

Review of the Prostheses List Advisory committee and associated sub- committees

Australian Government
Department of Health

July 2021

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Important note regarding the timing and reliances of this Review of the Prostheses List Advisory Committee (PLAC) and its associated sub-committees ('the Review')

The work that informed this Report was conducted between June 2021 and August 2021. As a consequence, the findings of the Review may have been influenced by:

- ▶ Passage of time, so that some of the observations made in the Report may no longer be relevant as at the date of publication;
- ▶ Impacts of COVID-19 on the operations of the PLAC and its associated sub-committees;
- ▶ The ongoing implementation of the Department of Health's reform program relating to the Prostheses List which may have affected the operations of the PLAC and its associated sub-committees; and
- ▶ The hibernation agreement between the Medical Technology Association of Australia and the Department of Health in relation to Prostheses List reform work that was in place at the time of writing of the Report.

The findings of the Review relied almost entirely on stakeholder consultation. Several statements made in this Report therefore reflect subjective stakeholder perspectives, which have not been verified.

Acronyms and Abbreviations

Acronym	Definition
AGCF	Australian Government Charging Framework
ARTG	Australian Register of Therapeutic Goods
BSRIWG	Benefit Setting and Review Framework Industry Working Group
Department	The Australian Federal Department of Health
ESC	Economic Sub-Committee
HTA	Health Technology Assessment
IHPA	Independent Hospital Pricing Authority
MBS	Medicare Benefits Schedule
Minister	The Federal Minister for Health and Aged Care
MSAC	Medical Services Advisory Committee
Panel	Panel of Clinical Experts
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration
TAAD	Technology Assessment and Access Division

Glossary

Term	Definition
Advisory Member	Advisory Members are members of the Prostheses List Advisory Committee who do not have voting rights. These members include 'invited attendees'.
Australian Government Charging Framework	The Australian Government Charging Framework is a policy which sets out the activities where the government charges the non-government sector for a specific government activity such as, regulation, goods, services, or access to resources or infrastructure.
Australian Register of Therapeutic Goods	The Australian Register of Therapeutic Goods is a register of therapeutic goods accepted for importation into, supply for use in, or exportation from Australia.
Benefit Setting and Review Framework Industry Working Group	The Benefit Setting and Review Framework Industry Working Group is responsible for developing a revised framework for benefit setting and benefit review reflecting the use of HTA including evaluation of the value, cost-effectiveness and innovation of medical technology.

Term	Definition
Expert Member	Expert Members are members of the Prostheses List Advisory Committee parent committee who retain voting rights. The PLAC Chair is an Expert Member, with voting rights dependent upon the circumstance.
Health Technology Assessment	A Health Technology Assessment involves a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services.
Independent Hospital Pricing Authority	The Independent Hospital Pricing Authority is an independent government agency, established to contribute to reforms to improve Australian public hospitals per the National Health Reform Act 2011 (Cth).
Medicare Benefits Schedule	The Medicare Benefits Schedule is a list of health professional services that the Australian Government subsidises.
Medical Services Advisory Committee	The Medical Services Advisory Committee is an independent non-statutory committee which provides advice to the Minister for Health and Aged Care on matters relating proposed public funding of medical services.
Pharmaceutical Benefits Advisory Committee	The Pharmaceutical Benefits Advisory Committee is an independent non-statutory committee which provides advice to the Minister for Health and Aged Care on matters relating new medicines for listing on the Pharmaceutical Benefits Scheme.
Pharmaceutical Benefits Scheme	The Pharmaceutical Benefits Scheme Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price.
Prostheses List Advisory Committee	The Prostheses List Advisory Committee is a committee which provides advice to the Minister for Health and Aged Care.
Therapeutic Goods Administration	The Therapeutic Goods Administration is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia.
Technology Assessment and Access Division	The Technology Assessment and Access Division is a division of the Federal Department of Health which supports Health Technology Assessment in Australia.

1. Executive Summary

In the 2021-22 Federal Budget, the Australian Government announced an investment of \$22 million over 4 years to reduce the cost of medical devices used in the private health sector and to streamline access to new medical devices ('the Prostheses List Reform'). Over time, it is anticipated that the benefits of medical devices on Prostheses List will better align with the price paid in the public hospital system, supported by the Independent Hospital Pricing Authority (IHPA).

As the first step in this latest round of Prostheses List Reform, EY was appointed to undertake a Review of the Prostheses List Advisory Committee (PLAC) and its associated sub-committees ('the Review'). The purpose of this Review was to examine the role, function and membership of the PLAC and its sub-committees, and to provide the Department of Health ('the Department') with Options and Recommendations for the future governance of the Prostheses List and accession process. This Review is comprised of a documentation review and a stakeholder consultation process.

1.1 Prostheses List Advisory Committee

The Australian Government's intent of introducing the Prostheses List was to enable control over high inflation of medical device costs. The Prostheses List is a Schedule of the Private Health Insurance (Prostheses) Rules. It lists the medical devices and their associated benefits which private health insurers are required to pay when the item is used in specified circumstances. As at July 2021, there are approximately 11,000 items on the Prostheses List.

The Prostheses List is overseen by the Federal Minister for Health and Aged Care ('the Minister'), and is supported by the Prostheses List Advisory Committee (PLAC). The PLAC's purpose includes:

- ▶ Making recommendations to the Minister on whether applications to list medical devices should be granted or not and if any conditions of listing are appropriate;
- ▶ Advising the Minister about the benefits for medical devices to be listed on the Prostheses List;
- ▶ Advising the Minister on requests to amend current listings on the Prostheses List; and
- ▶ Reviewing the listing and/or benefits of listed medical devices as appropriate and make recommendations to the Minister.

The PLAC itself receives specialist advice from eight Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts ('Panel').

As a Health Technology Assessment (HTA) committee, the PLAC may also refer relevant matters to the Therapeutic Goods Administration (TGA), the Medical Service Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC) and their sub-committees.

Policy responsibility for HTA and administration for HTA committees is managed by the Department and currently rests with the Technology Assessment and Access Division.

Background

In recent years, the Department has undertaken a number of reviews relating to the Prostheses List which, amongst other things, highlighted a number of issues associated with the governance of the Prostheses List. These issues included a lack of a fit for purpose Prostheses List assessment process and limited focus on post-listing review. The PLAC is the key body responsible for these elements and so this Review considers whether its role, membership, composition and structure should be improved.

1.2 Key findings, options and recommendations of this Review

1.2.1 Findings

This Review has found that there are five key issues regarding the governance arrangements of the Prostheses List which prevent the PLAC from effectively fulfilling its intended purpose:

Table 1 - Review Findings

	Finding	Summary
1	<p>Structure, focus and composition of the PLAC and its sub-committees</p> <p>The structure, focus and composition of the PLAC and its sub-committees impair its ability to fulfill its purpose.</p>	<p>The PLAC and its sub-committees are supported by a complex array of both clinicians and industry stakeholders. This structure has evolved over time and has become unwieldy.</p> <p>For a number of reasons, the PLAC focuses on application-driven activity and less so on regular post-listing reviews (i.e. items already on the Prostheses List and/or their benefits).</p> <p>Furthermore, the composition of the PLAC to include clinical experts and industry representatives with vested interests means that the committee is often distracted by disputes and matters which are straightforward and/or are not expected to have a material impact on overall funding through the Prostheses List.</p>
2	<p>Management of the PLAC's workload</p> <p>There is a large volume of applications, which can be lengthy and are circulated relatively close to meetings.</p>	<p>Although there have been some recent improvements to the application 'triage' system, the PLAC is still required to consider 400 to 600 applications received by the Department per Prostheses List round, and usually discuss in detail approximately 20% to 25% of these applications. Documents (including summary of the assessments) provided to the meeting are very large, frequently exceeding hundreds of pages. Also, these documents are distributed only two weeks prior to meeting, limiting the level of scrutiny available from PLAC Members.</p>
3	<p>Support from the Department</p> <p>The Department is constrained in its ability to provide the necessary data and information to enable the PLAC to conduct its post-listing review responsibilities.</p>	<p>There are limited provisions in the legislation that support post-listing reviews, even though it is a responsibility of the PLAC.</p> <p>The Department has limited capability and capacity to conduct post-listing price, utilisation and clinical outcome surveillance to take to the PLAC for consideration. This is, in part, due to the volume of applications received per PLAC Meeting, but also due to limitations associated with data availability and analytical capabilities to provide PLAC with insights on medical devices utilisation, prices and clinical outcomes.</p>
4	<p>Consistency of advice from the PLAC</p>	<p>Although there is relevant documentation, including prior decisions made by the PLAC ('precedent'), relating to the PLAC's advice and recommendations, the rationale for some decisions made in the past is not always clear.</p>

	Finding	Summary
	The advice provided by the PLAC and its sub-committees is not always consistent and has varied in quality and content at times.	<p>The Technology Assessment and Access Division (TAAD) is currently responsible for the administration of the PLAC.</p> <p>The PLAC and its sub-committees would benefit from improved documentation and greater clarity regarding the criteria used to formulate advice on prostheses listing, benefit setting, utilisation review and benefit review.</p>
5	<p>Relationship with the MSAC, the PBAC, the TGA and IHPA</p> <p>The PLAC does not maintain strong relationships with other HTA committees.</p>	<p>The PLAC maintains diverse views on the perceived mandate, function and responsibilities of other HTA committees. The PLAC does not maintain strong relationships with other HTA committees. Furthermore, these committees do not frequently leverage expert skills from one another. This is also relevant to the PLAC's relationships with the TGA.</p> <p>Further, the PLAC currently has limited awareness and understanding of the role IHPA will have in the reforms, and how it will impact on their work.</p>

1.2.2 Potential options

A high-level set of potential options have been identified as being available for the Department's consideration. These options are outlined in Table 2 below. The findings of the review are then used to justify the preferred option, which is Option 3, in Section 1.2.3.

Table 2 - Review Options

	Option	Remarks
1	Retain the PLAC in its current form, function and membership.	<p>Although this potential option is the least disruptive, the issues identified in this Review would continue to persist.</p> <p>The Department would need to take into consideration how an unchanged PLAC may meet the overall intent of the Prostheses List Reforms.</p>
2	Abolish the PLAC and have the CAGs and Panel of Clinical Experts report directly to the relevant area of the Department who will advise the Minister on the listing and/or setting of benefits for medical devices.	<p>This option removes the PLAC as an oversight body, but enables the Department to maintain clinical advisors and expertise through the existing CAGs and the Panel of Clinical Experts. The Department would require resourcing and capability to absorb the PLAC's functions. Maintenance of the CAGs and Panel would continue to pose an administrative burden upon the Department and any issues pertaining to the membership of those bodies would continue.</p>

	Option	Remarks
3	<p>Divide the PLAC's functions between a peak clinical decision-making body (Prostheses List Clinical Advisory Committee, or PLCAC) and a stakeholder discussion body (Prostheses List Industry Working Group, or PLIWG).</p> <p>Abolish the CAGs and establish an additional expert panel to provide specific expertise as required (Clinical Expert Panel, or CEP).</p>	This option will require some structural changes, but by doing this, it will help to address the issues found in this Report.
4	<p>Abolish the PLAC and the CAGs and establish an alternative mechanism for the Department to access clinical expert advice regarding medical devices as required.</p>	<p>This option requires the most change and will require significant consideration by the Department. The abolishment of the PLAC and the CAGs means there would be no formal channel for regular clinical advice and so this responsibility would now sit solely with the Department.</p> <p>The relevant area of the Department which will absorb the PLAC's functions would require resourcing and in-house HTA capability development.</p>

Although the Department ought to consider each of these potential options in the context of the broader intent of the Prostheses List Reform, Option 3 would best meet the governance requirements for the Prostheses List.

1.2.3 Recommendations

Pursuant to Option 3, 11 Recommendations have been developed for consideration by the Department, which address the findings of this Review by suggesting the following changes and improvements to the current administrative and governance arrangements of the PLAC and its associated sub-committees:

Table 3 - Review Recommendations

	Recommendation	Rationale
1	The PLAC and its functions should be replaced by the PLCAC and the PLIWG.	Division of the PLAC's functions into clinical and industry advisory bodies will enable the Minister to receive more robust and consistent clinical advice (PLCAC), while maintaining a broader view of policy matters relating to the medical device benefit setting scheme (PLIWG).
2	A reconstituted Clinical Experts Panel (CEP) should be introduced to replace the abolished CAGs and to provide specialised clinical advice to support the	Establishing a CEP that replaces the CAGs will provide both the Department and PLCAC with the specialised advice it requires across all Prostheses List Categories regarding the clinical utility of medical devices and the clinical outcomes associated with the use of those medical devices. Having a smaller group

	Recommendation	Rationale
	PLCAC and the Department as required.	of clinical experts to manage will also reduce the administrative burden on the Department.
3	Processes for each HTA committee to access the relevant expertise of other HTA committees should be established.	<p>The establishment of the PLCAC and the CEP provides an opportunity to make their expertise available to other HTA committees (the MSAC, IHPA and the TGA), which may enhance collaboration and functionality between the PLCAC and other committees. This will benefit HTA more broadly through reduced duplication of efforts and better use of the full range of skills available to the Department.</p> <p>To facilitate this, the PLCAC and CEP should strengthen its functional relationships with other HTA committees.</p>
4	Reviews of the clinical appropriateness, utilisation and benefits of medical devices on the Prostheses List should occur more regularly.	Regular review will ensure that products on the Prostheses List are continuously and rigorously tested for clinical effectiveness and value for money, which will drive competition and encourage industry innovation.
5	The Department's capability for post-listing price, utilisation and clinical outcome surveillance should continue to be increased.	By continuing to enhance the Department's responsibility for post-listing surveillance, the PLCAC will be able to focus its attention on interpreting the clinical drivers and implications of the results and make recommendations accordingly.
6	The Department should continue to provide documentation of prior Prostheses List decisions.	<p>The introduction of standard templates for responses, which include explanations and reasons for referrals and decisions, will improve the consistency of decision-making.</p> <p>These templates should be designed to be comprehensive covering all key aspects of the application, the context at the time and the rationale for decisions/recommendations made. This will provide future assessments with a detailed understanding on which to base those decisions.</p>
7	All matters relating to safety and efficacy of medical devices should be referred by the PLCAC to the TGA for action.	These matters are the responsibility of the TGA and align with its expertise. The PLCAC or CEP considering similar matters would either create inefficiencies or risk inconsistencies in findings.
8	Clear criteria which outline the Prostheses List assessment process should be developed.	Clear assessment criteria for medical device listing, benefit setting, utilisation review and benefit review should be published by the Department.

	Recommendation	Rationale
		This will improve the consistency and transparency of advice relating to the listing and benefits of items on the Prostheses List.
9	Clear criteria should be established to define when a formal HTA is required.	Clear criteria for an HTA will enable the TAAD to run a consistent, well-understood and efficient triaging system for applications; and also allow the PLCAC and the CEP to determine if an application should be referred for a HTA process as this may only become only evident once an assessment has occurred.
10	The workload of the PLCAC and the CEP should be more effectively streamlined.	<p>This change is intended to reduce inefficiencies in the assessment process.</p> <p>This would mean that only applications and revisions of a significant nature are considered by the PLCAC, with more straightforward matters and/or matters that are not expected to have a material impact on overall funding through the Prostheses List to be considered by the Department.</p> <p>The PLCAC and CEP bring unique clinical skills to the assessment process and so add the most value to the assessment of complicated matters and/or matters that may have a material impact on the overall funding through the Prostheses List. Meanwhile the Department is capable of appropriately assessing more minor and uncomplicated applications efficiently.</p> <p>More details are provided in Section 6.</p>
11	All listings on the Prostheses List should have a date for the next review.	<p>At that point, the Department would consider the ongoing need for the medical device to be on the Prostheses List and the level of the benefit set.</p> <p>A mandatory and defined trigger for review will support greater competition and innovation on the Prostheses List.</p>

The Department may consider these recommendations wholly or in part to deliver improvements to the Prostheses List accession process and enhance its support to the Minister.

1.2.4 Conclusion

This Review finds that there is a continued role to support the Minister in the governance of the Prostheses List, however significant amendments are required to better facilitate this function. Enhancement of Prostheses List governance arrangements and functional relationships would contribute to the strengthening of Australia's overall HTA capability, and support the Australian Government's objective of delivering a safe, effective and efficient health care system.

The Findings, Options and Recommendations defined in this Review require further consideration to ensure that they meet the overall policy intent of, and harmonise with, broader Prostheses List Reform efforts. The Department should not merely replace the current arrangements, but should carefully review and enhance the arrangements, systems,

data and capability which underpin governance of the Prostheses List with a view of both meeting the overall Reforms and enhancing HTA in Australia more broadly.

2. Introduction

2.1 Prostheses List reforms

In the 2021-22 Federal Budget, the Australian Government announced an investment of \$22 million over 4 years to reduce the cost of medical devices used in the private health sector and to streamline access to new medical devices. This investment is part of a broader set of reforms aimed at improving the affordability and value of private health insurance for Australians.

Prior to this latest funding announcement, the Department has been working through a program of reforms to the Prostheses List, including three rounds of benefit reductions in each of 2018, 2019 and 2020.¹

In addition, a number of reviews relating to the Prostheses List have been conducted as summarised in Table 4 below.

Table 4 - List of reviews relating to the Prostheses List

Year	Review
2007	Review of the Prostheses Listing Arrangements ('Doyle Review')
2009	Review of Health Technology Assessment in Australia ('HTA Review')
2009	Public and Private Hospitals: Productivity Commission Research Report
2016	Industry Working Group on Private Health Insurance Prostheses Reform ('Sansom Report')
2017	Senate Community Affairs Reference Committee: Price regulation associated with Prostheses List Framework
2017	Prostheses Benefit Setting Framework: Comparative analysis of benefit setting Models ('Clarke Report')
2020	Options for a Revised Framework for Setting and Reviewing Benefits for the Prostheses List ('BSRIWG Report')
2020	Review of the General Miscellaneous Category of the Prostheses List ('EY Report')

Amongst other things, these reviews identified issues and challenges associated with governance of the Prostheses List. These included:

- ▶ **The application of the criteria for listing on the Prostheses List** – there has been evidence of items on the Prostheses List that arguably do not meet the criteria and inconsistencies in how assessments are made. This is, in part, driven by issues with the listing criteria and the objectives of the Prostheses List themselves.
- ▶ **The listing assessment process** – which can lack a thorough, rigorous and robust assessment of the clinical benefits of the item and its value relative to alternatives;

¹ Fact Sheet on 'Modernising and improving the private health insurance Prostheses List', Department of Health.

- ▶ **Monitoring and reviewing** – limited focus on post-listing monitoring of utilisation and benefits, which can result in inconsistencies in the range and benefits of items on the Prostheses List; and
- ▶ **Independence in the assessment process** – in particular, the involvement of medical device manufacturers, private hospitals and private health insurers in the listing process and the potential for conflicts of interest.

2.1.1 About this Review

As described in Section 3.1.1, the PLAC is the key advisory body involved in maintaining the items and benefits included on the Prostheses List. As such, this Review of the PLAC and its associated sub-committees forms the first part of the latest round of Prostheses List Reforms.

2.2 Scope and purpose of the Review

This Review focuses on the purpose, functions and membership of the PLAC and its associated sub-committees (the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (Panel)). It aims to provide the Department with options and recommendations to the Prostheses List accession process within the broader context and intent of the Prostheses List Reforms.

The Terms of Reference for this Review are provided at Appendix A. This Report is structured around those Terms of Reference as follows:

- ▶ **Section 3:** Summary of the current governance arrangements of the PLAC;
- ▶ **Section 4:** Issues identified by the Review, with a discussion of these findings;
- ▶ **Section 5:** Options for reform to the Prostheses List accession process and implications for PLAC; and
- ▶ **Section 6:** Recommendations for reform.

The PLAC also interacts with a number of other bodies involved in HTA in Australia. As such, the impacts of recommendations on other HTA bodies have been considered.

2.3 Methodology

The following steps were undertaken to assess the role, function and membership of the PLAC and its associated sub-committees:

- ▶ **Documentation review:** A schedule of the documents reviewed and their sources is in Appendix C. The documents included governance documents (such as terms of reference and operational guidelines) and administrative documents (such as meeting minutes and accompanying papers). These documents established the formal arrangements and intent of PLAC and its sub-committees. Further clarification and/or context was sought from the Department and through stakeholder interviews.
- ▶ **Stakeholder consultations:** Targeted stakeholder consultations were conducted through a mixture of in-person and virtual interviews led by Dr Tony Sherbon. These included:
 - ▶ PLAC Chair, Expert Members and all other Members;
 - ▶ CAG Chairs;
 - ▶ Members of the Panel of Clinical Experts;
 - ▶ The TAAD at the Department;
 - ▶ Other relevant Government and HTA bodies, including IHPA, PBAC, MSAC and the TGA;
 - ▶ Medical device sponsors;
 - ▶ Private hospitals;
 - ▶ Private health insurers; and
 - ▶ Consumer peak bodies.

A full list of stakeholders consulted is in Appendix D.

- ▶ **Information review and quality assurance:** information collected was consolidated and cross-referenced with the Terms of Reference for the Review. Where gaps or inconsistencies were identified, further information was requested.

In particular, a range of opinions were heard through stakeholder consultations, which, in many cases, conflicted with other opinions, as well as occasionally conflicting with the documentation. In these cases, where possible, clarification and/or confirmation was sought.

- ▶ **Information analysis:** the sources were analysed for key themes, which became the findings in this Report.
- ▶ **Options and Recommendations and report:** Based on these findings, options and recommendations were developed.

2.4 Limitations

As noted above, this Review relies on a mixture of factual and opinionated qualitative information. Opinions and perceptions have been reported throughout but should not be accepted as fact unless explicitly stipulated.

3. Current governance arrangements

3.1 Prostheses List

The Australian Government's intent of introducing the Prostheses List was to control inflation of medical device costs, and to improve accessibility to medical devices to privately insured Australians. The Prostheses List commenced in 1985 and was deregulated in 1999, with re-regulation announced in 2003.

The Prostheses List is a Schedule of the *Private Health Insurance (Prostheses) Rules* ('Prostheses Rules'). It lists the medical devices, human tissues, and their associated benefits which private health insurers are required to pay when the item is used in specified circumstances. The Prostheses Rules sets out the listing criteria which the medical device must satisfy for inclusion as a listed item. As at July 2021, there are approximately 11,000 items on the Prostheses List.

While the PLAC is a non-statutory committee, the Prostheses Rules identify that the Minister may have regard to a recommendation of the Prostheses List Advisory Committee. PLAC members are a mix of Ministerial and Departmental appointments, which adds to the complexity of the administrative arrangements.

More information on the structure of the Prostheses List may be found at Appendix A.

For the purpose of the Prostheses List, 'prostheses' are generally defined as surgically implanted medical devices, devices designed and essential for implantation, or for maintaining the implant, human tissue items and other specified devices. This Report will refer to these as 'medical devices', acknowledging both policy issues surrounding the definition and criteria for 'prostheses', which are out of scope for this report.

3.1.1 Governance of the Prostheses List

The Minister is ultimately responsible for the governance of the Prostheses List, supported by expert advice and recommendations made by the PLAC. The PLAC is responsible for:

- ▶ Making recommendations to the Minister on whether applications to list medical devices should be granted or not and if any conditions of listing are appropriate;
- ▶ Advising the Minister about the benefits for medical devices to be listed on the Prostheses List;
- ▶ Advising the Minister on requests to amend current listings on the Prostheses List; and
- ▶ Reviewing the listing and/or benefits of listed medical devices as appropriate and making recommendations to the Minister.²

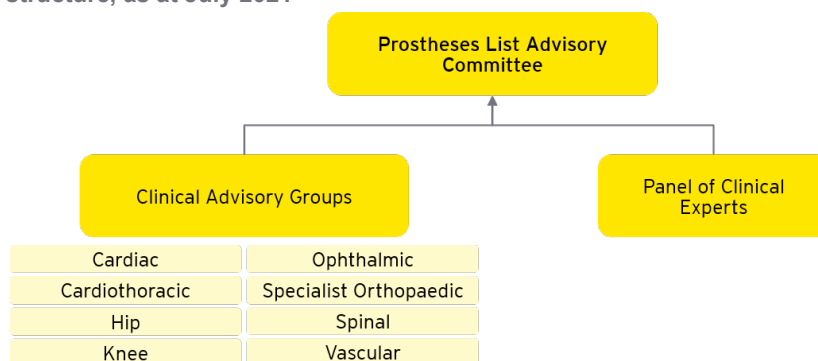
The PLAC comprises an Independent Chair and individuals with expertise in health technology assessment, specialist surgery and/or interventional work, health economics and consumer issues, and representatives of various stakeholders in private healthcare (manufacturers, hospitals and insurers).

The PLAC maintains functional relationships with other HTA bodies, including the TGA, the MSAC and the PBAC. The PLAC meets quarterly, with appointment terms lasting for approximately two years.

The PLAC is supported by eight CAG sub-committees and a Panel of Clinical Experts, as outlined in Figure 1.

² *Prostheses List Advisory Committee - Terms of Reference*, Department of Health.

Figure 1 - PLAC structure, as at July 2021



3.2 Health technology assessment in Australia

To ensure that health services and technology are generally accessible to the Australian community, the Government subsidises a range of health-related goods and services through various public funding arrangements, including the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Scheme (MBS). For members of private health insurance funds, the Australian Government ensures reimbursement for medical devices from insurers through the Prosthesis List.

HTA is defined as ‘a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services’.³ HTA is intended to provide an understanding of the benefits and comparative value of health technologies and procedures. This information is a key evidence base for health policy makers, health professionals and health consumers.

HTA in Australia is fundamentally oriented on three key questions on the product or item:

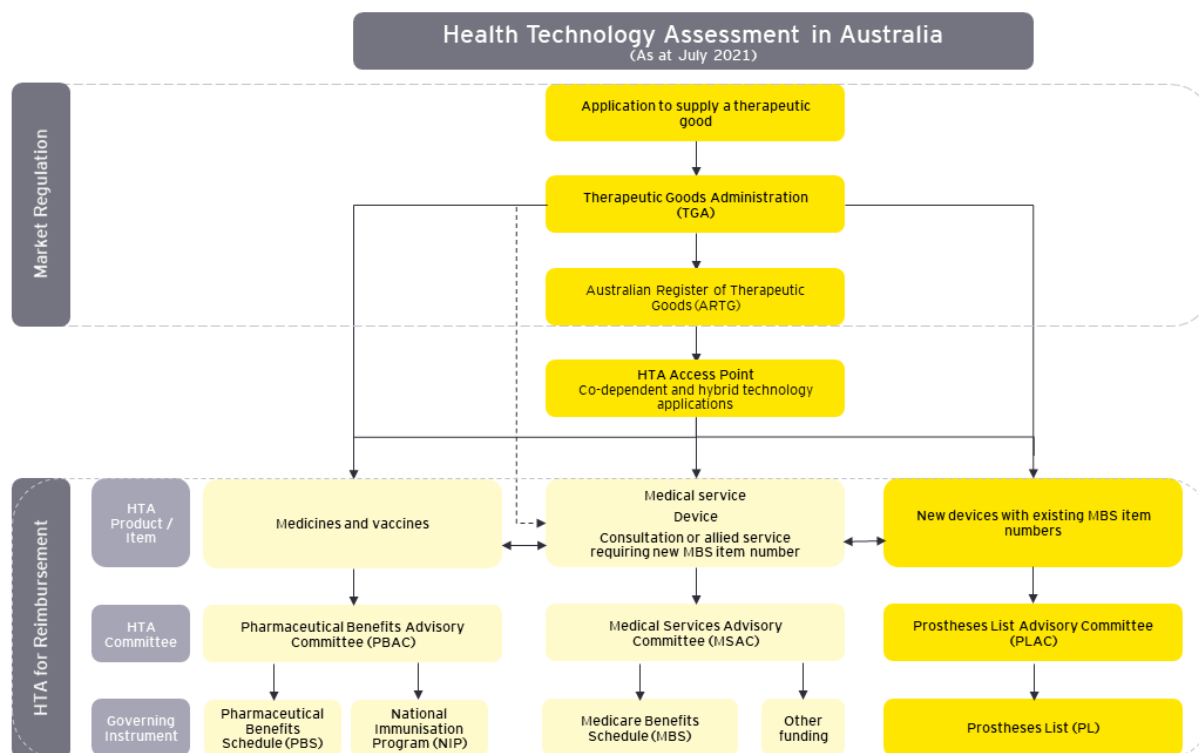
- ▶ Is it safe?
- ▶ Does it improve health outcomes?
- ▶ Is it cost effective (i.e. is it ‘value for money’)?⁴

A high level visualisation of the processes and governance bodies which underpin HTA in Australia are outlined below in Figure 2.

³ About Health Technology Assessment, Department of Health, available at <https://www1.health.gov.au/internet/hta/publishing.nsf/Content/about-1>

⁴ Above n 3.

Figure 2 - Health technology assessment in Australia, as at July 2021



3.2.1 Therapeutic Goods Administration

The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. The TGA carries out its regulatory responsibilities through:

- ▶ Pre-market assessment;
- ▶ Post-market monitoring and enforcement of standards;
- ▶ Licensing of Australian manufacturers; and
- ▶ Verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

In accordance with Australian law, a medical device cannot be legally supplied until it is assessed by the TGA and receives an Australian Register of Therapeutic Goods (ARTG) entry (or be exempt from ARTG inclusion). As this is a requirement for supply in Australia, it has also been adopted as a listing criteria for the Prostheses List. A sponsor may submit a Prostheses List application, while TGA approval is pending; applications even if considered by the PLAC, will not progress to the decision maker, until the TGA finalises the assessment and issues an ARTG entry.

3.2.2 Medical Services Advisory Committee

The MSAC is an independent non-statutory committee which:

- ▶ Appraises new medical services proposed for public funding;
- ▶ Provides recommendations and advice to the Minister on whether the service should be publicly funded; and
- ▶ Reviews existing services funded through the MBS or other programs.

The MSAC uses the best available evidence to assess comparative safety, clinical effectiveness, cost-effectiveness and total cost of the service.

An application for listing on the Prostheses List may be assessed concurrently by the MSAC where a medical device is associated with a medical service. As discussed further in this

Report, the PLAC may leverage from the MSAC and its sub-committees (the PICO Advisory Sub-Committee and the Evaluation Sub-Committee) in its compilation of advice to the Minister.

3.2.3 Pharmaceutical Benefits Advisory Committee

The PBAC is an independent expert body which recommends new medicines and vaccines for listing on the PBS. Similar to the MSAC, the PBAC provides recommendations to the Minister on whether a medicine or vaccine should be included on the PBS. In doing so, the PBAC considers medical conditions for which the medicine was registered for use, and its clinical effectiveness, safety and cost-effectiveness compared to other treatments.

The PBAC is supported by two sub-committees:

- ▶ The Drug Utilisation Sub Committee; and
- ▶ The Economics Sub Committee.

Medical devices containing medicines may be assessed concurrently by both the PLAC and the PBAC.

4. Issues identified in the Review

Overview

This section evaluates the PLAC and its sub-committees using the following structure:

- ▶ **Finding:** Key themes identified through the documentation review and the stakeholder consultations are presented as findings in yellow boxes.
- ▶ **Summary:** A high-level summary of each key findings is provided immediately beneath.
- ▶ **Detailed explanation:** More detail is provided describing the evidence and causes of the Findings as drawn from the documentation review and stakeholder consultations.

4.1 Structure, focus and composition of the PLAC and its sub-committees

Finding 1

The structure, focus and composition of the PLAC and its sub-committees impair its ability to fulfill its purpose. The composition of the PLAC's membership is not appropriate in enabling the PLAC to fulfill its purpose as it comprises an unusual mix of both clinical experts and stakeholder advocates.

Summary: The PLAC and its sub-committees are supported by a complex array of both clinicians and industry stakeholders. This structure has evolved over time and has become unwieldy.

For a number of reasons, the PLAC focuses on application-driven activity and less so on regular post-listing reviews (i.e. items already on the Prostheses List and/or their benefits).

Furthermore, the composition of the PLAC to include clinical experts and industry representatives with vested interests means that the committee is often distracted by disputes and matters which are straightforward and/or are not expected to have a material impact on overall funding through the Prostheses List.

4.1.1 Structure and membership

As demonstrated in Figure 1 in Section 3.1.1, the PLAC is composed of three sections:

- ▶ The PLAC parent committee;
- ▶ Eight CAGs; and
- ▶ A Panel of Clinical Experts.

The PLAC comprises a combination of skills and representation across its members who may be broadly categorised into two main groups (*clinical experts* and *industry stakeholders*) with two minor groups (*industry expert* and *consumer representation*). Its membership is shown in Table 5.⁵

⁵ Prostheses List Advisory Committee', Department of Health, accessed at <https://www.health.gov.au/committees-and-groups/prostheses-list-advisory-committee-plac>.

Table 5 - Membership of the PLAC parent committee, as at July 2021

Role	Name	Specialty / Representing	Group
Chair	Professor Terry Campbell (AM)	N/A	Clinical expert
Expert member	Professor David Morgan OAM	Orthopaedic surgery	
	Dr Orso Osti	Spinal surgery	
	Associate Professor Rosemary Korda	Epidemiology	
	Professor Bill Heddle	Cardiology	
	Professor Allan Glanville	Thoracic medicine	
	Professor Anne Simmons	Bioengineering	
	Professor Abdullah Omari	Vascular medicine	
	Professor Robyn Ward	Medical Services Advisory Committee Representative	
	Adjunct Professor Jim Butler	Health economics	Industry expert
Advisory member	Ms Emma Bognar	Australian Private Hospitals Association	Industry stakeholders
	Ms Cathy Ryan	Cabrini Health	
	Dr Jui Tham	Members Health	
	Dr Greg Roger	AusBiotech	
	Ms Gabrielle Moreland	Day Hospitals Australia	
Invited attendee	Mr Paul Dale	Medical Technology Association of Australia	
	Mr Ben Harris	Private Healthcare Australia	

Role	Name	Specialty / Representing	Group
Consumer representative	Dr Henry Ko	N/A	Consumer

The PLAC differs from other HTA bodies in its composition. For example, the MSAC and the PBAC are predominantly characterised by scientific or clinical members. Given the PLAC's responsibility in providing both clinical and economic assessments, representation of both clinical experts and industry stakeholders appears to be rational. However, in practice, this composition significantly undermines the committee's achievement of its function due to sustained distraction by advocacy of vested interests from, and disputes between, Advisory Members.

Similarly, the PBAC considers factors such as clinical effectiveness, safety and cost-effectiveness when considering a medicine for listing on the PBS. However, around 80 per cent of its members are health practitioners. In addition, there are two consumer representatives, one industry representative and one health economist is supported by an Economics Sub-Committee, and unlike the PLAC, there are not multiple industry representatives with directly competing commercial interests.

Clinical Advisory Groups

The PLAC is supported by eight CAG sub-committees. The primary role of the CAGs is to undertake HTAs that consider the comparative clinical function and effectiveness of medical devices being considered for listing on the Prostheses List. These assessments constitute as formal advice to the PLAC and to the TAAD on a device's suitability for listing.

Distraction from CAG purpose

The CAGs were reported by some stakeholders to be the "engine room" of the PLAC, as they are responsible for undertaking suitability assessments for a device's listing on the Prostheses List on behalf of the PLAC. The *CAG Terms of Reference* define their functions as:

- ▶ Assessing whether an item satisfies the criteria for listing on the Prostheses List, including that the required MBS and ARTG have been sought;
- ▶ Assessing whether proposed amendments to current listings are valid;
- ▶ Advising an appropriate Grouping and comparative clinical effectiveness outcomes for a new Grouping;
- ▶ Advising the PLAC on the outcome of each assessment, specifically focusing on the application's ability to satisfy the criteria for listing;
- ▶ Advising the PLAC of any anomalies identified, in particular in relation to safety and performance concerns for reference to the TGA;
- ▶ Reviewing the listing and/or benefits of listed medical devices as appropriate and advising the PLAC; and
- ▶ Providing advice where requested by the PLAC or the Department.⁶

Some stakeholders also had the perception that CAGs tended to perform the TGA's role of assessing safety and performance rather than provide referral for any anomalies identified to

⁶ *Prostheses List Advisory Committee Clinical Advisory Groups - Terms of Reference*, Department of Health.

the TGA. However, CAGs assess comparative clinical effectiveness rather than safety and performance.

Volume of members

The eight CAGs align with eight categories on the Prostheses List as listed in Table 6:

Table 6 - Clinical Advisory Groups

Clinical Advisory Group	Number of members
Cardiac Prostheses Clinical Advisory Group	7
Cardiothoracic Prostheses Clinical Advisory Group	5
Hip Prostheses Clinical Advisory Group	5
Knee Prostheses Clinical Advisory Group	5
Ophthalmic Prostheses Clinical Advisory Group	6
Specialist Orthopaedic Clinical Advisory Group	13
Spinal Prostheses Clinical Advisory Group	6
Vascular Prostheses Clinical Advisory Group	5

A list of members for each CAG is provided in Appendix E.

Each CAG comprises individuals with contemporary subject matter expertise and additional skills required by the PLAC, and a consumer representative. CAG Chairs are not required to sit upon the PLAC parent committee.

Combined, the CAGs have a total of 53 members. Stakeholders consulted agreed that this number is unwieldy, and supported the need to refine the number of members on both CAGs and the Panel of Clinical Experts.

While stakeholders consulted recognised the continued need for expert clinical advice in the governance of the Prostheses List, particularly in relation to clinical utility and outcomes, this need is not currently being met by the CAGs.

Panel of Clinical Experts

The Panel of Clinical Experts is a sub-committee of the PLAC. It assesses the clinical functionality and effectiveness of medical devices being considered for listing on the Prostheses List where there are no CAGs. Similar to the CAGs, the Panel provides clinical advice to both the PLAC and the Department.

At face value, there is little difference in the purpose of the Panel and the role and function of the CAGs, as demonstrated in Table 7 below. However, operationally, there are differences: the CAGs have meetings three times per year to discuss their assessments, while individual clinicians from the Panel are approached to provide their independent assessment of an application.

Table 7 - Comparison of roles and functions of the Panel and CAGs

Panel of Clinical Experts Terms of Reference⁷	CAG Terms of Reference⁸
“The primary role of the Panel is to assess applications to list medical devices, or amend an existing listing on the Prostheses List and advise on whether the medical device satisfies the criteria for listing on the Prostheses List...”	“The role of the CAGs is to undertake assessments on the suitability to list on the Prostheses List under the Private Health Insurance Act 2007. This includes assessing whether an item satisfies the criteria for listing on the Prostheses List...”

As such, this has led to stakeholders consulted questioning the need for both types of sub-committees. This is supported by the observation that there is no fundamental difference in the skills required between the Panellists and CAG members as seen in Table 8 below.

Table 8 - Comparison of membership of the Panel and CAGs

Panel of Clinical Experts Terms of Reference⁹	CAG Terms of Reference¹⁰
“The Prostheses List Panel of Clinical Experts (Panel) is an expert sub-committee of the Prostheses List Advisory Committee (PLAC). The Panel is composed of clinicians with contemporary subject matter expertise, and additional skills where identified by the PLAC.”	“The Prostheses List Clinical Advisory Groups (CAGs) are sub-committees of the Prostheses List Advisory Committee (PLAC). The sub-committees are composed of a Chair, individuals with contemporary subject matter expertise, and additional skills where identified by the PLAC.”

There are 27 Panellists, comprising specialisations in Ear, Nose and Throat; General Miscellaneous; Neurosurgical; Plastic and Reconstructive; and Urogenital, for which there are no CAGs.

A list of Panellists is provided at Appendix E.

Despite these similarities in definition, stakeholders consulted generally did not view the Panel as a sub-committee of the PLAC in practice, but rather a stand-alone resource which is not involved in the advisory responsibilities in the same way as CAGs. It was reported that there are no Panel meetings or reporting obligations.

Health Economics Sub-committee

The *PLAC Operating Guidelines* refer to the existence of a Health Economics Sub-committee (HESC). However, the HESC is no longer operational.

⁷ *Prostheses List Advisory Committee Panel of Clinical Experts - Terms of Reference*, Department of Health.

⁸ *Prostheses List Advisory Committee Clinical Advisory Groups - Terms of Reference*, Department of Health.

⁹ *Prostheses List Advisory Committee Panel of Clinical Experts - Terms of Reference*, Department of Health.

¹⁰ *Prostheses List Advisory Committee Clinical Advisory Groups - Terms of Reference*, Department of Health.

There were differing levels of awareness of the HESC's status, including some stakeholders that were unaware of its initial existence, and others unaware of its conclusion around 2018. The HESC had four members immediately prior to its conclusion.

The current health economics expertise directly accessible to the PLAC is a single health economist on the committee. However, three former members of the HESC remain on the PLAC, but are not identified as health economists.

As such, matters requiring health economic skills are now generally referred to MSAC. This arrangement between the PLAC and the MSAC was stated to work well, although this functional relationship could be strengthened.

Consumer representatives

Consumer representatives are not said to detract from the PLAC's achievement of its purpose. The PLAC parent committee is currently represented by a single independent consumer representative (i.e. not representative of a consumer group), while consumer representatives also sit on each CAG.

Having just a single consumer representative on the PLAC was suggested by stakeholders as being less than ideal, given the importance for the PLAC to consider consumer needs and also the difficulty for a single consumer representative to understand the complexities of HTAs. An alternative suggestion was to increase the number of consumer representatives on the PLAC from one to three (in addition to the consumer representatives that are on the CAGs) so that a diverse range of views, expertise and skills may be considered by the PLAC.

4.1.2 Roles

The roles and responsibilities of individuals on the PLAC parent committee appear to be unclear. Although the role of the Chair was well understood, stakeholders consulted demonstrated little clarity as to the specific responsibilities of other roles, including the distinction between members and non-members, and experts and advisors. A closer examination of key governance documents, including the *PLAC Terms of Reference*, *PLAC Operational Guidelines* and other publicly available information, demonstrates an incongruence in how roles are defined.

Inconsistency between these sources has likely contributed to confusion between members of different types in how they should fulfill the PLAC's intended purpose. There appears to be little restriction as to the level of engagement required for each role. PLAC meeting minutes do not indicate any noticeable difference between the participation of members based on their membership type.

The existing documents relating to roles of different member types are described in more detail below.

Terms of Reference

The *PLAC Terms of Reference* identifies three different roles:

- ▶ Independent Chair;
- ▶ Clinical and Technical Expert Members; and
- ▶ Advisory Members.

The *PLAC Terms of Reference* is largely silent on the specific skills or representation required by each role. It states that for the PLAC to achieve its purpose, it requires those with 'expertise in health technology assessment, specialist surgery/interventional work, health economics and consumer issues, and representatives of stakeholders in private

health insurance'.¹¹ However, it does not segment roles according to these skills, nor does it provide guidance as to the responsibilities attached to each role.

Operational Guidelines

The *PLAC Operational Guidelines* provides for three role types and up to 21 members in total. It states the number of participants eligible per role, and that roles should be allocated according to the member's skills, specialisation or representation. The composition is described as:

- ▶ Independent Chair;
- ▶ Expert Members;
 - ▶ 7 x clinicians;
 - ▶ 1 x health consumers;
 - ▶ 2 x health economists;
 - ▶ 1 x epidemiologist;
 - ▶ 1 x current MSAC member;
 - ▶ 1 x medical bioengineer; and
- ▶ Advisory Members;
 - ▶ 1 x Therapeutic Good Administration officer;
 - ▶ 2 x medical device industry representatives;
 - ▶ 2 x private health insurance representatives;
 - ▶ 3 x private hospital representatives.

The *PLAC Operational Guidelines* only provide guidance as to the Chair's responsibilities and restrict votership on matters related to listing of a device to Expert Members only.

Public documents

Official public documents, such as the Department's website, categorise the PLAC's membership according to five different roles:

- ▶ Chair;
- ▶ Consumer representative ;
- ▶ Expert Member;
- ▶ Advisory Member; and
- ▶ Invited attendee.

Representatives from the Department (including the TGA) and the Department of Veterans' Affairs may also attend PLAC Meetings as invited attendees.

Although there is some alignment between these sources on the roles of PLAC members, the inconsistencies likely contribute to the lack of clarity on how members should be involved on the PLAC.

Recent Meeting Minutes suggest that the inconsistency between these sources has likely contributed to confusion between Members in how they may fulfill the PLAC's intended purpose. There appears to be little restriction as to the level of engagement required for each role. Further, it was reported by some stakeholders consulted that there is little leadership from Expert Members in discussions, with engagement asymmetry led predominantly by Advisory Members.

4.1.3 Impact on the PLAC's achievement of its purpose

The PLAC is fundamentally applications-focused, concentrating its efforts on recommending devices for listing on the Prostheses List. Although some purport that the PLAC did fulfil its

¹¹ *Prostheses List Advisory Committee - Terms of Reference*, Department of Health.

requirements relating to regular review of the PLAC and benefits, recent Meeting Minutes reveal that this does not often occur.

Although process improvements have been made to streamline the PLAC's activities, Meeting Minutes from the past 12 months prior to this Review suggest minimal time is spent on post-listing review. This may be attributed to its membership and roles and, in particular, tensions between Advisory Members.

It is understood that the industry stakeholders have both been nominated to the PLAC as Advisory Members. At the time of this report, those appointments remain pending, nevertheless, the 'invited attendee' status enabled them to participate fully in the meeting as if they were Advisory Members even without the formal appointment.

Disputes between Advisory Members

Stakeholders consulted broadly recognised the contributions of Advisory Members on the PLAC and noted that they play an important role in the PLAC's core functions in providing knowledge and insight into the practical application of medical devices.

However, they commonly reported that PLAC meetings can be dominated by disagreement and dispute between some Advisory Members.

Contrasting interests of Advisory Members

Some Advisory Members represent sponsors whose revenue is positively impacted by items being included on the Prostheses List, while others are responsible for payments towards the usage of items listed. As such, disputes between Advisory Members have frequently been observed to be manifestations of existing tensions, or advocacy of individual interests.

Some identified that improvements made by the Department resulted in more discussions at the PLAC, rather than the previous more transactional "tick and flick" discussions. However, this has also allowed for disputes to occur between some Advisory Members. PLAC Members have generally observed that such disputes are unrelated to the PLAC's core business.

In consultations, some Advisory Members reported that a majority of disagreements are settled ahead of PLAC Meetings. However, stakeholders also reported that those disagreements that are not resolved are often brought to the PLAC and can be deviations from the PLAC's core function.

Perceived advocacy of vested interests by Advisory Members

There were observations from an inspection of meeting minutes that stakeholders have used the PLAC as an advocacy platform, dominating the discussions at PLAC meetings and deviating away from the assessment and review of listed items and benefits.

Advisory Members generally perceive PLAC Expert Members to have limited understanding of medical technology, particularly when the device is for an area outside of the member's specialisation. As such, Advisory Members tend to view their own roles as critical for the PLAC's functionality.

On the other hand, Expert Members, and other stakeholders consulted, perceived that the most common requirement of Advisory Members is additional product information from sponsors to assist in their decision-making. While they generally agreed that Advisory Members perform an important educational role, they were cautious not to overstate their contribution.

Prior to this Review, the Department of Health *Health Technology Assessment Committees Conflict of Interest Process Guide* was revised and tightened, lifting conflict of interest thresholds for members of HTA committees. Expert Members and stakeholders consulted remained unclear as to the continued eligibility of certain Advisory Members, as it was

commonly perceived that Advisory Members represent the vested interests of those who stand to benefit from listing and benefit decisions.

This perception, and the frequency for PLAC Meetings to be distracted by Advisory Members, have contributed to general support for limiting the participation of Advisory Members. In doing so, a formal pathway should be made available for Advisory Members to contribute any relevant factual information.

4.2 Management of the workload of the PLAC

Finding 2

The PLAC regularly addresses applications which are straightforward and/or are not expected to have a material impact on overall funding through the Prostheses List, detracting from the opportunity to provide expert advice on key issues, major applications and regular review of the Prostheses List.

Summary: Although there have been some recent improvements to the application 'triage' system, the PLAC is still required to consider 400 to 600 applications received by the Department per Prostheses List round, and usually discuss in detail approximately 20% to 25% of these applications. Documents (including summary of the assessments) provided to the meeting are very large, frequently exceeding hundreds of pages. Also, these documents are distributed only two weeks prior to meeting, limiting the level of scrutiny available from PLAC Members.

4.2.1 Triage process

Since early 2019, the Department has been implementing changes aiming to improve the quality of the information provided to the PLAC. The Department usually receives 400 to 600 applications per Prostheses List round, and information on assessments of these applications is provided to each PLAC meeting. Of these applications:

- ▶ Typically around half of the applications are new applications, and the other half are amendment, compression and expansion applications. The Department does not provide to PLAC any Part B applications, or Part A / Part C deletion of the PL billing codes, sponsors' transfer or duplication applications;
- ▶ Approximately 20 per cent of applications provided to the PLAC are discussed in detail and, for the remaining applications, PLAC members usually accept the recommendations provided in the PLAC meeting papers 'by exception'; and
- ▶ Out of all applications, approximately 10 to 20 applications per year are referred to 'focussed HTA', and about five to seven applications per year are assessed by MSAC.

This amended process has been credited with enabling the PLAC to better scrutinise and engage in robust discussions on applications rather than "ticking and flicking" applications.

This, however, has perpetuated other challenges, such as opening the PLAC to be a forum for dispute, as discussed above at Section 4.1.3. While the triage system has been recognised as improving the focus of the PLAC's work, the volume of work continues to pose a challenge to the PLAC.

Time to review meeting papers

The PLAC Operational Guidance stipulates that the Secretariat (based in the TAAD) circulates meeting papers to members two calendar weeks prior to a meeting. Some PLAC Members reported that they typically received papers in the week prior, although it may be that the papers were only accessed by those members at that particular time.

Volume of meeting papers

Papers for PLAC Meetings were not available for this Review, however packs were frequently 'voluminous', amounting to several hundreds of pages per cycle. The volume of information provided is said to be untenable, with many stating that it is not possible to comprehensively review and scrutinise papers within the given timeframes.

The volume of applications has also been attributed as an additional reason for the PLAC's limited capacity for post-listing review.

Availability of sponsor's initial application

Despite the significant amount of documentation provided to PLAC Members, the sponsor's initial application is stated to not be included for review, however, it is acknowledged all sponsor submissions are assessed by the CAGs or the PoCE.

Participants suggested that, if PLAC were to have a more active role in making decisions, then increasing the time available to review, or lessening the volume of documentation to review would be required.

Advocacy and dispute between Advisory Members

As noted in Section 4.1.3, significant PLAC meeting time is consumed by advocacy and dispute between Advisory Members limiting the capacity of the PLAC to properly fulfil its requirements.

4.3 Support from the Department

Finding 3

The Department is constrained in its ability to provide the necessary data and information to enable the PLAC to conduct its post-listing review responsibilities.

Summary: There are limited provisions in the legislation that support post-listing reviews, even though it is a responsibility of the PLAC.

The Department has limited capability and capacity to conduct post-listing price, utilisation and clinical outcome surveillance to take to the PLAC for consideration. This is, in part, due to the volume of applications received per PLAC Meeting, but also due to limitations associated with data availability and analytical capabilities to provide PLAC with insights on medical devices utilisation, prices and clinical outcomes.

4.3.1 Role of the Technology Assessment and Access Division

TAAD is a division of the Department which currently supports the work of the PLAC and provides administration of the PLAC in:

- ▶ Management of applications by Department staff, including:
 - ▶ initial assessment to ensure the application is valid; and
 - ▶ liaising with applicants on the requirements and progress of the application
- ▶ Provision of secretariat support by the Department to the PLAC and its sub-committees, including organising meetings and preparing papers;
- ▶ Assessment of applications against the criteria for listing by the PLAC and its sub-committees and making recommendations to the Minister or the Minister's delegate;
- ▶ Making the Prostheses Rules;
- ▶ Developing and maintaining IT systems to support the Prostheses List arrangements; and

- ▶ Providing and maintaining information for stakeholders about the Prostheses List processes and policy on the Department's website.¹²

TAAD also provides support to the MSAC and the PBAC, and high level policy advice and briefings for the Senior Executive, Minister and Government.

As such, although this Review does not formally include an assessment of TAAD itself, its role in supporting the PLAC through provision of documentation and recall of prior decisions ('precedent') are important considerations.

Stakeholders consulted generally regarded the efforts of TAAD positively and praised improvement in the quality of its work over the last 12 months. The considerable volume of applications triaged (approximately 400 to 600 applications per meeting) by TAAD is both recognised and appreciated by PLAC Members.

Resourcing

This Review is unable to determine the current nor required resourcing of TAAD to support the work of the PLAC. The number of full time employees dedicated to supporting the PLAC is not available in the Department of Health Cost Recovery Implementation Statement – Administration of the Prostheses List. It is recognised that configuration of the cost recovery scheme associated with the administration of the Prostheses List and supporting PLAC is not aligned with requirements of the Australian Government Charging Framework (AGCF) which sets out the whole of Government charging policy, and consequently, is not in alignment with the Public Governance, Performance and Accountability Act 2013 (Cth).¹³

An assessment should be conducted into the resources required by the Department in supporting any reforms to the PLAC following this Review. The reforms plans announced in the 2021-22 Budget (May 2021) indicate the Department will be updating the existing cost recovery arrangements to align with the AGCF.

4.3.2 Supporting listing and/or benefits review

Volume of applications

In competitive markets for prostheses, prices for items which have been available for an extended period of time tend to reduce in price as like, newer or improved items emerge. Several stakeholders therefore consider that part of the PLAC's role should be to maintain or reduce the benefits of items already on the Prostheses List where possible.

However, as discussed in Section 4.2, the PLAC and the CAGs do not often conduct post-listing reviews due to the large volume of applications for listing and the focus this requires.

Post-listing price, utilisation and clinical outcome surveillance

There is general awareness that post-market prices for medical devices on the Prostheses List in Australia remain inflated compared to international medical devices markets.

However, PLAC Members have noted that the PLAC rarely reviews existing listings and/or benefits of the Prostheses List. This is supported through the Minutes, which demonstrate an absence of post-listing review. This may be attributed both to documentary limitations (Section 4.4.1) and resourcing restrictions of TAAD (Section 4.3.1).

¹² Provided by the Department of Health.

¹³ Alignment of cost recovery arrangements will be aligned with legislative requirements as a part of broader PLAC Reforms.

Other reasons include:

Processes for reviewing items similar to new items

Members reported that although a substantial amount of applications for listing are for 'like items', there is no process to guide the PLAC on how to assess benefits for comparable items post-listing and so the PLAC is hesitant in fulfilling this duty. Some reported that this hesitation prevents the PLAC from fulfilling its review and oversight role.

Limited use of data

Potential sources for utilisation and clinical outcome data on medical devices are not currently used by the PLAC or TAAD for the purposes of post-listing reviews of the Prostheses List.

Five possible sources of data have been identified to gain utilisation data: (1) Hospital Casemix Protocol ('HCP1') Data; (2) registry data, such as the National Joint Replacement Registry; (3) health fund data, for benefits paid for usage of medical devices; (4) aggregated data, provided by IHPA; and (5) post-market surveillance, conducted by the TGA.

Several stakeholders expressed concern at the accuracy and up-to-date relevance of the above data sources, including the HCP1 dataset. However, despite some limitations regarding recency, this is an accurate and detailed dataset with significant untapped potential for TAAD and PLAC to understand recent trends and drivers of utilisation at a granular level.

This Review suggests that the Department explores ways of better using this dataset, including, if necessary, tightening data collection processes to improve recency and accuracy. In addition, given the levels of uncertainty in the datasets available to the PLAC, it is suggested that TAAD provide information-sharing sessions on the processes and structures that exist around those datasets.

The absence of a formal pathway for the Department to share post-market information with the PLAC has challenged its ability to review items and/or benefits.

Perception of responsibility

The responsibility for post-listing reviews is set out in both the PLAC Terms of Reference and the CAG Terms of Reference. Despite this, some stakeholders consulted maintain a strong belief that the PLAC has no responsibility for post-listing review, and that this responsibility should lie with the Department. As a result, such regular post-listing reviews were not conducted by TAAD and PLAC.

4.4 Consistency of advice from the PLAC

Finding 3

The Department is constrained in its ability to provide the necessary data and information to enable the PLAC to conduct its post-listing review responsibilities.

Summary: There are limited provisions in the legislation that support post-listing reviews, even though it is a responsibility of the PLAC.

The Department has limited capability and capacity to conduct post-listing price, utilisation and clinical outcome surveillance to take to the PLAC for consideration. This is, in part, due to the volume of applications received per PLAC Meeting, but also due to limitations associated with data availability and analytical capabilities to provide PLAC with insights on medical devices utilisation, prices and clinical outcomes.

4.4.1 Documentation and precedent

Members had diverse views on the quality and content of advice provided by the PLAC and its sub-committees. Issues in quality and content relate to:

- ▶ Limited documentation of advice issued by CAGs;
- ▶ Absence of CAG Chairs on the PLAC parent committee;
- ▶ Lack of systems to recall precedent; and
- ▶ No formal criteria to commence a focused HTA.

These points are discussed in more detail below.

Limited documentation of advice issued by CAGs

The applications for listing on the Protheses List are not provided to the PLAC Members, which has been identified as a key challenge by Members. The CAGs are responsible for providing the preliminary advice to the PLAC, which considers the advice along with further information prepared by TAAD on the application.

While the CAGs are held in high regard for their expert knowledge by the majority of participants, it was noted that they occasionally provide limited supporting information to the PLAC regarding a recommendation to support or reject an item's listing.

Absence of CAG Chairs on the PLAC

The issue of limited documentation supporting a CAG's advice is exacerbated as some CAG Chairs are not members of the PLAC. This further limits the PLAC's ability to understand insights from the CAG. For this reason, participants generally voiced support for requiring CAG Chairs to be represented on the PLAC.

Lack of systems to recall previous decisions

The PLAC does not have a system through which it is able to recall the reasons for previous decisions and recommendations. The Protheses List is managed through the Protheses List Management System (PLMS).¹⁴ However, this system cannot easily recall specific details on historical reasons for decisions relating to a listing application to provide further information on prior decisions relating to like or similar products. This is a risk to the PLAC, as it increases the risk of litigation where like-items are not listed, or are inconsistent in the benefit level proposed due to inconsistent assessments. As such, the PLAC has developed a dependence on the corporate memory of PLAC members.

However, some stakeholders consulted do not support a requirement to refer to precedent. The PLAC Operational Guidelines do not stipulate the need to refer to precedent.

The unavailability of a formal system to recall precedent limits the PLAC's capability to conduct post-listing review.

No formal criteria to commence a focused HTA

Full and focused HTAs are the responsibility of the MSAC. The MSAC uses scientific evidence to assess the quality, safety, efficacy and cost effectiveness of health services and to provide the necessary information to understand the benefits and comparative value of health technologies and procedures. In certain circumstances, the PLAC may request a focused HTA to assess certain aspects of an application by an external contractor, usually Hereco.

¹⁴ At the time of this Review, this system is due to be subsumed through expansion of the Health Products Portal.

Although full and focused HTAs maintain a defined role in the process of listing a device on the PLAC, the PLAC has previously raised concerns with both the criteria to commence a formal HTA, and the assessment process itself. There are no formal criteria on the factors to trigger an HTA, nor guidance on the processes to be followed should an HTA be required. PLAC Members acknowledge that this has been a source of confusion in the past.

4.5 Relationship with the MSAC, the PBAC, the TGA and the IHPA

Finding 5

The PLAC does not maintain strong relationships with other HTA committees.

Summary: The PLAC maintains diverse views on the perceived mandate, function and responsibilities of other HTA committees. The PLAC does not maintain strong relationships with other HTA committees. Furthermore, these committees do not frequently leverage expert skills from one another. This is also relevant to the PLAC's relationships with the TGA.

Further, the PLAC currently has limited awareness and understanding of the role IHPA will have in the reforms, and how it will impact on their work.

As an HTA committee, the PLAC maintains functional relationships with the TGA, PBAC and MSAC, although it is apparent that there is little understanding of each committee's specific role in relation to governance of the Prostheses List. Approximately 20 per cent of all applications are referred to the PLAC. The *PLAC Terms of Reference* provides the authority to refer applications to other HTA committees, including the MSAC, the PBAC and the TGA.

4.5.1 Medical Services Advisory Committee

The *PLAC Terms of Reference* enables the PLAC to refer applications to the MSAC and its ESC where:

- ▶ The new medical device employs a medical service that is not currently covered in the MBS;
- ▶ The new medical device might be used in a medical service that is currently described in the MBS, but potentially extends the range of indications/patients beyond the original intent of the MBS item/s;
- ▶ The applicant claims use of a medical device delivers superior health outcomes relative to existing alternative devices, and seeks a higher benefit;
- ▶ The application is for a first in class medical device; or
- ▶ The application is for an innovative medical device where an appropriate comparator listed on the Prostheses List cannot be easily identified. This may relate to the device itself, the patient population or the circumstances of use of the device.¹⁵

In some circumstances, applications may be submitted directly to the MSAC, bypassing the PLAC, if there are no appropriate MBS items associated with the use of the device, or if it is a novel technology.

The Department reports that approximately four to five applications are referred to the MSAC per cycle. Most members report having clarity on the criteria for the MSAC referral due its availability in the PLAC Terms of Reference.

4.5.2 Pharmaceutical Benefits Advisory Committee

The PLAC Terms of Reference stipulate that the PLAC should liaise with the PBAC and/or its sub-committees for:

¹⁵ *Prostheses List Advisory Committee - Terms of Reference*, Department of Health.

- ▶ Advice on comparative clinical effectiveness and cost effectiveness of a new medical device incorporating a medicine; or
- ▶ The development of assessment processes that maximise the use of the clinical and technical expertise of each body and reduce duplication of assessment.¹⁶

Although the PLAC Terms of Reference enables this, the PLAC does not appear to liaise with the PBAC in PLAC Meetings. Stakeholders consulted also did not report frequent liaison with the PBAC.

4.5.3 Therapeutic Goods Administration

As part of an Australian Government Department, the TGA does not currently have a formal Expert Advisor role on the PLAC.

The TGA's role in HTA is in the assessment of safety, quality and performance of new health technologies for entering on the ARTG. Manufacturers and sponsors may then also apply for their item to undergo an HTA for reimbursement through private health insurance arrangements, as per the Prostheses List.

Both the PLAC Terms of Reference and CAG Terms of Reference enable the PLAC and CAGs to refer items to the TGA for further investigation and appropriate action where there are concerns about the safety of medical devices that arise during the assessment of an application as seen below in Table 9:

Table 9 - Comparison of TGA referrals between PLAC and CAG

PLAC Terms of Reference ¹⁷	CAG Terms of Reference ¹⁸
"The PLAC will refer any concerns about safety of medical devices that arise during assessment of applications to list medical devices to the Therapeutic Goods Administration for investigation and appropriate action."	"Advising the PLAC of any anomalies identified, in particular, in relation to safety and performance concerns for reference to the Therapeutic Goods Administration..."

The TGA has supported this process with the availability of the TGA Medical Device Incident Report and Investigation Scheme (IRIS), which manages all reports of adverse events or problems associated with medical devices for further investigation. The IRIS is not specifically designed for HTA committees, and no specific process exists for HTA committees to report such concerns.

Some PLAC and CAG Members reported that CAGs have provided safety and efficacy advice despite this being the role of the TGA, and there is little evidence to demonstrate the PLAC's referral of applications to the TGA. However, this point is contested.

4.5.4 Independent Hospital Pricing Authority

IHPA is currently supporting the Department in reducing the benefits of items on the Prostheses List. Despite PLAC also having a responsibility for benefit setting, the PLAC and CAG members are generally unaware of how IHPA's public reference pricing work would impact the PLAC's work.

¹⁶ *Prostheses List Advisory Committee - Terms of Reference*, Department of Health.

¹⁷ *Prostheses List Advisory Committee - Terms of Reference*, Department of Health.

¹⁸ *Prostheses List Advisory Committee Clinical Advisory Group - Terms of Reference*, Department of Health.

The Department advises that this will likely become clearer as the reforms progress. The role of IHPA in supporting the Department to benchmark the Prostheses List to prices in public hospitals commenced from 1 July 2021, which was after consultation for this Review had been completed.

5. Potential options for reform to the Prostheses List accession process

Based on the Findings in Section 4, a high-level set of potential options have been identified to reform the Prostheses List accession process, with implications on the PLAC and its associated sub-committees. These potential options have been developed for the Department's consideration based on the information available and within scope of this Review.

Although there are a number of options which the Department may consider, in Section 6 it is explained why Option 3 was assessed as best meeting the objectives of this Review, including:

- ▶ Delivering sufficient scrutiny of new and amendment applications;
- ▶ Providing enhanced advice to the Minister on the suitability of a medical device for the Prostheses List;
- ▶ Strengthening the Department's HTA capability, particularly in its clinical and economic assessments; and
- ▶ Providing streamlined ongoing administration of the Prostheses List, including post-listing review.

The Department should consider these potential options and any relevant recommendations within the context and intent of the broader Prostheses List Reforms.

Option 1: Retain the PLAC in its current form, function and membership.

Remarks: Although this option is the least disruptive, the issues identified in this Review would continue to persist. The Department would need to take into consideration how an unchanged PLAC may meet the overall intent of the Prostheses List Reforms.

The Department retains the PLAC in its current form, function and membership. Issues identified in this Review will require further consideration to meet the overall intent of the Prostheses List Reforms.

Option 2: Abolish the PLAC and have the existing CAGs and Panel of Clinical Experts report directly to the relevant area of the Department who will advise the Minister on the listing and/or setting of benefits for medical devices.

Remarks: This option removes the PLAC as an oversight body, but enables the Department to maintain clinical advisors and expertise through the existing CAGs and the Panel of Clinical Experts. The Department would require resourcing and capability to absorb the PLAC's functions. Maintenance of the CAGs and Panel would continue to pose an administrative burden upon the Department and any issues pertaining to the membership of those bodies would continue.

The Department abolishes the PLAC and the relevant area of the Department absorbs its role and functions. The CAGs are retained, but are reconstituted to report directly to the relevant area of the Department. The Department will refer matters for specialist clinical advice to the CAGs, and be primarily responsible for advising the Minister on the listing of items and/or benefits setting on the Prostheses List.

Option 3: The PLAC be replaced by:

A Prostheses List Clinical Advisory Committee (PLCAC) composed of an independent Chair, clinical experts, epidemiologists, medical bioengineers, health economics expertise, medical device logistics management expertise, and at least two consumer representatives.

This committee would initially report to the Department but could eventually become a committee of the MSAC. This committee would advise the Department on the clinical benefits, appropriate utilisation and value for money of both listed medical devices and new applications for listing.

The PLCAC will retain the formal advisory role to the Minister on governance of the Prostheses List.

A Prostheses List Industry Working Group (PLIWG) composed of medical device industry representatives, private hospital representatives, private health insurance representatives, health economics expertise and at least two consumer representatives.

This committee would advise the Department on the policy matters affecting the medical device benefit setting scheme as well as providing the industry and funder views on the levels of benefits set for medical devices under the scheme including issues relating to IHPA's determination of medical device benefits.

The PLIWG will act in an advisory capacity to the PLCAC and should not have any formal reporting or decision-making role.

Remarks: This option is mildly disruptive, but is underpinned by structures which are intended to address the issues found in this Report.

Under this option, the Department terminates the operations of the PLAC, the CAGs and the Panel, and divides its functions across a newly established Clinical Expert Panel (CEP), supported with complementary input from an industry working group.

Option 4: Abolish the PLAC and the CAGs and establish an alternative mechanism for the Department to access clinical expert advice regarding medical devices.

Remarks: This option requires the most change and will require significant consideration by the Department. The abolishment of the PLAC and the CAGs means there would be no formal channel for regular clinical advice and so this responsibility would now sit solely with the Department.

The relevant area of the Department which will absorb the PLAC's functions would require resourcing and in-house HTA capability development.

The Department abolishes both the PLAC and the CAGs. The Department will absorb the PLAC's functions, however, will need to identify a pathway forward to source and access clinical expert advice on medical devices to support its responsibilities.

5.1 Review of the Prostheses List Reform

Although it does not impact the options listed above, the Department has outlined its intention to review the Prostheses List Reform to ensure that activities have delivered upon their intended outcomes. This may present further options which are not available at the time of this Review.

6. Recommendations

This Review makes 11 recommendations, pursuant of Option 3, which are intended address the Findings in Section 4. This section will provide Recommendations using the following structure:

- ▶ **Recommendation:** A recommendation on actions for consideration by the Department in reforming governance of the Prostheses List accession process;
- ▶ **Rationale:** A high-level summary of reasons and benefits which can be expected from the implementation of the recommendation;
- ▶ **Detailed explanation:** Further detail provided to the recommendation, including any processes or arrangements which the Department need to consider.

To ensure alignment between the Findings of the Review and the proposed Recommendations, Table 10 provides a mapping of the relationship between Findings and the relevant Recommendations.

Table 10 - Mapping of Findings and Recommendations of this Review

Recommendations		Finding 1: Structure, focus and composition of the PLAC and its sub-committees	Finding 2: Management of the workload of the PLAC	Finding 3: Support from the Department	Finding 4: Consistency of advice from the PLAC	Finding 5: Relationship with the MSAC, the PBAC, the TGA and IHPA
1	Replace the PLAC and its functions with the PLCAC and the PLIWG	✓				
2	Introduce a reconstituted CEP	✓	✓			
3	Improve functional relationships between HTA committees				✓	✓
4	Introduce regular reviews of clinical appropriateness and utilisation medical device			✓	✓	
5	Increase the Department's capability for post-listing surveillance			✓	✓	
6	Enhance documentation of prior decisions		✓	✓	✓	
7	Refer matters relating to safety and efficacy to the TGA				✓	✓
8	Develop clear criteria which outline the Prostheses List assessment process		✓	✓	✓	

Recommendations		Finding 1: Structure, focus and composition of the PLAC and its sub-committees	Finding 2: Management of the workload of the PLAC	Finding 3: Support from the Department	Finding 4: Consistency of advice from the PLAC	Finding 5: Relationship with the MSAC, the PBAC, the TGA and IHPA
9	Develop clear criteria to identify an HTA requirement		✓	✓		
10	More effectively streamlining the workload of the PLCAC and the CEP		✓	✓		✓
11	Introduce review dates for all medical device listings			✓	✓	

Recommendation 1: Replace the PLAC and its functions with a PLCAC and PLIWG

The PLAC should be replaced by:

A Prostheses List Clinical Advisory Committee (PLCAC) composed of an independent Chair, clinical experts, epidemiologists, medical bioengineers, health economics expertise, medical device logistics management expertise, and at least two consumer representatives.

This committee would initially report to the Department but could eventually become a committee of the MSAC. This committee would advise the Department on the clinical benefits, appropriate utilisation and value for money of both listed medical devices and new applications for listing.

The PLCAC will retain the formal advisory role to the Minister on governance of the Prostheses List.

A Prostheses List Industry Working Group (PLIWG) composed of medical device industry representatives, private hospital representatives, private health insurance representatives, health economics expertise and at least two consumer representatives.

This committee would advise the Department on the policy matters affecting the medical device benefit setting scheme as well as providing the industry and funder views on the levels of benefits set for medical devices under the scheme including issues relating to IHPA's determination of medical device benefits.

The PLIWG will act in an advisory capacity to the PLCAC and should not have any formal reporting or decision-making role.

Rationale: Division of the PLAC's functions into clinical and industry advisory bodies will enable the Minister to receive more robust and consistent clinical advice (from the PLCAC), while maintaining a broader view of policy matters relating to the medical device benefit setting scheme (from the PLIWG).

Relevant Findings:

Finding 1 - Structure, focus and composition of the PLAC and its sub-committees

The division of the PLAC's functions between a clinical advisory body and an industry working group are demonstrated in Figure 3 and Figure 4.

Figure 3 - Proposed role of the PLCAC in HTA

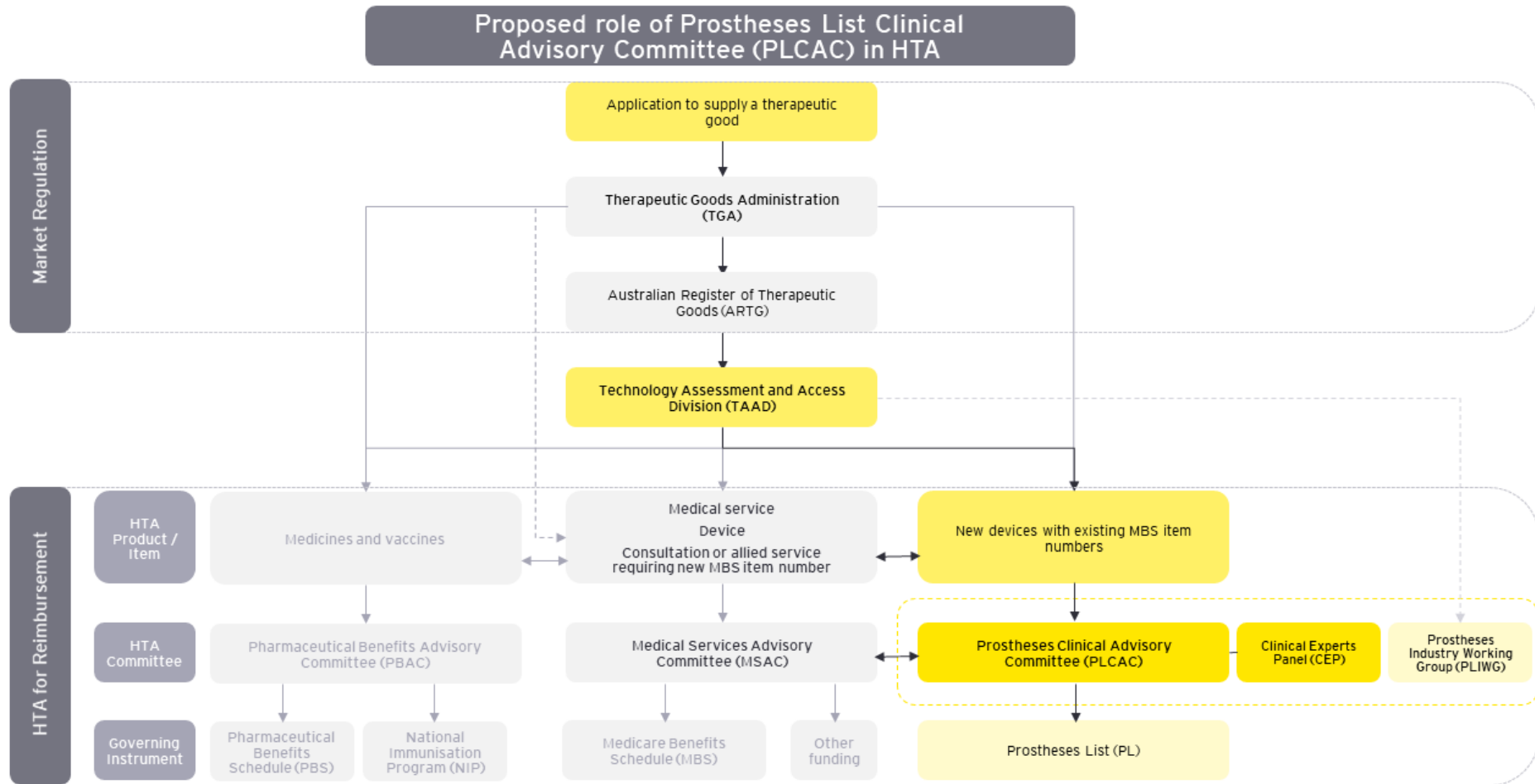
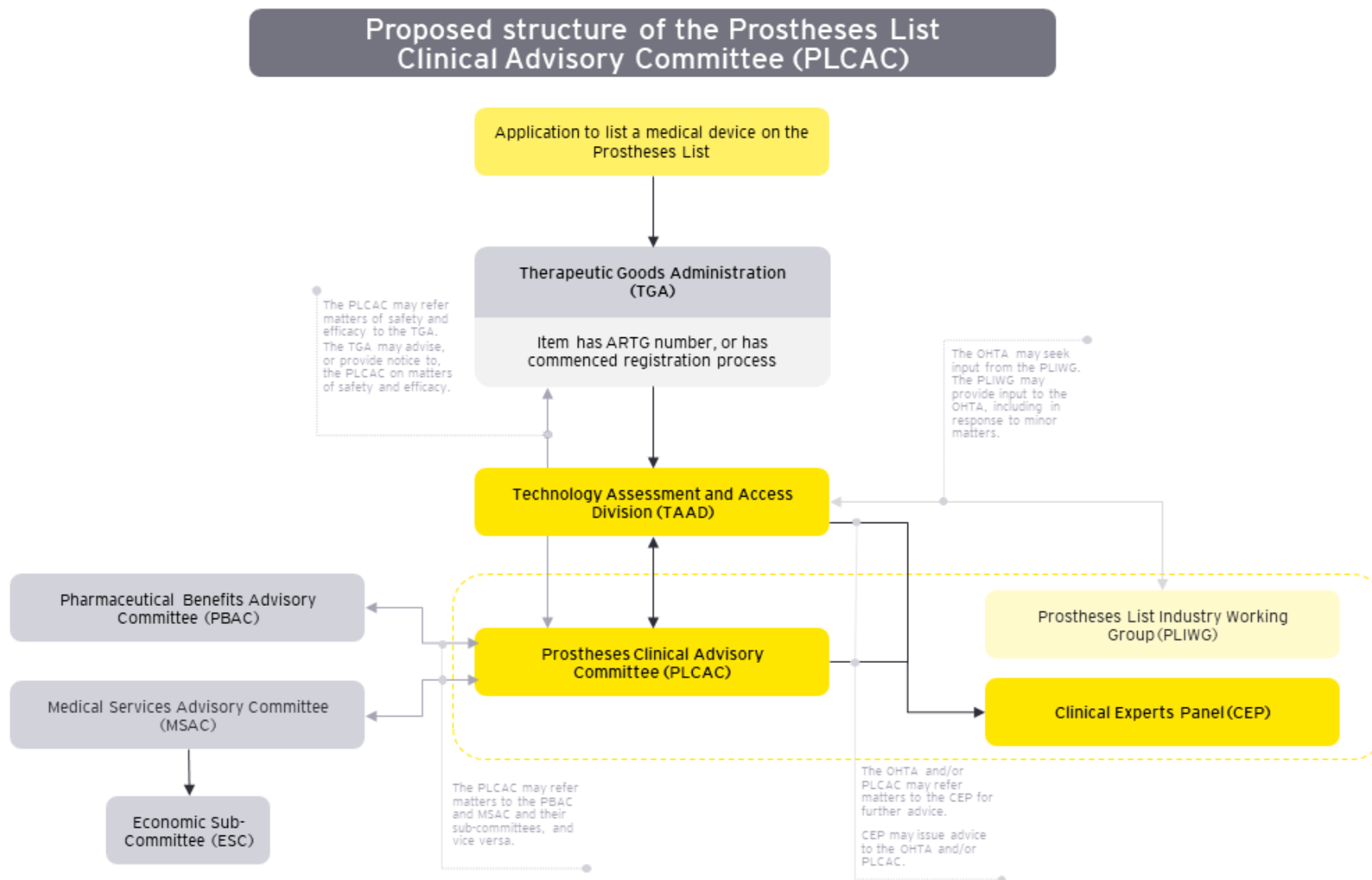


Figure 4 - Proposed structure of the PLCAC



6.1 Prostheses List Clinical Advisory Committee

To enable a continuance of a formal advisory function to the Minister on matters relating to assessment for listing and post-listing review of items and/or benefits on the Prostheses List, a PLCAC should be established.

Terms of Reference

The PLCAC's Terms of Reference should be strengthened to clarify and reinforce the PLCAC's purpose, roles and function in making recommendations to the Minister on clinical benefits, appropriate utilisation and value for money of both listed medical devices and new applications for listings. The Terms of Reference should also outline the functional relationships of the PLCAC, particularly with the TGA, MSAC, the Department and PLIWG.

Membership

In alignment with other HTA committees, the PLCAC should prioritise clinical expertise to assess clinical and cost effectiveness. The PLCAC should be composed of:

- ▶ An Independent Chair;
- ▶ Clinical experts;
- ▶ Epidemiologists;
- ▶ Medical bioengineers;
- ▶ Health economics expertise;
- ▶ Prostheses logistics management expertise; and
- ▶ At least two consumer representatives.

The PLCAC should not merely transpose the current membership of the PLAC; members should be carefully selected with consideration of the Findings of this Review.

The Department should consider reviewing the Clinical Advisory Groups and Panel of Clinical Experts Nomination and Appointment Process in line with Findings of this Review to ensure that the process supports the nomination and appointment of appropriately skilled experienced individuals.

Current members should also not automatically qualify as part of the reconstituted Clinical Expert Panel.

Reporting

While the Prostheses List Reforms are implemented, the PLCAC would initially report to the relevant area of the Department. Following a Review of whether the intent of the Prostheses List Reforms have been realised (scheduled for 2024), further consideration should be made as to whether the PLCAC may be more effective in becoming a sub-committee of the MSAC.

In its reconstitution, the PLCAC should consider input from the PLIWG, but economic input should be primarily sought from the MSAC ESC.

6.2 Prostheses Industry Working Group

To reorient the work of the PLCAC, a separate PLIWG should be developed as an alternative channel for feedback.

Terms of Reference

Terms of reference and operational guidelines should be developed to guide the purpose, role and function of the PLIWG. The PLIWG would not have a formal advisory function nor formal reporting line to either the PLCAC or the Department.

The PLIWG may incidentally advise the Department on policy matters which may affect the medical device benefit setting scheme more broadly. It may also provide views on benefit

levels under the scheme, including any issues relating to IHPA's determinations of medical device benefit levels, and to the Department more broadly where required.

Membership

The membership of the PLIWG should be advisory rather than advocating in nature, and may include:

- ▶ Prostheses industry representatives;
- ▶ Private health insurance representatives;
- ▶ Private hospital representatives;
- ▶ Health economics expertise; and
- ▶ At least two consumer representatives.

Similar to the approach taken by the PLCAC, the PLIWG should not merely be a transposition of current advisory participants of the PLAC, but rather, selected on the basis of their ability to provide the advice required per the purpose, role and function of the PLIWG. A separate nomination and appointment process should be developed to support this.

The Department may also choose to make the PLIWG available for consultation more broadly.

Reporting

Members of the PLIWG may be able to make formal submissions on specific applications to the Department. This information may be considered by the Department, and provided as part of papers prepared for the PLCAC. The Department and PLCAC members should be guided in their consideration of such advice but are not obligated to accept the PLIWG's advice.

The PLIWG may prepare submissions for minor issues. The Department may determine the course of action required to address concerns or issues raised in any such submissions.

Recommendation 2: Introduce a reconstituted Clinical Experts Panel

A reconstituted Clinical Experts Panel (CEP) should be introduced to replace the abolished CAGs and to provide specialised clinical advice to support the PLCAC and the Department as required.

The CEP should provide specialised clinical advice on the clinical utility of medical devices and the clinical outcomes associated with the use of those medical devices to the PLCAC, by request or requirement of the PLCAC. Clinical utility should include consideration of the relative value of the medical device to other medical devices, drawing upon health economics expertise as necessary. This clinical advice should focus on those medical devices already listed and those proposed to be listed on the Prostheses List.

This body should not be focussed on clinical safety and efficacy issues with medical devices, which is the responsibility of the TGA. Where safety and efficacy issues are raised by the Panel, the matter should be referred by the PLCAC to the TGA for consideration.

The Panel's membership should include those with functional clinical expertise, with a particular focus on orthopaedics and cardiology.

The Department should consider how perceived, actual and potential conflict of interests of Panel members will be managed.

Rationale: A reconstituted CEP that replaces the abolished CAGs will provide both the Department and PLCAC with the specialised advice it requires across all Prostheses List Categories regarding the clinical utility of medical devices and the clinical outcomes

associated with the use of those medical devices. Having a smaller group of clinical experts to manage will also reduce the administrative burden on the Department.

Relevant Findings:

Finding 1 - Structure, focus and composition of the PLAC and its sub-committees

Finding 2 - Management of the workload of the PLAC

Reconstitution of the Panel of Clinical Experts

Although the utility and positive contribution of the CAGs were identified in this Review, the configuration and membership of CAGs (in their current form) do not enable the PLAC to fulfill its core functions and purpose. As such, the CAGs should be abolished and the existing Panel should be reconstituted into a CEP which the PLCAC may draw upon for advice relating to specific applications.

To ensure alignment with this revised approach, a terms of reference and operating guidelines should be designed for the CEP. These should outline the responsibilities of the PLCAC, and formalise arrangements for engagement.

To streamline matters, the Department may refer matters for specialised clinical advice to the CEP. These may include specialised clinical advice on the:

- ▶ Clinical utility of a medical device; or
- ▶ Clinical outcomes associated with the use of a medical device, including the relative value of the applicant medical device against relevant alternatives.

The ordinary work of the CEP should be in supporting the Department in its assessments where required. This advice from the CEP should constitute part of the briefing information required by the PLCAC to make a recommendation.

The Department should be clear in its reasons for referring matters to the CEP. It should provide the CEP with any assessment criteria as a frame of reference, and receive its advice in alignment with new documentary standards.

Where the PLCAC requires further information, its referral of matters to the CEP should be consistent with the processes followed by the Department. This will assist the CEP in remaining focused and oriented upon providing relevant expertise, and heighten the level of impartiality and scrutiny required by members in assessing applications.

Where a question of a medical device's safety and efficacy is raised in advice from the CEP, this matter should be referred to the TGA. Any advice from the CEP which constitutes as safety and efficacy should not be included in advice to the PLCAC as they are not constituted to do so.

Membership

The Department should place significant consideration into how it manages and arranges the CEP. It should not merely transpose CAG members onto the CEP, but identify those with the relevant functional clinical expertise required for the Department and PLCAC to fulfill their respective functions. Given the significant volume and complexity in orthopaedics and cardiology, the CEP should, at a minimum, have functional clinical expertise in these specialisations.

The Department should also consider how perceived, actual and potential conflicts will be managed.

Recommendation 3: Improve functional relationships between HTA committees

Processes for each HTA committee to access the relevant expertise of other HTA committees should be established. The MSAC, PBAC, IHPA and the TGA should be provided access to the PLCAC and the CEP to advise on clinical matters upon request.

Further, the PLCAC should strengthen the functional relationships with these bodies and their sub-committees and refer relevant matters to these bodies to enhance its advisory functions.

Rationale: The establishment of the PLCAC and the CEP provides an opportunity to make their expertise available to other HTA committees (the MSAC, IHPA and the TGA), which may enhance collaboration and functionality between the PLCAC and other committees. This will benefit HTA more broadly through reduced duplication of efforts and better use of the full range of skills available to the Department.

To facilitate this, the PLCAC and CEP should strengthen its functional relationships with other HTA committees.

Relevant Findings:

Finding 4 – Consistency of advice from the PLAC

Finding 5 - Relationship with the MSAC, the PBAC, the TGA and IHPA

Referrals to and from the PLCAC and the CEP

HTA in Australia will be enhanced through increasing access to the PLCAC and the CEP by HTA committees and other relevant bodies.

The reconstitution of the PLCAC and the CEP emphasise the need for functional clinical acumen and expertise to rigorously test medical devices for their clinical and cost effectiveness.

Governing documents, such as terms of reference and operating guidance, should outline arrangements to enable HTA and other various bodies to access the PLCAC and the CEP.

Referral and relational pathways should be redefined to provide clarification across all HTA committees as to the PLCAC's revised role in HTA, and the circumstances in which referrals and advice may be sought from the PLCAC. These should be developed and harmonised with the development of the PLCAC's assessment and outward referral criteria. This will ensure that the PLCAC has clarity in its role of supporting governance of the Prostheses List and enhance its advisory capabilities.

Further efforts may consider a variety of approaches, such as increased information sharing and updates between committees, or reviewing administrative arrangements to streamline referrals between bodies. Requests for advice from the PLCAC and the CEP should align with new documentary standards.

Uplifting the quality and consistency of advice issued by the PLCAC and the CEP will engender external confidence in the PLCAC and the CEP, and contribute to broader enhancements of HTA.

Recommendation 4: Introduce regular reviews of clinical appropriateness and utilisation medical device

Reviews of the clinical appropriateness, utilisation and benefits of medical devices on the Prostheses List should occur more regularly. The PLCAC should regularly make recommendations to remove obsolete and ineffective medical devices and consider advice for the Department on the revision of benefits where price and unexpected utilisation movements have been noted in the domestic or international market for listed medical devices.

Disputed post-listing benefit revisions should be discussed by industry and funding representatives at the PLIWG for consideration by the Department.

Rationale: Regular review will ensure that products on the Prostheses List are continuously and rigorously tested for clinical effectiveness and value for money, which will drive competition and encourage industry innovation.

Relevant Findings:

Finding 3 - Support from the Department

Finding 4 – Consistency of advice from the PLAC

Regular review of the Prostheses List

To rectify ongoing concern of the PLAC's limited fulfilment of post-listing review, the reconstituted PLCAC's terms of reference and any operating guidelines should uplift its responsibility for post-listing monitoring of medical devices upon the Prostheses List.

Reconstitution should be supported through the introduction of new criteria to support triggering a review.

Revisions to the PLCAC terms of reference and any operating guidelines should align the PLCAC's priorities across both assessing new applications and benefits setting with regular review, and the PLCAC should, in practice, not discriminate or prioritise fulfillment of one against the other. Reviews of significant medical devices should constitute as a standing item at each PLCAC Meeting.

To support this, the Department should provide reasons for a medical device's review, to guide the PLCAC's review discussions and ensure sustained focus upon scrutinising the item's continued clinical appropriateness and cost effectiveness. Reasons may include:

- ▶ **Obsolescence:** A medical device may be grandfathered, become obsolete or no longer available upon the market, and therefore should be removed from the list.
- ▶ **Clinically ineffective:** Post-market surveillance data has demonstrated that the medical device is not clinically effective compared to others on the market. This may include where devices lead to increased remedial work or infections.

Given the potential for obsolescence and clinical ineffectiveness, there is a need for a pre-determined post-listing review date to accompany all new items. This may be particularly relevant where the market has demonstrated rapid innovation for certain medical technologies.

Regular review of the Prostheses List will demonstrate the PLCAC's efforts to increase accountability, transparency and product accessibility in line with broader Prostheses List Reforms. This will enhance the PLCAC's advisory responsibilities to the Minister, strengthening overall management and oversight capabilities.

Post-market data to support regular Prostheses List review should draw upon both the domestic and international market to ensure that consumers are continuously being provided value for money.

Advice from PLIWG on benefit revision disputes

In instances where the revision or setting of benefits for a medical device are disputed, the PLCAC may seek input on a case-by-case scenario from the PLIWG to consider as a part of PLCAC discussions. Formal reasons for the PLIWG's advice should be consolidated for review by TAAD ahead of distribution to the PLCAC for discussion. These reasons should be made in line with enhanced documentation requirements. This approach will ensure that industry stakeholders are provided with a formal channel to provide input, but allow the PLCAC to remain focused on the assessment of clinical and cost effectiveness.

Alignment with 2021-22 Budget announcement

It is noted that Reforms plans announced in the 2021-22 Budget (May 2021) indicate that the Department will be improving post-listing monitoring, including an enhanced program of utilisation reviews.

Recommendation 5: Increase the Department's capability for post-listing surveillance

The Department's capability for post-listing price, utilisation and clinical outcome surveillance should continue to be increased. This should include the development of data and information sources for medical device utilisation, price and clinical outcome monitoring as well as strengthening of the HTA process.

Rationale: By continuing to enhance the Department's responsibility for post-listing surveillance, the PLCAC will be able to focus its attention on interpreting the clinical drivers and implications of the results and making recommendations accordingly.

Relevant Findings:

Finding 3 - Support from the Department

Finding 4 – Consistency of advice from the PLCAC

Consideration of a criteria to review

The Department should consider developing an internal criterion to support regular post-listing review by the PLCAC. This criteria should assist the relevant area of the Department in developing the datasets required to inform the need and necessity for both the Department and the PLCAC to conduct post-listing review.

Where anomalies in data extracted from post-market surveillance are detected, processes should accompany the criteria to enable further investigation and information gathering to inform a new recommendation.

Enhancement of post-market intelligence sources

This Review has identified five central sources for post-market intelligence:

- ▶ Hospital Casemix Protocol ('HCP1') Data;
- ▶ Registry data, such as the National Joint Replacement Registry;
- ▶ Health fund data, for benefits paid for usage of medical devices;
- ▶ Aggregated data, provided by IHPA; and
- ▶ Post-market surveillance and incident reporting, conducted by the TGA.

The Department should develop a data strategy for supporting post-market price, utilisation and clinical outcome surveillance. In doing so, it should aim to ensure accurate and recent data is available, and work with the PLCAC to identify key metrics and reporting requirements.

Development of the Department's post-market intelligence capability

In order to manage post-market intelligence sources, the Department should place due consideration into building its internal capability to manage, analyse and synthesise the data so that it may be utilised to inform regular review. These Departmental resources should be skilled in identifying errors or anomalies in reporting to escalate or trigger a review or further investigation, and guide continuous improvement efforts with data owners to ensure that the data required meets the needs of the PLCAC.

Development of formal processes to support post-market information sharing

It is recognised that post-market intelligence may arise from these five central sources. The Department should collaborate with information owners to identify and develop comprehensive information sharing arrangements for post-market information. These arrangements should also consider the PLCAC and the CEP. The development of such systems and processes may include additional policies, procedures or guidelines which consider quality, efficiency and accessibility of information to inform decision-making.

Recommendation 6: Enhance documentation of decisions

The Department should continue to provide documentation of prior Prostheses List decisions to improve the consistency of decision-making in the future.

Rationale: The introduction of standard templates for responses, which include explanations and reasons for referrals and decisions, will improve the consistency of decision-making.

These templates should be designed to be comprehensive covering all key aspects of the application, the context at the time and the rationale for decisions/recommendations made. This will provide future assessments with a detailed understanding on which to base those decisions.

Relevant Findings:

Finding 2 - Management of the workload of the PLAC

Finding 3 - Support from the Department

Finding 4 – Consistency of advice from the PLAC

Development of standard templates

To uplift the quality and standard of documentary evidence, the Department should develop templates to document the PLCAC's recommendations and advice to the Minister. This would enable for a more uniform approach to corporate and historical record-keeping, and enhance the ability to recall precedent. These templates should, at a minimum, provide the PLCAC's final recommendation to the Minister; substantive reasoning for this recommendation; and provide any material facts from advice sought to inform this recommendation, such as any referrals made to the MSAC, the TGA or the CEP. These templates should also demonstrate how the medical device has met the criteria for assessment for listing and benefits setting.

This template should also be appropriated for the CEP's advice to the PLCAC.

Integration with IT solutions

These templates should be developed with the intent of strengthening documentation and record-keeping of government decision-making, and should be supported by an integrated IT solution for applications management which enables the ability to recall precedent.

Completed templates should be archived and itemised in such a way that enables swift identification of the relevant medical devices (e.g. reference code), and consistent with any government recordkeeping requirements. This IT solution should be usable by the Department, the PLCAC and the CEP members to enable easier reference to precedent.

Inclusion in minutes and with contemporaneous applications

The minutes for PLCAC Meetings should include reference codes for the documentation of the PLCAC's final decision. This will streamline the ability to refer back to the PLCAC's final recommendations and reasoning where precedent is required in a decision. Further, where new applications are escalated to the PLCAC for consideration, the Department should include references to any precedent which may be relevant to the PLCAC's decision-making process. Completed templates should be attached as supplementary material to enable PLCAC members to consider as a frame of reference.

Timing

With consideration of other process improvements and streamlining efforts recommended in this Review, documentation for each PLCAC Meeting should be made available at least two weeks prior to meetings. Although this is outlined in the current PLAC Terms of Reference, this is not often fulfilled by TAAD. The Department should consider integrating this as part of its internal performance measures.

Recommendation 7: Increase referrals on safety and efficacy to the TGA

All matters relating to safety and efficacy of medical devices should be referred by the PLCAC to the TGA for action. The PLCAC should strengthen its functional relationship with the TGA to enable referrals and enhance its advisory functions.

Rationale: These matters are the responsibility of the TGA and align with its expertise. The PLCAC or CEP considering similar matters would either create inefficiencies or risk inconsistencies in findings.

Relevant Findings:

Finding 4 – Consistency of advice from the PLAC

Finding 5 - Relationship with the MSAC, the PBAC, the TGA and IHPA

Clarification of guidelines to refer matters to TGA

The PLCAC's reconstitution and reorientation should enable it to focus predominantly on clinical benefits, appropriate utilisation and value for money of medical devices for recommendation to the Minister. However, this should strictly preclude any and all matters relating to safety and efficacy, and the PLCAC should ensure that it does not deviate into dealing with such matters.

To support this, the PLCAC's reconstituted terms of reference and operating guidelines should be designed to clarify the criteria and process for referring matters to the TGA. These revisions should be modelled upon the current PLAC Terms of Reference and its provision of a criteria for applications for referral to the MSAC. Similarly, this criterion should propose a threshold and provide a uniform understanding of 'safety' and 'efficacy' for PLCAC members.

Strengthening the functional relationship with the TGA

The advice sought from the TGA on safety and efficacy should be included in the PLCAC's recommendations for listing and benefits setting. Any referrals to the TGA, and advice from the TGA received by the PLCAC, should be included as reasons.

To enable this to occur, the Department and PLCAC should consider ways in which they may strengthen their relationship with the TGA. This may also include functional improvements, such as providing greater visibility to the TGA of the carriage of the Department's and PLCAC's work, or in the TGA's ability to provide relevant updates and information at PLCAC Meetings.

As a part of this, the Department and PLCAC should also consider ways in which referrals to the TGA may be streamlined. This will ensure that safety and efficacy considerations are addressed in a uniform manner, and enhance the consistency and quality of the Department's and PLCAC's advisory functions.

Recommendation 8: Develop clear criteria which outline the Prostheses List assessment process

Clear assessment criteria for medical device listing, benefit setting, utilisation review and benefit review should be developed by the Department. IHPA should publish its process and methodology for public reference pricing.

Rationale: Clear assessment criteria for medical device listing, benefit setting, utilisation review and benefit review should be published by the Department.

This will improve the consistency and transparency of advice relating to the listing and benefits of items on the Prostheses List.

Relevant Findings:

Finding 2 - Management of the workload of the PLAC

Finding 3 - Support from the Department

Finding 4 – Consistency of advice from the PLAC

Clarification of the assessment criteria of listing and benefits setting

The Department should establish clear and accessible assessment criteria to guide how the PLCAC should make recommendations for prostheses listing and benefits setting. This should be developed by the Department with the aim of heightening the accessibility of the Prostheses Rules.

This assessment criteria should harmonise with the development of templates, and clearly demonstrate why the medical device qualifies for listing, and reasons for the benefits recommended. This criteria should not replace the existing Prostheses Rules, but increase its accessibility to the Department, the PLCAC and the CEP to ensure a uniform understanding and applicability across all.

This criteria should provide a frame of reference for when matters require referral to the PLCAC or the CEP by the Department. This should assist in orienting PLCAC discussions and mitigate its tendency to deviate from its core purpose. The criteria should also identify the circumstances in which referrals for further advice should be made, such as matters of safety and efficacy to the TGA.

The criteria should clarify how submissions of advice tendered by the PLIWG to the Department should be considered by both the Department and the PLCAC. The Department and the PLCAC should have no obligation to accept the advice tendered by the PLIWG. Advice tendered by the PLIWG may be referred onwards to the MSAC's ESC should the Department and PLCAC require further validation of advice independent of stakeholders' interests.

The criteria should also be made available to the CEP as a frame of reference, and to guide where advice is being sought.

Publication of public reference pricing

It is commonly acknowledged that functional clinical experts may not necessarily have requisite skills to perform benefits setting. To support the PLCAC's function, IHPA should publish the process and methodology it uses to develop public reference pricing. This should enhance transparency and enable robust debate on value for money; decrease the information asymmetry currently being exhibited between those in a clinical advisory capacity and industry advocates; and contribute to an application's satisfaction of the aforementioned assessment criteria for benefits setting.

Clarification of criteria for utilisation and benefits review

Efforts to streamline work related to the Prostheses List should enable the relevant area of the Department and the PLCAC to increase their capacity for post-listing review. Currently, no criterion exists to instigate a post-listing review. Clarification of a criteria for a review of utilisation and benefits would strengthen the Department's and the PLCAC's support of the Minister and overall governance of the Prostheses List. A range of circumstances should be considered, such as:

- ▶ **Utilisation anomalies:** With due consideration of enhanced post-market surveillance, the Department should review items where there is an excess or deficiency in the utilisation of the device, which is not aligned with the data supplied by the manufacturer or sponsor.
- ▶ **Incident reporting:** With due consideration of an enhanced functional relationship with the TGA, where the TGA shares issues of safety and efficiency regarding a medical device with the PLCAC, the Department should review medical devices with regard to the impact of safety and efficiency upon potential utilisation.

The Department should identify baselines and thresholds required to trigger reviews and, as such, utilisation and benefits review should be made a standing item in the TAAD and the PLCAC's ordinary work.

Recommendation 9: Develop clear criteria to identify an HTA requirement

Clear criteria should be established by the Department to define when a formal HTA will be conducted prior to the consideration of new applications or benefit revisions.

Rationale: Clear criteria for an HTA will enable the Department to run a consistent, well-understood and efficient triaging system for applications; and also allow the PLCAC and the CEP to determine if an application should be referred for a HTA process as this may only become evident once an assessment has occurred.

Relevant Findings:

Finding 2 - Management of the workload of the PLAC

Finding 3 - Support from the Department

Clarification on criteria for focused and formal Health Technology Assessments

The Department should clarify the circumstances in which a formal HTA is required prior to the consideration of new applications or benefit revisions. This criteria should harmonise with the assessment criteria for medical device listing and benefit setting to guide the information sought through the HTA.

The criteria should consider the circumstances in which a focused HTA or a formal HTA may be required. An assessment against this criteria should occur prior to considering new applications or benefit reviews. This will enable the Department to receive the further information required to determine the need to escalate discussions on a medical device to the PLCAC, as well as enabling HTA information to be included for discussion at the PLCAC.

The criteria should seek to provide the Department and PLCAC with identifying information gaps in applications. This will reduce the need for the Department and PLCAC to call upon industry advocates to provide further information for a manufacturer or sponsor's application. These efforts should ensure that any needs for further information are mitigated ahead of PLCAC Meetings, enabling them to make informed decisions more efficiently.

Recommendation 10: Streamline workloads to optimise clinical capability available for assessments

The workload of the PLCAC should be more effectively streamlined so that only applications and revisions of a significant nature are considered by the PLCAC.

Significant matters should include all novel medical device applications, significant benefit revisions and removals of medical devices from the Prostheses List.

Other matters should be the subject of consideration of the relevant area of the Department with the proposed advice to the Minister published for each matter for 28 days so that industry or funders can review these delegated advisory decisions and raise them for discussion at the Department.

Rationale: This change is intended to reduce inefficiencies in the assessment process.

This would mean that only applications and revisions of a significant nature are considered by the PLCAC, with more straightforward matters and/or matters that are not expected to have a material impact on overall funding through the Prostheses List to be considered by the Department.

The PLCAC and CEP bring unique clinical skills to the assessment process and so add the most value to the assessment of complicated matters and/or matters that may have a material impact on overall funding through the Prostheses List. Meanwhile, the Department is capable of appropriately assessing uncomplicated applications efficiently.

Relevant Findings:

Finding 2 - Management of the workload of the PLAC

Finding 3 - Support from the Department

Finding 5 - Relationship with the MSAC, the PBAC, the TGA and IHPA

Streamlining workload through implementation of an escalation process

The Department should formalise a criteria and process for which matters should be escalated to the PLCAC to maximise use of the relevant clinical capability required for assessments.

The introduction of criteria for new applications and reviews should clarify escalation points in the assessment of medical devices for listing and review of medical devices and benefits on the Prostheses List. The criteria based upon the clinical capability required should provide guidance as to what may be considered a 'minor matter' for action by the Department. This may include matters which are relatively uncomplicated, or do not require specialised clinical experience. This criteria will enhance the Department's internal decision-making capability, making it less reliant upon the PLCAC for minor matters or matters outside of the PLCAC's scope of responsibilities.

The escalation process should consider trigger points to which the Department should refer matters onwards to the PLCAC where it requires further clinical capability. These points may be due to limited in-house capability in the need for functional clinical expertise, or if robust debate is required to rigorously test an item such as for a novel technology. Trigger points may also include instances such as:

- ▶ **Novel applications for listing:** Where a new technology has arisen, which is new and novel and therefore requires a HTA, and no like devices are available to comparatively assess all or some of the device.
- ▶ **Significant benefit revisions:** Where a substantive data anomaly in utilisation detected by the Department has warranted further scrutiny due to misalignment with information provided by the sponsor and/or manufacturer.

- **Removal of medical devices from Prostheses List:** Where the TGA has raised significant concerns as to the safety of a medical device listed on the Prostheses List, which has led to the ARTG entry being changed for a medical device due to evidence of increased risk.

This process should consider whether all information required has been sought from relevant sources, such as safety and efficacy considerations from the TGA, before escalation to the PLCAC.

All matters escalated to the PLCAC should include a high-level summary of the Department's requirement and decision to escalate. This will contribute to the Department's continuous improvement efforts in enabling identification of capability and resource planning to further streamline its functionality.

Publication of minor matters

To further relieve the Department and the PLCAC from dealing with matters that are straightforward and/or are not expected to have a material impact on overall funding through the Prostheses List, a process should be identified through which the Department should publish such matters for review by stakeholders. Where further advice is sought, applications should be made available for 28 days (or some other relevant period) to relevant stakeholders to provide further comment. In the absence of a formal contributory role, the PLIWG may respond to these matters in writing for consideration by the Department. Publication may occur at any time to avoid backloading immediately ahead of a PLCAC Meeting.

This approach should mitigate challenges currently experienced by the PLAC in the tendency for disputes to arise between industry stakeholders, and provide an optional channel to seek industry contributions.

Recommendation 11: Introduce review dates for all medical device listings

All listings to the Prostheses List should be accompanied by a review date for the relevant area of the Department to consider the ongoing need for the medical device to be on the Prostheses List and the level of the benefit set.

Rationale: At that point, the Department would consider the ongoing need for the medical device to be on the Prostheses List and the level of the benefit set.

A mandatory and defined trigger for review will support greater competition and innovation on the Prostheses List.

Relevant Findings:

Finding 3 – Support from the Department

Finding 4 – Consistency of advice from the PLAC

Introduction of planned review dates

To enhance the Minister's responsibility for oversight and management of the Prostheses List, all new listings for the Prostheses List should include a review date by the Department and, if necessary, the PLCAC. This approach will strengthen the Department and the PLCAC's review functions, and will contribute to efforts to enhance transparency and accountability arrangements which underpin the Prostheses List.

The relevant area of the Department and PLCAC should also develop a workplan to review all current items listed on the Prostheses List.

The introduction of planned review dates should contribute to resource and capability planning for the Department. Reviews will be further enhanced by the regular provision and availability of relevant post-market data, such as utilisation trends. As such, the Department will need to develop data strategies to meet review needs.

7. Reliances and limitations

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In carrying out the work and preparing this report, EY has worked solely on the instructions of the Department, and has not taken into account the interests of any party other than the Department. The report has been constructed based on information current as of 19 July 2021, some of which has been provided by the Department. Since this date, material events may have occurred since completion which is not reflected in the report. The report is based in part on information and data supplied by the Department. We have not sought to verify the accuracy of data or information provided to us by the Department.

Other specific limitations to the report are described in Section 2.4.

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8. Appendices

Appendix A – Structure of the Prostheses List

As of 2021, the Prostheses List contains three parts:

- ▶ **Part A** - Surgically implantable devices and integral single-use aids used to implant or maintain the implanted device;
- ▶ **Part B** - Human tissue-based products that are regulated by the TGA as 'biologicals'; and
- ▶ **Part C** - Devices which do not meet the criteria for Parts A or B and are determined at the Minister's discretion.¹⁹

Parts A and B are divided in a tiered system: categories, subcategories, groups and subgroups. The categories of the Prostheses List are:

- ▶ 01 - Ophthalmic
- ▶ 02 - Ear Nose and Throat
- ▶ 03 - General Miscellaneous
- ▶ 04 – Neurosurgical
- ▶ 05 - Urogenital
- ▶ 06 - Specialist Orthopaedic
- ▶ 07 - Plastic and reconstructive
- ▶ 08 - Cardiac
- ▶ 09 - Cardiothoracic
- ▶ 10 - Vascular
- ▶ 11 - Hip
- ▶ 12 – Knee
- ▶ 13 – Spinal.

These categories are then divided into sub-categories, and allocated into groups which reflects the devices':

- ▶ function;
- ▶ design;
- ▶ performance; and
- ▶ expected outcome.

The Prostheses List also provides information including:

- ▶ the billing code for each product;
- ▶ a name, description and size(s) of each product listed under the billing code; and
- ▶ the minimum amount of benefit insurers pay for each product.²⁰

The Prostheses List is updated approximately three times a year in 'cycles'.

¹⁹ Commonwealth of Australia, *Price regulation associated with the Prostheses List Framework*, available at https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework/Report.

²⁰ Above n 4.

Appendix B - Terms of Reference

EY was engaged by the Department to undertake this Review of the PLAC and its associated sub-committees with the following Terms of Reference:

Current role/purpose	
► Is the role of PLAC clearly defined and well understood?	Findings 1 – 2, 5
► Is the current membership, composition and structure of PLAC fit for the purpose of providing advice to the Minister for Health?	Findings 1 – 2, 4
► Is the PLAC providing sufficient scrutiny of new and amendment applications, for the delegate to have confidence in its advice? If not, what changes would be needed for PLAC to meet this mandate?	Findings 1 – 4
Potential role	
Implementation of Prostheses List Reforms	Recommendations 1 – 3
► What, if any, role would there be for the PLAC in the implementation of Prostheses List reforms?	
► Specifically, in relation to the Department strengthening its health technology assessment capability through systematic and formalised assessment of both clinical and economic evidence conducted through academic evaluation units taking on the majority of assessments rather than by Clinical Advisory Groups?	Recommendations 1 – 3, 6 - 11
Ongoing administration of the Prostheses List	Recommendations 1 – 3, 8, 10
► What role, if any, should there be for PLAC in the ongoing administration of the Prostheses List once reforms are implemented?	
► What role, if any, should PLAC undertake in the ongoing review of items listed on the Prostheses List?	Recommendations 4 – 5, 8, 11
Composition and governance	
► What should be the composition of PLAC?	Recommendations 1 – 2
► How should potential members be identified and appointed?	Recommendations 1 – 2
► What should be the governance structure of PLAC?	Recommendations 1 – 2
► In particular could it be a sub-committee of the MSAC or an independent committee/expert panel (that would seek HTA advice from the MSAC)?	

Appendix C - Schedule of Documents

The documents listed below were used by EY for the purposes of the desktop review.

Governance documents

- ▶ **Commonwealth of Australia**
 - ▶ Australian Government Charging Framework.
- ▶ **Department of Health**
 - ▶ Health Technology Assessment Committees Conflict of Interest Process Guide, June 2020;
 - ▶ Cost Recovery Implementation Statement 'Administration of the Prostheses List', July 2021
 - ▶ Cost Recovery Implementation Statement 'Prostheses List', April 2021;
 - ▶ Prostheses List Guide, February 2020.
- ▶ **Prostheses List Advisory Committee**
 - ▶ Parent committee
 - Current membership, as per the Department of Health at July 2021;
 - Terms of Reference, June 2017;
 - Operating Guidelines, April 2019;
 - Meeting Minutes: May 2020; September 2020; November 2020;
 - ▶ Clinical Advisory Groups
 - Current membership, as per the Department of Health at July 2021;
 - Terms of Reference, June 2017;
 - Operating Guidelines, May 2017;
 - Clinical Advisory Groups and Panel of Clinical Experts Nomination and Appointment Process, February 2020;
 - ▶ Panel of Clinical Experts
 - Current membership, as per the Department of Health at July 2021;
 - Terms of Reference, February 2018;
 - Operating Guidelines, no date;
 - Clinical Advisory Groups and Panel of Clinical Experts Nomination and Appointment Process, February 2020;
 - ▶ Health Economics Sub-Committee (inactive)
 - Terms of Reference, August 2017;
 - Operating Guidelines, August 2017.
- ▶ **Medical Services Advisory Committee**
 - ▶ Current membership, as per the Department of Health at July 2021;
 - ▶ Terms of Reference, November 2020;
 - ▶ Public Summaries: July 2020; November 2020; April 2020;
 - ▶ Economics Sub-Committee
 - Terms of Reference, October 2012.
- ▶ **Pharmaceutical Benefits Advisory Committee**
 - ▶ Operating Guidelines, September 2016;
 - ▶ Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme, December 2020;
- ▶ **Medical Technology Association of Australia**
 - ▶ Hibernation of Agreement with the Medical Technology Association of Australia (MTAA), July 2020
 - ▶ Agreement between the Government and the Medical Technology Association of Australia (MTAA), October 2017.

Open Source Information

- ▶ **Department of Health**

- ▶ Post-Budget stakeholder briefing on 'Modernising and improving the private health insurance Prostheses List';
- ▶ Fact Sheet 'Modernising and improving the private health insurance'.

Reports

- ▶ *Stopping the death spiral – creating a future for private health*, Grattan Institute, May 2021;
- ▶ *Review of the General Miscellaneous Category of the Prostheses List*, EY, July 2020;
- ▶ *Options for a Revised Framework for Setting and Reviewing Benefits for the Prostheses*, Menzies Centre for Health Policy, December 2020;
- ▶ *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models*, 2017;
- ▶ *Revised Benefit Setting and Review Framework Industry Working Group Meeting Communiques*;
- ▶ *Senate Community Affairs Reference Committee: Price regulation associated with Prostheses List Framework*, Commonwealth of Australia, May 2017.

Appendix D – Stakeholder Consultation List

The list below provides the stakeholders consulted as part of this Review.

Organisation	Representative	Role
Prostheses List Advisory Committee		
	Professor Terry Campbell (AM)	Chair
	Professor David Morgan OAM	Expert Member
	Professor Bill Heddle	Expert Member
	Professor Allan Glanville	Expert Member
	Associate Professor Rosemary Korda	Expert Member
	Professor Anne Simmons	Expert Member
	Adjunct Professor Jim Butler	Expert Member
PLAC Clinical Advisory Groups		
Cardiac	Associate Professor Glenn Young**	Chair
Cardiothoracic	Professor Jayme Bennetts	Chair
Hip	Professor Stephen Graves	Chair
Ophthalmic	Dr Con Moshegov	Chair
Specialist	Dr David Gill	Chair
Spinal	Dr Orso Osti	Chair
Vascular	Dr Peter Thursby OAM	Chair
Panel of Clinical Experts		
Ear, Nose & Throat	Professor Stephen O'Leary	Panellist
Plastic & Reconstructive	Dr Gillian Farrell	Panellist
Neurosurgical	Dr Patrick Lo	Panellist
Government committees and agencies		
Therapeutic Goods Administration	Tracey Duffy	First Assistant Secretary, Medical Devices and Product Quality Division
Pharmaceutical Benefits Advisory Committee	Professor Andrew Wilson	Chair
Medical Services Advisory Committee	Professor Robyn Ward	Chair
Independent Hospital Pricing Authority	Joanne Fitzgerald	Executive Director of Hospital Policy and Classification

Organisation	Representative	Role
	James Downie	Chief Executive Officer
Non-government organisations		
Consumer Health Forum of Australia	Jo Root	Policy Director
Medical Technology Association of Australia	Paul Dale*	Policy Director
Private Healthcare Australia	Ben Harris*	Director Policy & Research
Members Health Fund Alliance	Matthew Koce	Chief Executive Officer
	Dr Jui Tham	Medical Officer, Strategy & Development
	Eddie Morton	N/A
Day Hospitals	Jane Griffiths	Chief Executive Officer
	Gabby Moreland*	ACT Member Director
Catholic Health Australia	James Kemp	Chief Operating Officer
	Stephanie Panchision	Senior Policy Advisor
Australian Private Hospital Association	Lucy Cheetham	Acting Chief Executive Officer
	Emma Bognar*	N/A
Cabrini Health	Cathy Ryan*	Group Director Health Funding & Patient Services
Australian Medical Association	Tracey Cross	Senior Policy Advisor

* indicates that the representative is also a member of the PLAC.

** indicates that the stakeholder provided a written submission to this Review.

Appendix E – Schedule of PLAC Members, including CAGs and Panel of Clinical Experts

The lists below provide the memberships of the PLAC and its sub-committees as at July 2021.

Prostheses List Advisory Committee

Role	Name	Specialty / Representing
Chair	Professor Terry Campbell (AM)	N/A
Expert member	Professor David Morgan OAM	Orthopaedic surgery
	Dr Orso Osti	Spinal surgery

Role	Name	Specialty / Representing
	Associate Professor Rosemary Korda	Epidemiology
	Professor Bill Heddle	Cardiology
	Professor Allan Glanville	Thoracic medicine
	Professor Anne Simmons	Bioengineering
	Professor Abdullah Omari	Vascular medicine
	Professor Robyn Ward	Medical Services Advisory Committee Representative
	Adjunct Professor Jim Butler	Health economics
Advisory member	Ms Emma Bogнар	Australian Private Hospitals Association
	Ms Cathy Ryan	Cabrini Health
	Dr Jui Tham	Members Health
	Dr Greg Roger	AusBiotech
	Ms Gabrielle Moreland	Day Hospitals Australia
Invited attendee	Mr Paul Dale	Medical Technology Association of Australia
	Mr Ben Harris	Private Healthcare Australia
Consumer representative	Dr Henry Ko	N/A

Clinical Advisory Groups

Role	Name
Cardiac Prostheses Clinical Advisory Group	
Chair	Associate Professor Glenn Young
Member	Associate Professor Jayme Bennetts
	Dr Russell Denman
	Dr Angas Hamer
	Dr Sharad Shetty
	Professor Darren Walters
Consumer representative	Ms Eileen Jerga AM
Cardiothoracic Prostheses Clinical Advisory Group	
Chair	Associate Professor Jayme Bennetts

Role	Name
Member	Mr Bruce Davis
	Dr Hugh Wolfenden
	Dr Morgan Windsor
Consumer representative	Mrs Monica Schlesinger
Hip Prostheses Clinical Advisory Group	
Chair	Professor Stephen Graves
Member	Mr John Harris
	Associate Professor Graham Mercer
	Mr James Stoney
Consumer representative	Mr Neville Millen
Knee Prostheses Clinical Advisory Group	
Chair	Dr Peter Lewis
Member	Professor Stephen Graves
	Associate Professor Stephen Rackemann
	Associate Professor Christopher Vertullo
Consumer representative	Dr Colleen Papadopolos
Knee Prostheses Clinical Advisory Group	
Chair	Dr Peter Lewis
Member	Professor Stephen Graves
	Associate Professor Stephen Rackemann
	Associate Professor Christopher Vertullo
Consumer representative	Dr Colleen Papadopolos
Knee Prostheses Clinical Advisory Group	
Chair	Dr Peter Lewis
Member	Professor Stephen Graves
	Associate Professor Stephen Rackemann
	Associate Professor Christopher Vertullo
Consumer representative	Dr Colleen Papadopolos
Ophthalmic Prostheses Clinical Advisory Group	

Role	Name
Chair	Dr Con Moshegov
Member	Dr Andrew Chang
	Dr Iain Dunlop AM
	Dr Ralph Higgins OAM
	Dr Patrick Versace
Consumer representative	Ms Joanne Baumgartner
Specialist Orthopaedic Clinical Advisory Group	
Chair	Dr David Gill
Member	Dr Christopher Brown
	Dr Phillip Dalton
	Dr David Lunz
	Dr Ash Moaveni
	Dr John North
	Dr Aneel Nihal
	Dr Jeffery Peereboom
	Associate Professor Marinis Pirpiris
	Dr Peter Stavrou
Consumer representative	Dr Janney Wale
Spinal Prostheses Clinical Advisory Group	
Chair	Dr Orso Osti
Member	Dr Ian Cheung
	Mr Patrick Chan
	Dr Xenia Doorenbosch
	Dr Samya Lakis
Consumer representative	Ms Elizabeth Carrigan
Vascular Prostheses Clinical Advisory Group	
Chair	Dr Peter Thursby OAM
Member	Dr Toby Cohen
	Dr Andrew Lennox

Role	Name
	Professor Abdullah Omari
Consumer representative	Ms Eileen Jerga AM

Panel of Clinical Experts

Speciality	Name
Ear, nose and throat	Dr Hannah Burns
	Professor Simon Carney
	Professor Peter Friedland
	Professor Stephen O'Leary
	Professor Raymond Sacks
	Melville Da Cruz
	Associate Professor Daniel Novakovic
General miscellaneous	Dr Andrew Cotterill
	Dr Charles Fisher
	Dr Bill Fleming
	Professor Allan Glanville
	Dr Jane Holmes-Walker
	Dr Meron Pitcher
	Associate Professor Glynis Ross
	Mr Gil Shardey
	Dr Siew-Piau Tan
	Dr Scott Williams
	Dr Morgan Windsor
	Mr Michael Johnston
	Michael Mar Fan
Neurosurgical	Dr Jerry Day
	Dr David Johnson
	Dr Patrick Lo
	Dr Raoul Pope
	Dr David James Taylor
Plastic and reconstructive	Dr Paul Coceanig
	Dr Miles Doddridge
	Dr Gillian Farrell

Speciality	Name
	Dr Walter Flapper
Urogenital	Dr Emmanuel Karantanis

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