

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

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

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

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.'¹⁸The 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

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.

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 applications³⁸

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:

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.

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.

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 2017⁴⁶

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. <i>Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models</i> 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 communiqués 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 communiqués 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 communiqués 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](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

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).

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- 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 communiqués, 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;

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.

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>.