloyd Sansom AO was also previously part of a panel of three independent experts who undertook a broader review of health technology regulation in 2015, the Expert Review of Medicines and Medical Devices (MMDR). For further information on the MMDR go to *Expert Review of Medicines and Medical Devices*, http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation (accessed 11 April 2017).

hospitals, consumers, private health insurers, the medical profession and the Department of Health.[4]

3.7 The IWG review was tasked with assessing the current prostheses benefit setting system, including the Prostheses List Advisory Committee (PLAC) and its subcommittees, and advising the department on:

- creating a more competitive basis for purchase and reimbursement of prostheses and devices, including consideration of options for new pricing mechanisms;
- specific products or categories which present opportunities for immediate benefit rationalisation;
- refining the scope of products currently listed on the Prostheses List without adversely impacting on consumer access; and
- opportunities for deregulation.[5]

3.8 The report of the IWG was provided to the department in March 2016 and to the Minister for Health in April 2016.[6] In its report, the IWG indicated that it had reached agreement on a number of points, including that:

- a PL should be maintained;
- the PLAC and its advisory committee arrangements be revised;
- government should consider opportunities for enhanced co-operation between the PLAC and the Therapeutic Goods Administration (TGA);
- appropriate costs for inclusion should be considered when setting benefit levels;
- consideration should be given to legislating a price disclosure system, including public and private prostheses pricing;
- reference pricing be considered as an option for setting PL benefit levels, with appropriate domestic and international price benchmarks;
- consideration be given to amending the PL criteria;
- development of new PL guidelines; and
- if the government wished to make immediate benefit reductions, then benefits on the PL for cardiac, intra-ocular lens systems, hips and knees should be considered.[7]

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4 Department of Health, *Submission 38*, Attachment E, p. 3.

5 Department of Health, *Submission 38*, Attachment E, p. 1.

6 Department of Health, *Submission 38*, p. 11.

7 *Industry Working Group on Private Health Insurance Prostheses Reform Final Report*, http://www.health.gov.au/internet/main/publishing.nsf/content/iwg-phi-pros-ref (accessed 20 April 2017), pp. 1-2.

Government response to the IWG report

3.9 In the 2016–17 Budget the government committed to reconstitute the PLAC to further develop and advise on implementing changes to PL arrangements recommended by the IWG,[8] and, upon the public release of the IWG's report in October 2016, the Minister for Health announced that the government's prostheses reforms would include:

- reducing 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 20 February 2017;
- reconstituting the new Prostheses List Advisory Committee (PLAC) that will develop, consult and advise the Government on further changes to the prostheses listing arrangements;
- investigating a move towards applying a more robust and transparent price disclosure model of ongoing, sustainable reductions to the cost of medical devices through the new PLAC;
- faster access to new innovative medical device technologies through improved listing processes without compromising safety; and
- considering a transparent way to reimburse hospitals for the costs of maintaining inventory of medical devices so that they are on hand when needed.[9]

3.10 On 4 May 2017, the Minister for Health announced that the PLAC will commence targeted reviews of hip, knee, cardiac and spinal prostheses groups, following release of a draft Approach for Targeted Prostheses Reviews.[10]

Reforms already implemented

3.11 Of the reforms announced by the Minister for Health in 2016, two have been implemented to date – reductions in the benefit levels for certain types of prostheses and changes to the PLAC.

Reducing the cost of cardiac, intra-ocular, hip and knee prostheses

3.12 As mentioned above, in October 2016 the Minister for Health announced that there would be a reduction in certain benefit levels for some groups of devices on the PL. Specifically, there would be a 10 per cent reduction in the benefit level for cardiac devices and intra-ocular lenses and a 7.5 per cent reduction for hip and knee

8 Department of Health, *Submission 38*, p. 12.

9 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums,' *Media release*, 19 October 2016 (accessed 10 April 2017).

10 The Hon Greg Hunt MP, Minister for Health, 'Prostheses reforms to deliver better value for private health insurance,' *Media release*, 4 May 2017 (accessed 4 May 2017).

replacements. The reduced benefit levels would come into effect from 20 February 2017, with an estimated saving of $500 million over 6 years.[11]

3.13 The government intends that these savings will be passed on to consumers through lower increases in annual private health insurance premiums. The department confirmed that the savings had already been factored into the premium increases effective from 1 April 2017:

> As part of the process of submitting their application to the minister via APRA they [private health insurers] had to declare that they had applied the prostheses savings and what the differences were.[12]

3.14 The Private Health Insurance (Prostheses) Amendment Rules 2016 (No. 4) were to come into effect on 20 February 2017 to revise the benefits of 2,439 cardiac, intra-ocular lens, hip and knee prostheses on Part A of the Private Health Insurance (Prostheses) Rules 2016 (No. 4).[13]

3.15 Prior to the commencement date, the department identified that details relating to some billing codes on the Prostheses List were incorrect and made the Private Health Insurance (Prostheses) Amendment Rules 2017 (No. 1) to address this issue.[14] The explanatory statement for the new rules noted that this most recent amendment was made to 'ensure that benefit reductions as listed in the 2016 Amendment Rules take effect and that these devices remain eligible for benefits from insurers.'[15]

3.16 The reductions to PL benefit levels for cardiac, intraocular lens, hip and knee devices were made following the IWG's report indicating that these areas could be considered for immediate benefit reduction. This was based on data obtained by the IWG and analysed by the Chair of the IWG and the department.

3.17 Data in relation to prostheses pricing in the Western Australian public hospital system and internationally was provided to the Chair of the IWG, who then wrote to medical device sponsors with items on the PL requesting information in relation to the

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11 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums,' *Media release*, 19 October 2016 (accessed 10 April 2017).

12 Ms Tracey Duffy, Assistant Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 64.

13 Available to view on the Federal Register of Legislation, https://www.legislation.gov.au/Details/F2017C00119 (accessed 18 April 2017).

14 Department of Health, *Prostheses List Benefit Reductions, Private Health Insurance (Prostheses) Amendment Rules 2016 (No. 4) and Private Health Insurance (Prostheses) Amendment Rules 2017 (No.1)*, http://www.health.gov.au/internet/main/publishing.nsf/content/prostheses-list-benefit-reductions (accessed 12 April 2017).

15 Explanatory Statement, *Private Health Insurance Act 2007*, Private Health Insurance (Prostheses) Amendment Rules 2017 (No. 1), https://www.legislation.gov.au/Details/F2017L00089/Explanatory%20Statement/Text (accessed 21 April 2017).

net revenue for items in the categories of cardiac, hips, knees and intra-ocular lenses for the year to 31 December 2015. Sponsors were asked to provide the total revenue and volume sold in both the public and private hospital sectors, as well as information in relation to the value of any incentives provided.[16]

3.18 In its report, the IWG noted that the Chair of the IWG wrote to 57 medical device sponsors, with only 20 responses received. Similarly, the Chair wrote to State and Territory governments seeking similar information, and four jurisdictions provided a response.[17]

3.19 In evidence to the committee, the department stated that in response to requests for information, the Chair of the IWG 'very often received a reply that the issues they were seeking were covered by confidentiality arrangements.'[18]The department also provided evidence that:

> The data was provided at an aggregate level and does not clarify the level, how or if incentives were provided – whether as discounts, rebates or other direct or indirect purchasing incentives.[19]

3.20 Despite this, the IWG stated that:

> the responses received clearly indicated that a price differential exists between public and private sectors. The IWG noted that the differential varies between and within categories.[20]

3.21 While the details about the size and scope of PL benefit reductions were made public, the precise method, and the data used, for calculating the benefit reductions was not. The committee notes the IWG's recommendation to the department in its report:

> The IWG noted that benefit reductions may have relatively larger financial impacts on smaller companies, and recommended that these impacts be taken into consideration before benefit reductions are finalised.[21]

3.22 In a supplementary submission to the inquiry, a group of four Australian owned small and medium enterprises (SMEs) who develop, manufacture and distribute medical devices, stated that:

> The recent 7.5% price cut to hips and knees on the Prostheses List has reduced Global Orthopaedic Technology's top line revenue by $2.4 million which has dropped straight to the bottom line. As a result, it has implemented a hiring freeze and placed a significant research and

16 Department of Health, *Submission 38,* Attachment E, pp. 17-18.

17 Department of Health, *Submission 38,* Attachment E, p. 8.

18 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 69.

19 Mr Andrew Stuart, Deputy Secretary, Department of Health, answers to written questions on notice, 13 April 2017, (received 26 April 2017).

20 Department of Health, *Submission 38,* Attachment E, p. 8.

21 Department of Health, *Submission 38,* Attachment E, p. 8.

> development project on hold. The spectre of more price cuts will further undermine confidence and lead to employee redundancies, not just threatening its ongoing commitment to innovation but the viability of the business.[22]

3.23 Other device sponsors have also been critical of the approach taken in this initial targeted review and reduction of prostheses benefits on the PL. For example, Biotronik Australia Pty Ltd commented that:

> An adhoc cut of 7.5- 10% to benefits on the PL based on only a shallow assessment of price structures by the IWG & DoH undertaken in isolation is poor governance as it creates market and more importantly patient care dislocation. This is especially so when the industry is put on notice that further reform will lead to further disruption.[23]

3.24 The medical device industry association suggested that the benefit reductions were not based on evidence 'and arose due to pressure from private insurers to make some savings.'[24] In their evidence before the committee, the Medical Technology Association of Australia (MTAA), which was represented on the IWG and is also represented on the PLAC, indicated that these first cuts 'pre-dated the reformed and amended terms of reference of the PLAC which allows it to consider reforms to the Prostheses List (PL)'[25] and that:

> Essentially, while the department had requested companies provide information around the pricing of products and services that were being provided and discounting or whatever, the information the department got was that they were not able to draw definitive conclusions about what was really happening in the marketplace, and that really reflects the level of complexity that needs to be understood around the supply chain issues… One of the things around the price cuts was that there was absolutely no evidence, or no tangible evidence, on which the department would have provided advice to the minister as to the size of the PL benefit adjustments that should occur.[26]

3.25 It is important to note that not all stakeholders were critical of the first round of targeted cuts that came into effect in February 2017. Private health insurers have welcomed the changes to the PL:

> We estimated the government's recent price reductions would realise approximately $24 million in savings to our customers, and we have fully

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22 Joint submission from four Australian medical device manufacturers and distributors, *Submission 39.1*, [p. 5].

23 Biotronik Australia Pty Ltd, *Submission 22*, p.5.

24 Medical Technology Association of Australia, answers to questions on notice, 15 March 2017, received 29 March 2017, p. 1.

25 Medical Technology Association of Australia, answers to questions on notice, 15 March 2017, received 29 March 2017, p. 1.

26 Ms Andrea Kunca, Director of Access, Policy, Procurement and Innovation, Medical Technology Association of Australia, *Committee Hansard*, 15 March 2017, p. 5.

> passed on those savings. Our 2017 premium increase is 35 basis points lower than it otherwise would have been because of the government's recent reductions to some prostheses prices. Prostheses reforms are, in other words, delivering material benefits to consumers by helping to keep downward pressure on private health insurance premiums.[27]

3.26 The committee notes that, following the reductions in benefit levels for some groups on the PL, the Minister for Health wrote to the Chair of the Independent Hospital Pricing Authority (IHPA) requesting a report regarding:

- average public sector prosthesis costs (by Diagnosis Related Group (DRG));
- average public sector private insurance payments for prosthesis (by DRG);
- average private sector prosthesis costs by DRG;
- an assessment of the validity and reliability of the average costs, including identifying data limitations; and
- proposals to increase the robustness of the private collection if it were to be used for price setting (compel private hospitals to participate, independent review of submissions etc.).[28]

3.27 In his letter, the Minister stated that, 'We need a better balance between price and access for private patients,'[29] and that the information provided in the report:

> will provide the Prostheses List Advisory Committee and the Department of Health data to help inform areas for potential reductions in the costs of medical devices and deliver more savings to private health insurers.[30]

Committee view

3.28 The committee has heard that the PL benefit reductions to cardiac, intra-ocular lens, hip and knee prostheses, which came into effect on 20 February 2017, were based on a recommendation of the IWG which included stakeholders from across all relevant sectors.

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27 Mr Craig Drummond, Chief Executive Officer, Medibank Private, *Committee Hansard*, 31 March 2017, p. 2.

28 The Hon Greg Hunt MP, Minister for Health, correspondence to Mr Shane Solomon, Chair, Independent Hospital Pricing Authority, provided by Mr Andrew Stuart, Deputy Secretary, Department of Health, answers to questions on notice, 16 March 2017, received 29 March 2017.

29 The Hon Greg Hunt MP, Minister for Health, correspondence to Mr Shane Solomon, Chair, Independent Hospital Pricing Authority, provided by Mr Andrew Stuart, Deputy Secretary, Department of Health, answers to questions on notice, 16 March 2017, received 29 March 2017.

30 The Hon Greg Hunt MP, Minister for Health, correspondence to Mr Shane Solomon, Chair, Independent Hospital Pricing Authority, provided by Mr Andrew Stuart, Deputy Secretary, Department of Health, answers to questions on notice, 16 March 2017, received 29 March 2017.

3.29 The committee notes, however, that the decision by the Minister for Health to make the cuts and the size of the cuts, appears to have been made with limited access to sufficient data. The committee notes that the Minister has subsequently requested data and advice from the IHPA which will assist the Minister in making further changes to the PL.

3.30 The committee notes that the reforms undertaken to date have received both praise and criticism from stakeholders. Despite this, there is considerable support for ongoing reforms, and a willingness on the part of stakeholders to participate in the improvement of the PL framework.

Reconstituted Prostheses List Advisory Committee

3.31 The other key PL reform undertaken to date is the re-constitution of the PLAC. The new PLAC was announced in October 2016, and is comprised of an independent Chair, Professor Terry Campbell, and individuals with expertise in health technology assessment, specialist surgery/interventional work, health economics and consumer issues, and representatives of stakeholders, including medical device sponsors, private hospitals and private health insurers. There are up to 21 members at any one time, including up to 12 expert members, and up to 8 advisory members. The list of current members of the PLAC is attached at Appendix 3.[31]

3.32 During evidence presented during the inquiry, the committee was informed by the department that the newly constituted PLAC has 'a much more non-aligned membership than it may have done in the past.'[32]

PLAC Terms of Reference

3.33 The terms of reference for the PLAC state that, in addition to its role in making recommendations to the Minister on applications to list medical devices on the PL and related matters, it will also:

- develop options for improving application and assessment processes as recommended by the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) to drive improved cost effectiveness of new and current medical devices;
- revise its governance structure including its sub-committees to ensure alignment with the purpose of the Committee and reform directions outlined by Government;
- make recommendations to the Minister on moving to a benefit setting mechanism that reflects real market dynamics for medical devices, such as price disclosure and/or reference to pricing in other markets; and

31 *Prostheses List Advisory Committee Operational Guidelines*, December 2016, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-plac (accessed 11 April 2017).

32 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 71.

- assist the department to advise the Minister on any other policy matters pertaining to the medical device listing arrangements.[33]

3.34 The PLAC is assisted in its consideration of PL applications by 11 sub-committees:

- nine Clinical Advisory Groups (CAGs);
- the Panel of Clinical Experts; and
- the Health Economics Sub Committee (HESC).

3.35 The committee has been informed that the department currently engages 12 FTE (full time equivalent) staff to support the work of the PLAC and its subcommittees.[34] It is not clear from the evidence provided to the committee if additional resources have been provided to the PLAC to undertake its reform work.

3.36 Funding of the administration of the PL is undertaken on a cost recovery basis through fees paid for by medical device sponsors to apply for, list and maintain listing on the PL.[35] The 2016–17 Budget did not provide additional resources for the reconstituted PLAC or the reform process, indicating that 'the costs of this component to be met from within existing resources of the Department of Health.'[36]

PLAC and administration of the PL

3.37 Some stakeholders expressed concern about the resourcing of administration of the PL, and the impact that this has had, and continues to have, on the ability of the PLAC to function as effectively as it might, particularly in relation to review and updating of the PL to remove devices that should no longer be on the list.[37]

3.38 In its submission, Biotronik Australia Pty Ltd was critical of the existing arrangements, in which it said the secretariat was insufficiently resourced and lacked corporate knowledge which has led to delays and errors in processing applications[38]

3.39 There have been concerns expressed that the administration of the current Prostheses List does not allow for timely reviews of medical devices on the list, to 'weed out' items that are outdated or do not perform:

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33 Department of Health, *Submission 38*, Attachment B, p. 1.

34 Mr Andrew Stuart, Deputy Secretary, Department of Health, answers to written questions on notice, 13 April 2017 (received 26 April 2017).

35 Department of Health, *Cost Recovery Implementation Statement: Administration of the Prostheses List 1 July to 30 June 2017*, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm (accessed 19 April 2017), p. 3.

36 Budget 2016–17, Part 2: Expense Measures, http://www.budget.gov.au/2016-17/content/bp2/html/bp2_expense-15.htm (accessed 28 April 2017).

37 Applied Medical, *Submission 41*; Private Healthcare Australia, *Submission 7*; Australian Medical Association, *Submission 40*.

38 Biotronik Australia Pty Ltd, *Submission 22*, p. 7.

> the department has its heart in the right place but the problem is it is under resourced to deal with a list of 10,000.[39]

3.40 The committee notes the concerns expressed by some stakeholders in relation to the resourcing of the PLAC and other administration of the PL. The committee also notes the length of time taken for earlier reforms, for example those arising from the 2009 Health Technology Assessment (HTA) review, to be implemented.[40]

3.41 In its Cost Recovery Implementation Statement for 1 July 2016 to 30 June 2017, the department states that the costs of administering the Prostheses List are recovered from medical device sponsors through the payment of application fees to list new prostheses, a fee to list each new prosthesis and a periodic fee to maintain listing on the Prostheses List. These fees are set by the Private Health Insurance (Prostheses Application and Listing Fee) Act 2007 and associated rules.

3.42 The department notes that since January 2009, the fees have been:

- $600 to apply to list a new prosthesis
- $$200 to initially list a new prosthesis; and
- $200 each six months to maintain a listing.[41]

3.43 It does not appear that a review of fees has been undertaken since 2009.

3.44 The committee also notes that the key performance indicator for PL activity is the percentage of PL applications completed within 22 weeks of the date of application.[42] There appear to be no performance indicators for review of the PL, nor for other activities, including the proposed activities in the PLAC Reform Work Plan (work plan).

Committee view

3.45 The committee welcomes the government's intention to maintain continuity of operations of the PLAC whilst driving reforms of the PL. The reforms that have been made to date are a start to a process of reform that needs to continue and an excellent opportunity to review the best way to achieve longer term goals of the reform process.

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39 Mr Nicolas Taylor, Applied Medical, *Committee Hansard*, 16 March 2017, pp. 5-6.

40 Department of Health, *Cost Recovery Implementation Statement: Administration of the Prostheses List, 1 July 2016 – 30 June 2017*, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslist.htm (accessed 20 April 2017), p. 3.

41 Department of Health, *Cost Recovery Implementation Statement: Administration of the Prostheses List 1 July to 30 June 2017*, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm (accessed 19 April 2017), p. 3.

42 Department of Health, *Cost Recovery Implementation Statement: Administration of the Prostheses List, 1 July 2016 – 30 June 2017*, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslist.htm (accessed 20 April 2017), p. 8.

3.46 The committee notes the concerns raised by some stakeholders about the limited resources available to the PLAC to better support administration of the ever increasing PL itself, in addition to undertaking significant and fundamental reforms to the benefit setting regime.

3.47 It is also important to note that there are very complex interrelationships involved in the provision of prostheses through private health insurance, and a very real need to avoid cost-shifting to the public sector or significant adverse impacts on the various sectors involved. Achieving the balance between price and access for private patients that the Minister for Health desires, without causing significant disruption and unintended consequences in other areas, may require additional support to ensure appropriate consideration of all issues and consultation.

PLAC Reform Work Plan

3.48 The PLAC issued a work plan in late 2016, which sets out proposed activities to be undertaken by the PLAC to address the following issues:

- targeted PL benefit and category reviews;
- longer term PL benefits setting framework;
- review the criteria for listing on the PL; and
- minimise duplication and improve the process for listing on the PL.[43]

3.49 Key proposed activities in the work plan include:

- development of a framework to guide targeted reviews of benefits and categories;
- research, consultation and development of a benefit setting model;
- review and amend definitions and criteria for listing on the PL; and
- review the health technology assessment processes across the Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC) and PLAC to identify duplication, opportunities for data sharing, best use of clinical expertise and post market monitoring, and options for faster listing of devices.[44]

3.50 The PLAC pages on the department website provide updates on the work of the PLAC through communiques.[45] Five communiques were published between October 2016 and February 2017. A brief outline of progress on this work as set out in the communiques is outlined in the table below. Some further discussion in relation to specific issues and activities follows, where some progress has been made.

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43 Department of Health, *Submission 38*, p. 12.

44 Department of Health, *Submission 38*, Attachment F.

45 Department of Health, *Prostheses List Advisory Committee*, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-PLAC (accessed 20 April 2017).

Table 3.1: PLAC Reform Work Plan – progress on activities to February 2017[46]

Work Plan Issue for Consideration	**Progress on proposed Work Plan activities** (at 5 May 2017)
Targeted benefits and category review	Discussion on establishment of a formal structured mechanism to enable regular reviews of PL listings and benefits. Draft document 'Draft Proposed Approach for Targeted Prostheses Reviews' released for consultation.
Longer term benefits setting framework	Professor Philip Clarke, Centre for Health Policy, University of Melbourne, engaged to research pricing models for medical devices and develop potential options for a future benefit setting framework. Presentation on price disclosure in the government's subsidisation of pharmaceuticals. *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models* published.
Review the criteria for listing	Initial talks on potential options relating to how the assessment of critical consumable components, novel devices, appropriate suffixes and benefits could occur in the future.
Minimising duplication and improve the listing process	New committee, the Regulation and Reimbursement of Medical Devices group, established comprising the chairs of MSAC, PBAC and PLAC and department staff (TG and the Medical and Pharmaceutical Benefits Divisions). Group to explore collaboration between HTA bodies, information sharing, parallel processing, comparison of application processes and clinical evidence requirements.

Consultation on PL reforms

3.51 The PLAC communique of December 2016 indicates that the PLAC agreed to:

> convene stakeholder forums to enhance communication and broad engagement with stakeholders. These forums will provide opportunities for

46 The information in this table is derived from the five communiques published to date by the PLAC and a media release of 4 May 2017, the Hon Greg Hunt MP, Minister for Health, *Prostheses reforms to deliver better value for private health insurance*, http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt043.htm . The communiques are available at Department of Health, Prostheses List Advisory Committee, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-PLAC.

> input to the reform process and will be conducted in the second quarter of 2017, once progress has been made on the reform options.[47]

3.52 All stakeholders supported greater transparency from the department and the PLAC in decision making and operations of the PLAC.

Committee view

3.53 The committee notes that the work plan for the PLAC contains a list of proposed activities with proposed commencement times but does not provide any clear indication for those outside of the PLAC membership about what will indeed be occurring and within what timeframes.

3.54 Given the concerns raised across all stakeholder groups about ensuring both transparency and access to timely information in relation to proposed and actual PL reforms, the committee considers it appropriate for the PLAC to place greater emphasis on more clearly defining what activities will be undertaken, and setting some timeframes within which these activities will be completed. The committee considers it a necessary step that a work plan with defined activities, timeframes and concrete outcomes be finalised and published as a priority, in consultation with stakeholders.

3.55 In addition, the committee notes the need for appropriate and broad consultation in relation to significant regulatory and administrative changes that, as many have noted, have the potential for unforeseen and potentially perverse consequences.

3.56 It would be appropriate for the PLAC and the department to ensure that wide consultations are an integral part of the early and ongoing stages of the development and implementation of changes to the PL framework. It will be important to ensure that these consultations are properly organised and administered to enable timely and meaningful input from those who may be affected by any changes.

Targeted benefits and category review

3.57 The PLAC has included as part of its work plan the targeted review of PL benefits and groups. This work has commenced with the development of a formal mechanism within which to undertake PL listings and benefit reviews, as indicated in the PLAC work plan and communiques to date.

3.58 Professor Campbell, Chair of the PLAC, informed the committee that some specific groups had already been identified for targeting:

> The plan at the moment is not to review all existing prices but to look at a number of groups. That is out there in the public domain, and the one we

47 *Prostheses List Advisory Committee Communique No.3*, Department of Health, http://www.health.gov.au/internet/main/publishing.nsf/Content/EE9D7DA6EA42BDE0CA257BF00020623C/$File/PLAC%20communique%20No%203.pdf (accessed 21 April 2017), p.1.

> are starting with is hips and knees. We are then potentially looking at cardiac and maybe ophthalmic, the big ones.[48]

3.59 The committee notes with interest that the items mentioned by the PLAC chair as part of the first targeted review are the same groups for which benefit reductions have already been made.

Minimising duplication and improve the listing process

3.60 A number of reviews over the past decade have recommended better integration of HTA processes, including some inquiries undertaken by this committee.[49] Submissions to this inquiry have also argued for better coordination and reductions in duplication across HTA systems.[50]

3.61 In canvassing issues impacting on the operation and effectiveness of the PL framework, the IWG:

> noted some stakeholders held long-standing concerns regarding the lack of interaction and feedback between the TGA [Therapeutic Goods Administration] and PLAC; however, it was agreed that these were issues for the Review of Medicines and Medical Devices, and were not issues which could be addressed by this group.[51]

3.62 The committee notes that despite its terms of reference excluding consideration of '[w]ork by the Department of Health on the reimbursement systems, including reimbursement and or subsidy of medicine and medical devices',[52] the Review of Medicines and Medical Devices (MMDR) in its first report recognised the 'significant synergies' between the work of the different bodies undertaking health technology assessments in Australia, and recommended that the government:

> give consideration to organisational structures that will facilitate improved integration of:
>
> - Pre-market regulation of medicines and medical devices with health technology assessment of these products for subsidy and other purposes; and

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48 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, *Committee Hansard*, 16 March 2017, p. 57.

49 The Hon. Robert Doyle, *Review of the Prostheses Listing Arrangements*, 2007; Review of Health Technology Assessment in Australia, 2009; Senate Community Affairs Committee, *Availability of new, innovative and specialist cancer drugs in Australia*, 2015; Senate Community Affairs Committee, *The regulatory standards for the approval of medical devices in Australia*, 2011.

50 See for example, Royal Australasian College of Surgeons, *Submission 17*; Stryker, *Submission 29*; Australian Medical Association, *Submission 40*.

51 Department of Health, *Submission 38*, Attachment E, p. 4.

52 'Review of Medicines and Medical Devices: Terms of Reference', *Expert Review of Medicines and Medical Devices Regulation*, http://www.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation (accessed 24 April 2017).

- Post-market monitoring of medicines and medical devices for safety, efficacy and cost effectiveness.[53]

3.63 The Government response to the MMDR was released on 15 September 2016. In relation to the MMDR recommendation on improved integration of health technology assessments, the government supported the intent of the recommendation and noted 'recent organisational changes within the department to address process alignment and implement collaborative measures.'[54]

3.64 As indicated earlier, the PLAC Reform Work Plan published in December 2016 lists 'Minimising duplication and improve the listing process' as one of its four Issues for Consideration, and lists a number of proposed activities with desired outcomes which were due to commence from October 2016. The proposed activities include:

- review of the existing health technology assessment process across TGA, PLAC and MSAC to identify areas of duplication, opportunities for data sharing, optimal use of clinical expertise and post market monitoring;
- identification of opportunities for faster listing;
- consultation on proposed changes to processes including regulatory savings and transition requirements;
- refinement of proposed listing changes, including for example through a pilot; and
- publication revised process, and communicate the timelines, transition and implementation arrangements.[55]

3.65 In its second and third communiques, the PLAC noted that a new committee, the Regulation and Reimbursement of Medical Devices group, comprising the chairs of the PLAC, MSAC, Pharmaceutical Benefits Advisory Committee (PBAC) and departmental staff from the TGA and the Medical and Pharmaceutical Benefits divisions, had been convened to explore:

- opportunities for timely collaboration between the HTA bodies, especially in relation to new and emerging health technologies;

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53 Emeritus Professor Lloyd Sansom AO, Mr Will Delaat AM, Professor John Horvath AO, *Expert Panel Review of Medicines and Medical Devices Regulation: Report to the Minister for Health on the Regulatory Framework for Medicines and Medical Devices*, 31 March 2015, http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation#report1 (accessed 12 April 2017), pp. 171-172.

54 Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation May 2016*, http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp (accessed 12 April 2017), p. 27.

55 Department of Health, *Submission 38*, Attachment F.

- legislative provisions around information sharing between the HTA bodies, and how information could be shared without compromising security for stakeholders;
- collaboration on development of information technology systems to support parallel processing of applications;
- comparison of application processes; and
- comparison of clinical evidence requirements to identify similarities and differences.[56]

3.66 The PLAC's *Communique 4* of February 2017 notes that the Prostheses List Guide to listing and benefits for prostheses has been amended following feedback from stakeholders and discussions about parallel application processing at its previous meeting. To date, this appears to be the only concrete action in relation to improved coordination between HTA processes to date.

3.67 It is of interest to note that, at its December 2016 meeting and despite a legal requirement for products on the PL to be first listed on the Australian Register or Therapeutic Goods (ARTG),[57] the PLAC appears to have recommended listing a number of devices for which there was not an associated application or approval to be registered on the ARTG. The communique notes that the committee considered 114 applications to list new devices on the PL, that 104 of these were recommended for granting and 10 not recommended for granting on the grounds of insufficient clinical evidence provided. Yet, the communique also notes that in its discussions on these applications:

> the Committee noted that 22 of devices [sic] were not yet registered on the Australian Register of Therapeutic Goods (ARTG) and the TGA had not received an application to register on the ARTG.[58]

Committee view

3.68 The committee commends the PLAC, MSAC, PBAC and the department for establishing a working group to address issues in relation to duplication of effort and developing greater efficiencies across systems and processes, for example in relation to timing of consideration of applications. The committee is concerned that despite this being raised as an issue in numerous forums over a number of years, little appears to have been achieved in better integrating and sharing resources and processes where possible and appropriate, despite HTAs all being administered and supported by the same department.

3.69 The committee notes that there appears to be significant room for improvement in this area.

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56 Prostheses List Advisory Committee, *Communique No. 2* and *Communique 3*, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-plac.

57 Department of Health, *Submission 38*, p. 3.

58 Prostheses List Advisory Committee, *Communique 3*, December 2016, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-plac.

Chapter 4

> The anecdotal data goes to, I think, a clear and broad and accepted understanding that the private sector prices are, on average, too high. But there is a risk in arbitrary price reductions that you hit the wrong target in the wrong way and you lose products from the Australian market by unwittingly cutting too deep in a particular area or removing some of the current practices which involve clinical support. So, we are working in an area of a clear understanding that there is a problem but not a thorough dataset that provides a recipe.[1]

4.1 While all stakeholders agree that changes to the current Prostheses List (PL) framework are needed, it appears there is no one solution, and that no solution or suite of solutions will be agreeable to all stakeholders. As the Chair of the Prostheses List Advisory Committee (PLAC) has stated:

> 'If there is an answer to this issue that you are deliberating about, it is not going to be one answer; it is going to be multiple things in parallel including national and international reference prices… It is going to potentially be price disclosure if we can make that useful. It may be a number of other things.'[2]

4.2 This chapter will focus on trying to highlight some of the key areas identified by stakeholders where the current reforms could focus in attempting to address the historical and ongoing concerns in relation to prostheses prices for privately insured patients.

Do we need a Prostheses List?

4.3 A number of stakeholders to this inquiry have suggested that the PL should be phased out over time to allow the market to determine what private health insurers pay for prostheses. Private Healthcare Australia (PHA) submitted that the current Prostheses List framework is 'winning the battle but losing the war: price inflation is under control, but reimbursement levels remain significantly higher than other comparable health systems.'[3]

4.4 In their Pre-Budget Submission 2017–18, PHA recommended that, in addition to rapid implementation of the proposed PL reform agenda in 2017–18, the

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1 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 69.

2 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, Committee Hansard, 16 March 2017, p. 56.

3 Private Healthcare Australia, *Submission 7*, [p.7].

government 'should have an explicit deadline to exit regulation of medical device benefits in the private health sector.'[4]

4.5 The majority of submitters and witnesses, however, have argued that some form of PL is necessary and desirable, particularly given the complex system in which prostheses are selected, purchased, paid for and reimbursed when a patient is privately insured.

4.6 The Department of Health (department) provided the following figure to show the impact of deregulation and re-regulation, showing that re-regulation coincided with stabilisation of the average benefit paid per prosthesis.

Figure 4.1: Prostheses expenditure and average benefit per prosthesis – 1989/90 to 2015/16

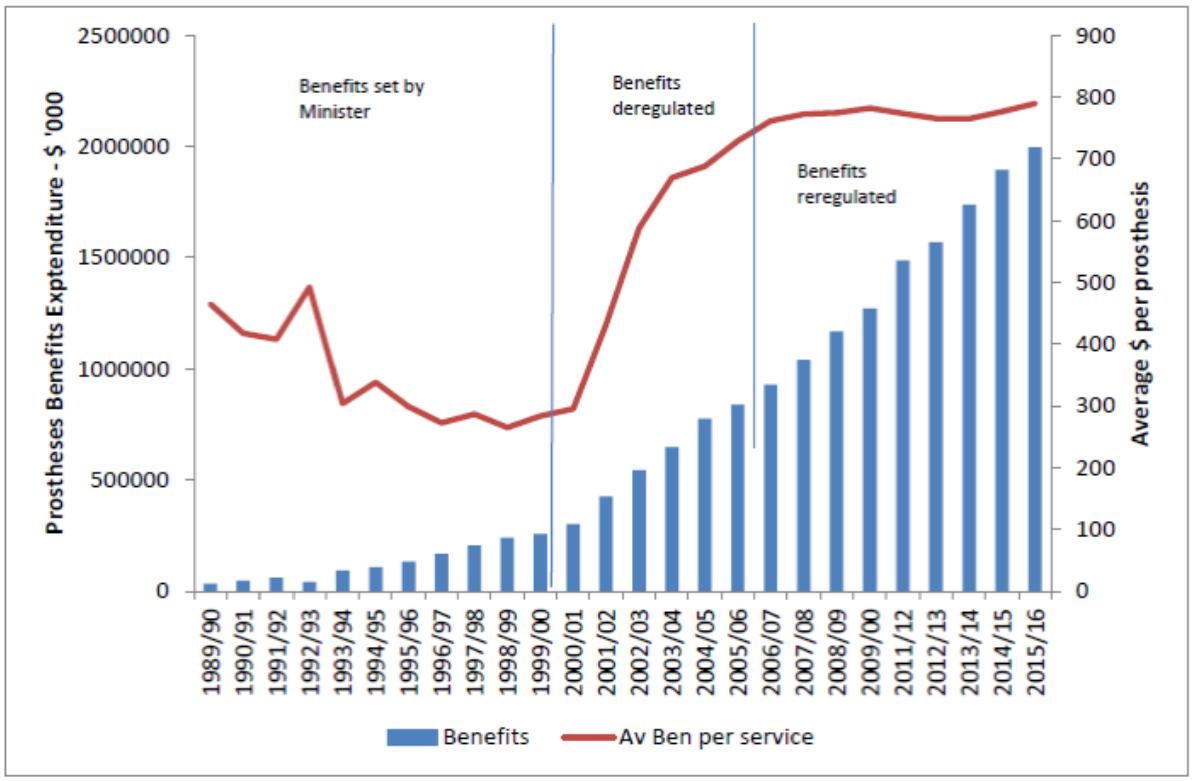

Figure 2: Prostheses expenditure and average benefit per prosthesis – 1989/90 to 2015/16

Sources:

Private Health Insurance Administration Council – *Operations of Registered Health Benefits Organisations Annual Reports* (1989/90 to 2005/2006)

Private Health Insurance Administration Council – *Operations of Private Health Insurers Annual Reports* (2006/07 to 2013/14)

Australian Prudential Regulation Authority - *Operations of Private Health Insurers Annual Reports* (2014/15 and 2015/16)

Source: Department of Health, *Submission 38*, p. 11.

4 Private Healthcare Australia, Pre-Budget Submission 2017-18, 19 January 2017, https://www.treasury.gov.au/~/media/Treasury/Consultations%20and%20Reviews/Consultations/2016/2017%20PreBudget%20submissions/Submissions/PDF/Private%20Healthcare%20Australia.ashx (accessed 19 April 2017), p. 17.

4.7 Ramsay Health Care Limited stated that:

> The Prostheses List was introduced to address issues arising from the previously deregulated environment, which saw rapid increases in prostheses pricing. The Prostheses List has also resulted in additional assurances of device safety and efficacy.[5]

4.8 Catholic Health Australia (CHA) members support the exploration of proposals to provide a more competitive approach to benefit setting whilst maintaining the benefit of certainty and access to technology provided by the PL and PLAC processes:

> The PL and PLAC have been instrumental in slowing the rising costs of devices and ensuring that patients continue to have access to appropriate and up to date technologies. CHA recommends that the PL and existing architecture of the PLAC be maintained and incorporated into any future model that is adopted by the Government and private health industry.[6]

4.9 All stakeholders have indicated a need for change. The degree of change, from moves to improve administration and transparency of PLAC, the PL and health technology assessment (HTA) processes more broadly, through to abolition of government regulation, is where there is little consensus between stakeholders.

Review of PL listing criteria

4.10 One of the key areas for reform of the PL framework being undertaken by the PLAC is a review of the criteria for listing on the PL. PLAC has listed the desired outcomes of the criteria review as:

- Privately insured Australians have access to medical devices that meet their healthcare needs through their private health insurance.
- Evidence requirements for listing on the Prostheses List are appropriate and defensible.[7]

4.11 The proposed activities to review the definition of prostheses include comparing the current definition with those used in comparable processes and regulatory arrangements, and to consult on any proposed changes to this definition, including in relation to any impacts and transition arrangements.[8]

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5 Mr Christopher Rex, Managing Director, Ramsay Health Care Limited, answers to questions on notice, 31 March 2017 (received 13 April 2017).

6 Catholic Health Australia, *Submission 25*, p. 2.

7 Department of Health, *Submission 38*, Attachment F, [p. 2].

8 Department of Health, *Submission 38*, Attachment F, [p. 2].

Defining prostheses

4.12 A broad range of stakeholders to this inquiry have called for a change to the definition of prostheses used for regulation of prostheses prices in the private sector.[9] In its report, the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) stated that they had agreed that the current definition of prostheses should be reviewed, particularly given 'the rapid development of novel medical technology.'[10]

4.13 Changes to the definition of prostheses have been argued for a number of reasons. The varying reasons help to highlight some of the issues that stakeholders consider need to be addressed through the current reform process. The key reasons and the arguments supporting them have been included below.

4.14 The main argument put by submitters to this inquiry is that the definition of prostheses should include medical devices that do not fit the current definition of prostheses but which provide superior outcomes. Cochlear Limited submitted:

> A revision of the definition of 'prostheses' and the introduction of a benefit re-evaluation process as part of the Prostheses List framework is recommended as way of ensuring the most cost effective interventions are provided and appropriate reimbursement benefits are maintained.[11]

4.15 Dr Janet Wale, formerly a consumer representative on the PLAC, states that there is inequitable access to medical devices for privately insured patients in private hospitals, in part due to how prostheses are defined for inclusion on the PL. She argues that, 'It is time that we work to develop consensus on an easily understood, publicly defensible definition.'[12]

4.16 In her submission, Dr Wale provides a list of medical devices, for example, cardiac ablation catheters, which, despite having an evidence base for their use, are unavailable in private hospital settings as they cannot be included on the PL.[13]This view is supported by many other stakeholders.[14]

4.17 Device manufacturer, Applied Medical, argues that the current definition of prostheses goes beyond the original intention of the PL, and now includes 'low value

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9 See for example: Medical Technology Association of Australia, *Submission 2*, p. 21; Cochlear Limited, *Submission 8*, p. 14; Catholic Healthcare Australia, *Submission 25*, p. 3; Stryker Australia Pty Ltd, *Submission 29*, p. 9; Australian Medical Association, *Submission 40*, p. 4; Healthscope, *Submission 42*, p. 6.

10 Department of Health, *Submission 38,* Attachment E, p. 4.

11 Cochlear Limited, *Submission 8,* p. 4.

12 Dr Janet Wale, *Submission 11*, [p. 2].

13 Dr Janet Wale, *Submission 11*, [p. 3].

14 See for example: MTAA, *Submission 2*; Cochlear Limited, *Submission 8*; Catholic Health Australia, *Submission 25*.

surgical consumables which clearly do not meet the criteria considered by Parliament when the regulation of prostheses was first adopted.'[15]

4.18 Applied Medical argue that the definition of prostheses be reviewed, but with a view to rationalising the PL. Applied Medical argues that expanding the PL to include other items ultimately will not work, because:

> there will always be boundaries to what is, and is not, included on the Prostheses List, regardless of which definition of what constitutes a 'prosthesis' is selected. The inherent nature of the regulatory framework is such that there will always be distortions in patient and physician choice as a result of a misalignment of financial costs.[16]

4.19 Similarly, medical device sponsor, Biotronik, argues that items on the PL, for example, coronary stents, may be used in preference to items that are not eligible for listing, for example, drug-eluting balloon therapies, due to the 'impact on provider revenues.'[17]

4.20 The committee has also heard that amending the definition of prostheses may help in addressing one of the most pressing issues raised by stakeholders during the course of this inquiry. LifeHealthCare states that:

> incentives are being used by private hospitals to fund prostheses that are not currently included on the PL (e.g. cardiac ablation catheters or fractional flow reserve) due to limitations in PL definitions. We believe this should be addressed by expanding the definition of a prosthesis to include non implantable devices rather than relying on incentives, that are not transparent, in order to gain access to these prostheses.[18]

4.21 This view is shared by another sponsor, Cochlear Limited. Cochlear has suggested that, in addition to redefining prostheses, the role of the Health Economic Sub Committee (HESC) of the PLAC should be expanded so that it can, among other things, provide 'evaluation of cost effective interventions that utilise medical devices that fall outside the current definition of "prostheses"'.[19]

4.22 One submission has suggested expanding the definition of prostheses through the creation of a 'Part D' for the PL, to enable inclusion of medical devices which cost over $300 and which are single use but are not implanted.[20]

4.23 The IWG noted in its report that representatives from the private health insurance sector argued that consideration of a review of the definition of prostheses 'must only occur in the context of a revision of the benefit setting.'[21]

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15 Applied Medical, *Submission 41,* Attachment B, p. 11.

16 Applied Medical, *Supplementary submission 41*, p. 4.

17 Biotronik Australia, *Submission 22*, p. 6.

18 Joint submission from four Australian medical device manufacturers and distributors, *Submission 39,* Attachment 1, [p. 2].

19 Cochlear Limited, *Submission 8*, p. 10.

20 Name withheld, *Submission 43*, [p. 4].

What should legitimately be included in setting a benefit level?

4.24 Considerable debate has occurred during this inquiry in relation to whether the benefit level for the reimbursement of prostheses should include support services associated with a prosthesis.

4.25 Mr Chris Rex, Chief Executive Officer, Ramsay Health Care Limited, questioned the current system thus: 'it has always intrigued me—and continues to do so—why prostheses are actually treated separately from all other cost inputs into procedures.'[22]

4.26 The department has advised that, currently, applications to list a new device on the PL are required to propose a benefit for the device which would cover the costs of both producing and supplying the device to the patient. In some cases, ancillary services and after care are also included in the benefit.[23]

4.27 Biotronik Australia Pty Ltd, which manufactures and supplies cardiac and combined drug and device therapies, notes that in relation to the current system:

> the PL benefits were negotiated on the basis that the benefit should include all costs associated with delivery, implantation and support of the prostheses and hence the publicised significant benefit differences between public and private are justified.[24]

4.28 Biotronik argues that there are sound reasons why services are included in the costing of prostheses for the PL, citing as an example where these services are included in professional bodies' standards of care for patients, such as those set by the Cardiac Society of Australia and New Zealand. Biotronik states that in public hospital settings these services are usually provided through clinics in the hospital, but in the private sector, are often delivered by surgeons with the assistance of the medical device sponsors.[25]

4.29 Other medical device sponsors, for example, Applied Medical, state that it provide the same type and level of service in relation to their PL devices regardless of which setting is used, public or private hospital.[26]

4.30 Cochlear Limited also submitted that it provides the same level of professional training, and patient management, and support in both public and private hospital settings, and listed the annual cost of doing so in its submission.[27]

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21 Department of Health, *Submission 38,* Attachment E, p. 9.

22 Mr Chris Rex, Chief Executive Officer, Ramsay Health Care, *Committee Hansard*, 31 March 2017, p. 12.

23 Department of Health, answers to written questions on notice, 16 April 2017 (received 26 April 2017).

24 Biotronik Australia Pty Ltd, *Submission 22.1*, p. 6.

25 Biotronik Australia Pty Ltd, *Submission 22.1*, p. 6.

26 Applied Medical, *Supplementary submission 41*, p. 7.

27 Cochlear Limited, *Submission 8*, p. 12.

4.31 However, Cochlear, which does not have high a volume of sales, supplies prostheses to public and private hospitals under the same purchasing arrangements, that is, on individual orders per patient.

4.32 Cochlear argues that product management and support of devices on the PL should be factored in to the benefit levels set.[28]

4.33 AusBiotech, a network of Australian small and medium companies in the life sciences industry, including medical technology, argues that any evaluation of and changes to benefit setting methodologies should consider that the:

> Totality of the service delivered is taken into account when determining the value of the prosthesis benefit for a product, i.e., not only 'clinically relevant requirements', as mentioned by the IWG, but also other aspects of service (e.g., education provided), the relative size of the private market, attractiveness of Australia for launching new technologies, etc.[29]

4.34 The committee notes that this appears particularly relevant for the small to medium Australian medical device sponsors, which may supply prostheses to both sectors without significant variation in price, and which may be most impacted by significant changes to the current benefit setting framework.

4.35 In its evidence, the private hospital operator, Healthscope Ltd, stated that it negotiates contracts with medical device sponsors which enable the cost of handling of prostheses to be covered through those contracts.[30]

4.36 Healthscope Ltd also indicated that prior to the current PL framework:

> there used to be a handling fee of five per cent applied to the value of a prosthetic device that was designed to compensate the hospital for the cost we incur in moving devices in and out of the hospital and the like. From a Healthscope perspective, if the outcome from this review was more transparency on pricing and some form of handling fee in that range that was designed to compensate hospitals for costs incurred, that would be an outcome that we think we would not be uncomfortable with.[31]

Committee view

4.37 The committee notes that the majority of stakeholders have supported a review of the definition of prostheses and reconsideration of what should be included in setting a benefit level for prostheses reimbursement. The committee also notes that the PLAC has included a review of the listing criteria, including revising the definition of prostheses and longer term work on revising how benefit levels are set, in its work plan.

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28 Cochlear Limited, *Submission 8*, pp. 11-13.

29 AusBiotech Ltd, *Submission 15*, p. 4.

30 Mr Michael Sammells, Chief Financial Officer, Healthscope Ltd, *Committee Hansard*, 31 March 2017, p. 7.

31 Mr Michael Sammells, Chief Financial Officer, Healthscope Ltd, *Committee Hansard*, 31 March 2017, p. 8.

4.38 In undertaking a review of the definition of prostheses and other fundamental changes to the current system, consideration should be given to the range of issues raised by stakeholders, through this inquiry and other earlier reviews.

4.39 The committee notes that several submitters commented on the use of medical devices that are not surgically implanted, or that do not require hospitalisation to implant.[32] There is a need for consideration of how these kinds of devices can be reimbursed.

4.40 The committee considers that opportunities to redefine the criteria should not be limited to expanding the definition to broaden the kind of devices included.

4.41 In particular, it is important for the PLAC and the department be mindful of, and take steps to address, the broader implications of changing the definition of prostheses, within the context of other proposed reforms. Consideration should also be given to how changes to the definition and listing criteria may address some of the ongoing issues raised by submitters, including finding a more transparent and robust way of setting benefit levels.

Setting a PL benefit level – which model?

4.42 In addition to reviewing the definition of prostheses and the criteria for listing, government reforms also include consideration of alternative models for the setting of benefits for items on the PL.

4.43 The IWG was presented with some potential options, including international reference pricing, price benchmarking using weighted averaging of public and private sector prices, and the price disclosure model used for the Pharmaceutical Benefits Scheme (PBS). Upon consideration of the various models presented to it, the IWG agreed, in relation to possible models for benefit setting, that:

> Should Government seek medium term benefit reductions across the PL, it would be appropriate to consider legislating a price disclosure system for prostheses, encompassing both public sector and private sector medical device pricing; [and] …reference pricing taking into account domestic and relevant international prices, be considered as a mechanism to set the PL benefit.[33]

4.44 Work is now under way to research and identify possible models for consideration by the PLAC, as outlined in Chapter 3 of this report. A consultant has been engaged to research and compare:

- pricing models, including reference pricing and market based approaches;
- international and domestic benchmarking;
- price disclosure; and

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32 See for example: Australian Diabetes Society and Endocrine Society of Australia, *Submission 9*; Dr Janet Wale, *Submission 11*; AusBiotech, *Submission 15*; Medtronic, *Submission 36*.

33 Department of Health, *Submission 38*, Attachment E, p. 7.

- benefit setting frameworks.[34]

4.45 A report by the consultant, providing a comparative analysis of benefit setting models, was released by the department on 4 May 2017. The report looks at international and domestic examples of benefit setting models and price disclosure that will assist the PLAC in its work.[35]

4.46 The committee notes that there is also concurrent work being undertaken by the PLAC itself, through consideration of applications to list novel devices on the PL:

> There are one or two [PL applications for novel devices] that are in train where we are using it very much as the new frontier, if you like. They are new and they do not clearly fit into any of the existing groupings, and that is where I am working with my colleagues in MSAC [Medical Services Advisory Committee] and the TGA [Therapeutic Goods Administration], because I think what we need to do there is to do a proper evaluation, and in some cases that has already been done by MSAC as part of their work for deciding on MBS item numbers et cetera, coming up with a cost-effective price.[36]

4.47 The department has stated that for new prostheses to be used within newly devised medical processes, the PLAC will take advice from the MSAC on the cost effective price of the device in the context of the whole healthcare service.[37]

4.48 The committee notes that the desired outcome of current work being undertaken by the PLAC is that '[b]enefits on the Prostheses List reflect the appropriate reimbursement costs of supplying medical devices to patients.'[38] In relation to adopting new benefit setting models, there appear to be a wide variety of options even within a particular type of pricing model, and possible combinations of models that can be used.

Reference pricing

4.49 The IWG and the PLAC have indicated that consideration of reference pricing, with possible domestic and international benchmarking, is being undertaken to identify a possible longer term benefit setting model.

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34 Department of Health, *Submission 38*, pp. 12-13.

35 Health Economics Unit, Centre for Health Policy, Melbourne School of Population and Global Health, University of Melbourne, *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models*, Department of Health, March 2017, http://www.health.gov.au/internet/main/publishing.nsf/Content/EE9D7DA6EA42BDE0CA257BF00020623C/$File/PROSTHESES%20BENEFIT%20SETTING%20FRAMEWORK_SENT_DOH_1%20V2.PDF (accessed 4 May 2017).

36 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, *Committee Hansard*, 16 March 2017, p. 57.

37 Department of Health, answers to written questions on notice, 16 April 2017 (received 26 April 2017).

38 Department of Health, Submission 38, Attachment F, [p.1].

4.50 In effect, reference pricing would include comparing the price of prostheses in the private sector in Australia with other markets, potentially domestically (in the public health sector), or internationally and setting a benefit level that was in line with comparable benchmarks.

4.51 There has been a mixed response to this suggested model. Some stakeholders, notably medical device sponsors, have been critical of this model, outlining the challenges of finding suitable comparators, either domestically or internationally.[39]

4.52 Some medical device sponsors have indicated that it could usefully be used as an input to a decision on benefit levels, but should not be the only consideration, and would necessitate alternative approaches for new devices where there is no comparator. In its submission, Cochlear Limited stated that:

> International reference pricing (IRP) may be used as an input into the benefit setting process for new technologies that have not yet been launched in Australia. However, due to the complexity of adjusting for differences in health care systems across multiple jurisdictions, there may be significant challenges in defining algorithms to adjust median IRPs to inform benefit levels of prostheses in the Australian Private Health Insurance environment.[40]

4.53 Healthscope Limited supports the introduction of reference pricing 'while having regard to the different market dynamics in other countries.'[41]

4.54 Private health insurers consider reference pricing to be a suitable option that has been successful in other countries and could be applied in Australia:

> Reference pricing is a well-accepted system which is currently used in several countries. For instance, Japan has employed international reference pricing for over a decade. France, Italy, the Czech Republic, Russia and the U.K. are other exemplars of domestic or international reference pricing. In applying this model to prostheses pricing in the Australian health system, the proposed reform would closely resemble similar recent reforms to the Pharmaceutical Benefits Scheme (PBS) where more stringent requirements on price disclosure and international references are expected to yield $3.1 billion in savings by 2018.[42]

4.55 Some medical device sponsors have recommended that any new benefit setting model that relies on comparisons between different markets, in particular the domestic public and private hospital sectors, should use information at a billing code level.[43] This would in effect mean that each individual medical device would be compared to itself.

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39 MTAA, *Submission 2*, p. 13.

40 Cochlear Limited, *Submission 8*, p.15.

41 Healthscope, *Submission 42*, p. 6.

42 Private Healthcare Australia, *Submission 7*, [p. 12].

43 See, for example: Styker Australia, *Submission 29*; Joint submission from four Australian medical device manufacturers and distributors, *Submission 39*.

4.56 However, the committee notes that this issue was dealt with as part of the 2009 Review of Health Technology Assessment in Australia, which found that this approach adds unnecessary administrative burden and recommended that groupings of devices be used as the basis for any benefit setting.[44]

4.57 As referred to in the PHA submission above, the current reform process being undertaken by PLAC includes consideration of the model developed for the PBS, which is also administered by the department.

Price Disclosure – the Pharmaceutical Benefits Scheme pricing model

4.58 It has been suggested that the reforms that have been undertaken to address issues with the pricing and reimbursement of pharmaceuticals in Australia might also be applied in reforming the PL framework. The representative body for not-for-profit private health insurers, hirmaa, sees merit in applying a similar model of price disclosure to the PL:

> We look to the PBS system as having some good examples of what we could do in this space. We do not see a big difference between pharmaceuticals and devices. We think there should be mandatory legislated price disclosure consistent with the PBS or maybe even stronger, with very harsh penalties for not disclosing.[45]

4.59 Some caution has been expressed by other stakeholders, including CHA, in adopting a model based on the reimbursement of medicines, given the inherent differences between medicines and medical devices:

> I think there are challenges with that. Drugs—legal drugs—take a long time to come to market. They have a patented molecule, and generally that molecule will remain unchanged for years and years. If you look at prosthetics—let us take a surgical stapling device—it is a little bit like a car: each year there will be slight modifications to it, whether they are true enhancements or not, the model number will change, the name will change and there will always be this challenge of, 'Is it the same circular stapler that was listed two years ago?'[46]

4.60 AusBiotech has similarly urged caution, and highlights the cost of administrative costs to sponsors, particularly small to medium companies:

> This [PBS] model has the potential to improve price transparency and reduce rebates for existing categories of products. However, the implementation and administration of this system would be expensive and our members have expressed concern that the burden of these costs would be passed on to industry.[47]

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44 Department of Health, *Submission 38*, p. 10.

45 Mr Matthew Koce, Chief Executive Officer, hirmaa, *Committee Hansard*, 16 March 2017, pp. 19-20.

46 Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 31.

47 Ausbiotech, *Submission 15*, p. 8.

4.61 Applied Medical states that although price disclosure might be suitable as part of a range of reforms, on its own it would not 'deliver the price reductions necessary to see Australians paying market based competitive rates for prostheses in the private health system.'[48]

Committee view

4.62 The committee understands that there are potentially several models that may be used in the Australian context to help maximise cost effectiveness and access to prostheses for privately insured patients.

4.63 It is clear from the evidence presented to this inquiry that stakeholders are very aware of the options currently under consideration but there are different views on the effectiveness of the various options.

4.64 The committee acknowledges that stakeholders have made significant efforts to critique the various options and considers it important for any further research and analysis to include consideration of this work in arriving at final options for the government to consider.

4.65 It should be noted, however, that while no one model will suit all stakeholders, there may need to be compromise and negotiation to ensure that the final model is workable and delivers desired outcomes.

Whole of episode payment reimbursement

4.66 Some submissions have signalled a desire to move eventually to a whole of episode reimbursement model.[49] For example, PHA stated that a:

> longer-term opportunity is to integrate prostheses costs into an episode-based payment. Agreeing on a predetermined reimbursement per procedure (e.g. per MBS item) would create stronger incentives for manufacturers to compete on price and improve the sustainability of the overall health system.[50]

4.67 The MTAA does not support a move towards using payments which would set a reimbursement level for the whole 'episode of care'. The MTAA states that using such a model:

> encourages the pursuit of the lowest cost product as opposed to the highest value product (in terms of the contribution to the patient's health outcome). This will reduce the number of innovative products available in the private sector and eventually erode the value of private insurance to consumers, which, based on a Government survey from 2015 was already a significant concern.[51]

48 Applied Medical, *Supplementary submission 41*, p. 17.

49 See for example: Private Healthcare Australia, *Submission 7*; Applied Medical, *Supplementary submission 41*.

50 Private Healthcare Australia, *Submission 7*, [p. 8].

51 Medical Technology Association of Australia, *Submission 2.1*, p. 5.

4.68 Catholic Health Care indicated that benefit levels based on episodes of care are likely to be the future, but there is a long way to go:

> Inevitably, I think, the health industry should move to episodic, value based purchasing. The challenges are that, in the private sector, the vast majority of doctors are not employed by and are remunerated separately from the hospital. Often their incentives are quite different to those for the hospitals. That is why it really would require a restructure of both the Medicare system and the health insurance system.[52]

Committee view

4.69 The committee acknowledges the extensive work undertaken by stakeholders in considering the best approach in reforming the PL and in arriving at a better way of considering the appropriate reimbursement level for prostheses paid for through private health insurance.

4.70 It is clear that there are a number of options that might be suitable, and choosing the right model should be a process undertaken with consideration of the research, analysis and comparison that has been undertaken by stakeholders, in addition to that being undertaken by Professor Clarke on behalf of the PLAC.

4.71 Whichever method is chosen for the determination of benefit levels to be paid by private health insurers, or whether the government ultimately chooses to let the market decide what prices are paid by private health insurers for medical devices, it is hoped that the Department of Health and the various committees genuinely work together in a more coordinated way, and with effective consultation to ensure the best possible outcome of the current reform process, and ultimately, a better deal for taxpayers and consumers.

4.72 It is clear from the submissions and other evidence received by the committee that there are many inter-related issues for consideration through the reform process currently under way. There are significant problems with the current model for the reimbursement of prostheses through the PL, many of which have been raised on more than one occasion through reviews and also through the research and analysis undertaken by stakeholders themselves.

4.73 As Stryker Australia has noted in its submission:

> It is not possible to reform any individual component of the health system without consideration of flow on impacts to other stakeholders. As such, any reform must involve extensive consultation and a strong evidence-based approach. Ad hoc or reactive reform enacted under short term political or media pressure is unlikely to achieve the overriding goal of sustaining a high quality and affordable healthcare system.[53]

52 Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 32.

53 Stryker Australia, Pty Ltd, *Submission 29*, p. 9.

Data collection

Device registries

4.74 The committee heard that the development of device registries, such as the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), have played an important role in improving outcomes of surgeries and identifying devices which were not performing to the same standards as comparable devices. For example, the AOA submitted that the AOANJRR had shown that large-head metal-on-metal hip joint 'lookalike prostheses' were not performing to the same standards as the original product.[54]

4.75 In its final report the IWG agreed that there should be a formalised process of post-marketing review and considered the absence of this process to be a major failure of the current PLAC arrangements. In particular, the IWG noted that the PLAC has failed to delist devices where there was evidence from current registries of devices not performing as well as comparable products.[55]

4.76 However, the IWG also noted that the PLAC is not currently resourced to introduce a post-marketing review process. The IWG supported more coordination between the PLAC, registries and the TGA to identify both superior and inferior devices.[56]

4.77 Currently registries such as the AOANJRR are maintained and funded by the applicable medical college.[57] The department levies device manufacturers and passes this funding on to the relevant college.[58] The information provided to inform the registry is voluntary but the colleges receive a high percentage of involvement as this is best practice amongst contributors to the registry.[59]

4.78 The department noted that in the future such information could be automatically captured by the e-health system, stating that:

> These things will need to be built in the e-health system, but there is a future pathway to every operation and every device being in a system… and

54 Dr Peter Lewis, Deputy Director, Australian Orthopaedic Association National Joint Replacement Registry, Australian Orthopaedic Association, *Committee Hansard*, 16 March 2017, p. 46.

55 Department of Health, *Submission 38*, Attachment E, p. 10.

56 Department of Health, *Submission 38*, Attachment E, p. 10.

57 Ms Tracy Duffy, Assistant Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

58 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

59 Ms Tracy Duffy, Assistant Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

then being able to capture down the track whether there is re-hospitalisation in respect of those issues and devices.[60]

Independent Hospital Pricing Authority

4.79 The IHPA collects data from both public and private hospitals in two separate collections through the National Hospital Cost Data Collection (NHCDC) process. The NHCDC includes information on costs associated with prostheses and other medical devices.[61]

4.80 The data provided by states and territories on public hospitals is used to determine the National Efficient Price which provides a price signal or benchmark for the efficient cost of providing public hospital services. The public sector NHCDC captures 90 per cent of acute admitted hospital activity.[62]

4.81 Information from private hospitals is provided to IHPA on a voluntary and confidential basis and accounts for approximately 60 per cent of total overnight private hospital separations.[63]

4.82 To ensure consistency of data provided by public hospitals, the IHPA conducts quality assurance and validation processes, including an independent financial review.[64] However, data provided by private hospitals is not subjected to such processes.[65]

4.83 As outlined in Chapter 2, there is a significant difference between the prices paid for prostheses in public and private hospitals and there is a lack of transparency around the rebates and discounts received by private hospitals.

4.84 In answers to questions on notice, the IHPA provided information on the costs of prostheses provided in private hospitals and noted a number of caveats around comparison of data between public and private hospitals.[66] In particular, the committee notes that there is a year's gap between the information available on public and private hospitals, that private hospital data is not subject to independent financial review and that the private hospital data is based on an older version of the Australian Refined Diagnosis Related Groups.[67]

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60 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, pp. 66-67.

61 IHPA, *Submission 37*, [pp. 1-2].

62 IHPA, *Submission 37*, [p. 1].

63 IHPA, *Submission 37*, [p. 1].

64 IHPA, *Submission 37*, [p. 1].

65 IHPA, answers to questions on notice, 15 March 2017 (received 3 April 2017).

66 IHPA, answers to questions on notice, 15 March 2017 (received 3 April 2017).

67 Australian Refined Diagnosis Related Groups (AR-DRGs) is an Australian admitted patient classification system which provides a clinically meaningful way of relating the number and type of patients treated in a hospital to the resources required by the hospital. Each AR-DRG represents a class of patients with similar clinical conditions requiring similar hospital services. See: http://www.aihw.gov.au/hospitals-data/ar-drg-data-cubes/ (accessed 11 May 2017).

Committee view

4.85 The committee believes that, in the absence of a formalised post-marketing review by the PLAC, device registries play a useful role in identifying prostheses which are not performing to an acceptable standard.

4.86 The committee supports better coordination between the PLAC, device registries and the TGA to identify both superior and inferior devices and to consider delisting poor performing devices from the PL.

4.87 The committee notes that the e-health system may have the capacity to play the role of a single device registry in the future and that this would enable the automatic collection of information on devices.

4.88 The committee notes that there are a number of factors which contribute to a lack of transparency around prostheses pricing. Notably, information from private hospitals is provided on a voluntary and confidential basis and there are a number of caveats attached to private hospital's data which limit the ability to compare public and private hospital data.

NDIS transition arrangements

4.89 The terms of reference for this inquiry include consideration of any implications for prostheses recipients of the National Disability Insurance Scheme (NDIS) transition period. The NDIS enables people with a disability to access support through individualised plans.

4.90 The Department of Health submitted that 'it is unlikely that the transition period of the NDIS will have any significant implications for recipients of prostheses funded by the prostheses listing arrangements.'[68]

4.91 However, one submission to this inquiry did raise some concerns in relation to the transition of Australian Hearing clients to the NDIS. Cochlear Limited indicated that there is:

> lack of clarity regarding the transition of Australian Hearing (AH) clients to the National Disability Insurance Scheme (NDIS). This is resulting in confusion and uncertainty individuals, providers and suppliers.[69]

4.92 The Cochlear submission states that '[n]o solution has been defined for the ongoing support of some of Australia's most severely hearing impaired and financially vulnerable - those AH clients > 65 years.'[70]

68 Department of Health, *Submission 38*, p. 13.

69 Cochlear Limited, *Submission 8*, p. 4.

70 Cochlear Limited, *Submission 8*, p. 4.

Chapter 5

Recommendations

Administration of the PLAC

5.1 The committee notes concerns raised by some stakeholders about the limited resources available to the Prostheses List Advisory Committee (PLAC) and is concerned that no additional resources appear to have been allocated for the Prostheses List (PL) reform process. The committee also notes that significant changes are likely to arise from the reform process, in particular, any rationalisation of the PL, which may impact on resources available to the department to administer the PL and the reform process. Further, the committee notes that PL listing fees have been stagnant since 2009.

5.2 The committee is encouraged by the government's focus on longer term goals but is concerned that the PLAC and the department have not allocated sufficient resources to undertake both short term and longer term reforms in addition to maintaining the PLAC's routine business.

5.3 Given the resourcing concerns raised in this inquiry, the committee considers it appropriate for the PLAC and the department to ensure that applications to list prostheses on the PL as a minimum have a concurrent application for listing with on the Australian Register of Therapeutic Goods.

Recommendation 1

5.4 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.

Recommendation 2

5.5 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.

Recommendation 3

5.6 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.

Recommendation 4

5.7 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 that are required to achieve this.

Recommendation 5

5.8 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.

Data collection

5.9 The committee notes that current device registries are maintained and sponsored by the relevant medical colleges and that the information to inform the registries is provided on a voluntary basis.

5.10 The committee is concerned that there is no formalised post-marketing review process to identify poor performing devices, and that even where device registries are capturing this evidence, that devices are not being considered for delisting from the PL.

Recommendation 6

5.11 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.

5.12 The committee notes the significant challenges in accessing and comparing information on the price differences between public and private hospitals.

5.13 The committee believes that greater price transparency is required in terms of discounts and rebates offered by prostheses manufacturers to private hospitals and that the Prostheses List framework currently lacks a mechanism to achieve this.

Recommendation 7

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

Transparency in benefits setting process

5.15 The committee acknowledges criticisms of the cuts to the benefit amount of some prostheses which came into effect in February 2017. In particular the committee notes the evidence received that the reductions have had a disproportionate impact on Australian medical device sponsors. However, the committee welcomes the government's efforts to reduce the price of prostheses and private health insurance premiums.

5.16 The committee further notes the efforts by the government to source robust data from the Independent Hospital Pricing Authority and other sources to better inform any further PL benefit reviews. The committee also welcomes the issuing of the Draft Approach for Targeted Prostheses Reviews for consideration by stakeholders.

5.17 The committee is concerned, however, that no clear schedule of reviews has been released yet, which would provide early notice for stakeholders and enable preparations for the reviews, given that reviews can have significant implications for a number of stakeholders, including medical device sponsors, private hospitals, surgeons, and ultimately, patients.

Recommendation 8

5.18 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.

Recommendation 9

5.19 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.

Transparency in pricing

5.20 The committee is concerned at evidence that the prices paid by private health insurers for prostheses on the PL is often significantly more than the price paid by public hospitals and comparable international markets. Further, the committee also heard that due to commercial-in-confidence arrangements between medical device sponsors and private hospitals, it is unclear what price the private hospitals actually pay per device.

5.21 The committee heard a number of advantages and disadvantages of various pricing models including price disclosure and domestic or international price benchmarking. The committee did not receive enough evidence to make a determination on which model would be most appropriate.

5.22 The committee notes the release in May 2017 of the comparative analysis of benefit setting models commissioned by the department to assist the PLAC in assessing which reimbursement model or models to recommend to the Minister for implementation. The analysis also included discussion of the costs and benefits of rationalisation and reduction of the PL. The committee welcomes this analysis and discussion as an important tool for further consultation and reform development.

5.23 The committee notes that the Commonwealth is a significant purchaser/funder of prostheses on the PL through the Department of Veterans' Affairs, which uses the PL as its reference point for payment to private hospitals.

5.24 Under the prostheses list when a privately insured patient uses a prosthesis device, the insurer must pay the PL minimum benefit to the hospital. This means the hospital receives the full PL price even if the hospital has only paid a part of the price and received the remainder as a discount or rebate.

5.25 The committee notes with concern that the same applies for the Department of Veterans' Affairs. In addition, the committee notes evidence from the Department of Health and the PLAC that there is currently no review mechanism in place for benefit levels on the PL.

Recommendation 10

5.26 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.

Recommendation 11

5.27 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.

Recommendation 12

5.28 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.

Recommendation 13

5.29 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.

Recommendation 14

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

5.31 The committee acknowledges that many stakeholders consider the current definition for inclusion on the PL limits patient access to non-implantable devices and to implantable devices not requiring hospitalisation.

Recommendation 15

5.32 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.

5.33 The committee acknowledges that the price of prostheses on the PL can include a range of services for the medical device, including before, during and after surgery and for the life of the device. However, the committee notes that significant issues remain to be addressed and is particularly concerned about the lack of transparency regarding these services, and whether they are necessary and legitimate costs to be passed on to private health insurers.

5.34 In disclosing the cost of a device, the committee considers that the nature and cost of services associated with medical devices should be transparent, to provide greater accountability for the reimbursement by private health insurers.

Recommendation 16

5.35 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.

Inquiry into private health insurance

5.36 The committee notes that the PL reforms can address issues relating to 14 per cent of reimbursements paid by private health insurance and notes that hospital costs make up 70 per cent of private health insurance benefits. The committee is concerned that hospital utilisation rates, rising hospital costs and an ageing population are also key factors impacting on the affordability of private health insurance in Australia.

5.37 The committee also notes with interest the rising trend of private patients receiving treatment in public hospitals, and the concerns raised in relation to this by health industry stakeholders.

5.38 On 29 March 2017 the Senate agreed that an inquiry into the value and affordability of private health insurance and out-of-pocket medical costs would be referred on 1 June 2017 to the Senate Community Affairs Committee for inquiry and report.

5.39 The committee will consider the impact of hospital utilisation and an ageing population on the affordability of private health insurance, and the increase in privately insured patients being treated in public hospitals, be considered in the upcoming inquiry into private health insurance.

Senator Rachel Siewert

Chair

APPENDIX 1

Submissions and additional information received by the Committee

Submissions

1	Prostheses Listing Advisory Committee
2	Medical Technology Association of Australia (plus a supplementary submission)
3	Bard Australia Pty Ltd
4	Matrix Surgical
5	CONMED Linvatec Australia
6	Australian and New Zealand Society for Vascular Surgery
7	Private Healthcare Australia
8	Cochlear Limited
9	Australian Diabetes Society and Endocrine Society of Australia
10	AMO Australia Pty Ltd
11	Dr Janet Wale
12	hirmaa
13	Baxter
14	Medibank Private Ltd
15	AusBiotech Ltd
16	nib health funds
17	Royal Australasian College of Surgeons

18 Reveale Surgical

19 iNova Pharmaceuticals

20 Department of Veterans' Affairs

21 Australian Orthopaedic Association

22 Biotronik Australia Pty Ltd (plus a supplementary submission)

23 Allergan

24 Confidential

25 Catholic Health Australia

26 Australasian Medical and Scientific Ltd

27 HBF Health Ltd

28 HCF

29 Stryker

30 Alcon Laboratories (Australia) Pty Ltd

31 Bupa

32 Johnson and Johnson Medical Pty Ltd

33 Consumers Health Forum of Australia

34 Surgical Devices Pty Ltd

35 LivaNova Australia

36 Medtronic

37 Independent Hospital Pricing Authority

38 Department of Health

39 Joint submission from four Australian medical device manufacturers and

distributors (plus two attachments and a supplementary submission)

40 Australian Medical Association

41 Applied Medical (plus an attachment and a supplementary submission)

42 Healthscope

43 Name Withheld (plus an attachment)

44 hearts4heart

45 Confidential

Additional Information

1 Council Lecture: Cataract, Cost, Curious Questions, from Mr David Moran, received 28 January 2017

Tabled Documents

1 Tables and graphs relating to price variation, tabled by hirmaa, at Canberra public hearing 16 March 2017

Correspondence

1 Correspondence clarifying evidence given at Canberra public hearing on 16 March 2017, received from Department of Health, 28 March 2017

Answers to Questions on Notice

1 Answers to Questions taken on Notice during 15 March public hearing, received from Medtronic, 29 March 2017

2 Answers to Questions taken on Notice during 15 March public hearing, received from Australian Medical Device Manufacturers and Distributors group, 29 March 2017

3 Answers to Questions taken on Notice during 15 March public hearing, received from Medical Technology Association of Australia, 29 March 2017

4 Answers to Questions taken on Notice during 15 March public hearing, received from Johnson and Johnson Medical, 30 March 2017

5 Answers to Questions taken on Notice during 15 March public hearing, received from Independent Hospital Pricing Authority, 3 April 2017

6 Answers to Questions taken on Notice during 16 March public hearing, received from Department of Health, 27 March 2017

7 Answers to Questions taken on Notice during 16 March public hearing, received from nib, 29 March 2017

8 Answers to Questions taken on Notice during 16 March public hearing, received from Australian Private Hospitals Association, 29 March 2017

9 Answers to Questions taken on Notice during 16 March public hearing, received from Private Healthcare Australia, 29 March 2017

10 Answers to Questions taken on Notice during 16 March public hearing, received from AusBiotech, 29 March 2017

11 Answers to Questions taken on Notice during 16 March public hearing, received from Department of Health, 30 March 2017

12 Answers to Questions taken on Notice during 31 March public hearing, received from Medibank, 11 April 2017

13 Answers to Questions taken on Notice during 31 March public hearing, received from Ramsay Health Care, 13 April 2017

14 Answers to Questions taken on Notice during 31 March public hearing, received from Healthscope, 13 April 2017

15 Answers to written Questions on Notice, received from Private Healthcare Australia, 20 April 2017

16 Answers to written Questions on Notice, received from Medical Technology Association of Australia, 21 April 2017

17 Answers to written Questions on Notice, received from Department of Health, 26 April 2017

APPENDIX 2

Public hearings

Wednesday, 15 March 2017

Parliament House, Canberra

Witnesses

Medical Technology Association of Australia
BURGESS, Mr Ian, Chief Executive Officer
BEN-MAYOR, Mr Maurice, Board member
KUNCA, Ms Andrea, Director of Access, Policy, Procurement and Innovation

Medtronic Australasia Pty Ltd
WILTSHIRE, Mr Andrew, Senior Director, Corporate Affairs
SYMONDS, Mr Douglas, Principal Analyst, Healthcare Economics and Reimbursement

Johnson & Johnson Medical Devices ANZ
FOX-SMITH, Mr Gavin, Managing Director

Stryker Australia
BEN-MAYOR, Mr Maurice, Managing Director

Device Technologies Australia Pty Ltd
STAMP, Mr Craig Marshall, General Manager

Global Orthopaedic Technology Pty Ltd
LILLEY, Mr Duncan Grant, Chief Operating Officer

LifeHealthcare
MUSCIO, Mr Matt, Chief Executive Officer

Independent Hospital Pricing Authority
DOWNIE, Mr James, Chief Executive Officer

Thursday, 16 March 2017

Parliament House, Canberra

Witnesses

Applied Medical
HILAL, Mr Said, President and Chief Executive Officer
TAYLOR, Mr Nicolas, Regulatory Consultant

Consumers Health Forum of Australia
ROOT, Ms Josephine, Policy Manager

Australian Diabetes Society
ROSS, Associate Professor Glynis, Vice-President and President-Elect

Australian Diabetes Society
HOLMES-WALKER, Associate Professor Deborah Jane, Executive Member, Secretary

Private Healthcare Australia
DAVID, Dr Rachel, Chief Executive Officer

hirmaa
KOCE, Mr Matthew, Chief Executive Officer

nib health funds
FITZGIBBON, Mr Mark, Managing Director and Chief Executive Officer

Hospital Contribution Fund
SHAY, Ms Cindy, Chief Benefits Officer

Bupa
DALTON, Dr Chris, National Medical Director and Member of the Prosthesis List Advisory Committee
LONGSHAW, Mr Adam, Director, Health and Benefits Management
CROSS, Ms Rebecca, Head of Government, Policy and Regulatory Affairs

Catholic Health Australia
GREENWOOD, Mrs Suzanne, Executive Director
WOODS, Dr Simon, Executive Director, Malvern, Cabrini

Australian Private Hospitals Association
ROFF, Mr Michael, Chief Executive Officer
CHEETHAM, Ms Lucy, Director, Policy and Research

AusBiotech Ltd
CROSS, Mr Glenn, Chief Executive Officer
ARTHUR, Ms Helen, National Programs Manager
MULLER, Mr Martin, Director of Finance, Asia Pacific, Cook Australia Pty Ltd

Australian and New Zealand Society for Vascular Surgery
LENNOX, Dr Andrew, Representative

Australian Orthopaedic Association National Joint Replacement Registry
GRAVES, Professor Stephen Ellis, Director
LEWIS, Dr Peter, Deputy Director

Prostheses List Advisory Committee
CAMPBELL, Professor Terry, Chair

Department of Health
STUART, Mr Andrew, Deputy Secretary
DUFFY, Ms Tracey, Assistant Secretary

Friday, 31 March 2017

Parliament House, Canberra

Witnesses

Medibank Private
DRUMMOND, Mr Craig, Chief Executive Officer
WILSON, Dr Andrew, Group Executive, Healthcare and Strategy

Healthscope Ltd
SAMMELLS, Mr Michael Craig, Chief Financial Officer

Ramsay Health Care
REX, Mr Christopher, Chief Executive Officer

APPENDIX 3

Prostheses List Advisory Committee

Committee members[1]

Chair: Professor Terry Campbell (AM)

Members:

Dr Henry Ko - Consumer Representative
A/Prof David Morgan OAM - Expert Member – Hip/Knee
Dr Orso Osti - Expert Member – Spinal
Dr Ian McRae - Expert Member – Health Economics
Dr David Robinson - Expert Member – Vascular
Dr Rosemary Korda - Expert Member – Epidemiology
Prof Bill Heddle - Expert Member – Cardiac/Cardiothoracic
Prof Allan Glanville - Expert Member – General/Lung
Prof Anne Simmons - Expert Member – Medical Technology
Adj/Prof Jim Butler - Expert Member – Health Economics
Ms Michelle Somlyay - Advisory Member – Australian Private Hospitals Association
Ms Cathy Ryan - Advisory Member – Catholic Health Australia
Dr Christopher Dalton - Advisory Member – Private Healthcare Australia
Dr Jui Tham - Advisory Member - hirmaa
Ms Andrea Kunca - Advisory Member – Medical Technology Association of Australia
Dr Greg Roger - Advisory Member - AusBiotech
Ms Gabrielle Moreland - Advisory Member – Day Hospitals Australia
Ms Adriana Platona – Therapeutic Goods Administration Representative
Prof Robyn Ward – Medical Services Advisory Committee Representative
Ms Letitia Hope – Department of Veterans' Affairs Representative

1 *Prostheses List Advisory Committee*, Department of Health, http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-plac (accessed 8 May 2017).