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Options for a Reformed Prostheses List Pre-Listing Assessment Framework and Governance Structure

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Summary

As part of the Australian Government Department of Health and Aged Care Prostheses List Reform program, Adelaide Health Technology Assessment have developed a framework and several options for governance that will align the Prostheses List (PL) processes with those of other health technology assessment (HTA) processes within the Government. This will help to ensure that the PL fulfils its purpose of ensuring that privately insured Australians have access to clinically effective prostheses that meet their health care needs.

The underlying principles that guide the HTA system in Australia state that HTA processes should be sustainable; transparent, accountable and independent; consultative and reflective of Australia community values; administratively efficient; flexible and fit for purpose; and, informed by robust and relevant evidence. These principles have guided the options provided for governance and helped to inform the framework under which a revised PL could operate.

A comparison of the PL, the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Scheme (MBS) processes was undertaken. Key differences included responsibility for undertaking the HTA, membership of stakeholders on committees, and provision of guidelines and templates for applications and evaluators. Other reviews of the PL process have identified similar issues. It is suggested that the following elements be included in a reformed PL process:

- Improved guidelines and templates to clarify eligibility for pathways, evidence requirements and presentation of information to encourage a consistent approach across all applications
- External, independent HTA evaluation of PL applications
- Stakeholders removed from decision-making committees
- Publication of Public Summary Documents that outline the rationale for decisions made by the committee.

Several alternatives for governance of a reformed PL process have been suggested by the department and stakeholders through a recent consultation process on assessment pathways. Most include optimising Prostheses List Advisory Committee (PLAC) membership through removing stakeholders whilst incorporating formal feedback mechanisms during the assessment process, re-examining the role of clinical experts and the Clinical Advisory Groups, the provision of improved guidelines and templates for applications and evaluation groups, and the publication of Public Summary Documents.

The governance options proposed are also related to the HTA pathways which are being developed in collaboration with stakeholders. Much of the efficiency gain in the process will be obtained through better pathways which appropriately resource assessment dependent on the risk to consumers, and to the health system more widely, of including a device on the PL.

In summary, the governance options proposed enable the PL process to reflect the underlying principles of HTA to a greater or lesser extent. Some options will require more resources for the Department, which may impact on sustainability, however cost-recovery will aid in this. The use of improved guidelines and templates, the provision of Public Summary Documents, and the use of external, independent evaluators will all contribute to the process becoming more transparent, accountable and independent. Formal feedback mechanisms that enable all stakeholders to engage in a timely manner ensure that the process is consultative and reflects Australian community values.

To ensure administrative efficiency, the new pathways will help allocate resources appropriately according to risk, and the guidelines and templates will add to this efficiency by clarifying the evidence that is required for eligibility for each pathway. The new pathways will also enable the process to be flexible and fit-for-purpose. Aligning the PL process with the other HTA processes, and being clear about the evidentiary requirements for each type of listing, will ensure that each decision is informed by robust and relevant evidence.

Acronyms

Acronym	Description
ADAR	Applicant developed assessment report (MSAC process)
ARTG	Australian Register of Therapeutic Goods
ATAGI	Australian Technical Advisory Group on Immunisation
CAG	Clinical Advisory Group
DCAR	Department contracted assessment report (MSAC process)
DUSC	Drug Utilisation Sub-committee
ESC	Evaluation Sub-committee (MSAC ESC) or Economic Sub-committee (PBAC ESC)
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
PASC	PICO confirmation Advisory Sub-committee
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PICO	Population Intervention Comparator Outcome
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
PoCE	Panel of Clinical Experts
TGA	Therapeutic Goods Administration

Glossary

Term	Definition
Assessment Group	An independent consultancy group with expertise in health technology assessment that is contracted by the Department of Health and Aged Care to assess applications.
Clinical Advisory Group	A group of clinical experts familiar with the use of the device type and/or for a range of conditions who can provide advice to the Assessment Groups (if required) and Department.
Health Technology Assessment	A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. The process is formal, systematic and transparent, and uses state-of-the-art methods to consider the best available evidence.
Post Market surveillance	Activities conducted after a device is released onto the market. These data pertain to issues that arise with the device's production, distribution and use. Post Market Surveillance data are collected passively through the manufacturer or regulatory agencies and are used to detect potential safety signals to the patient or user.
Technical Sub-committee	A Sub-committee of the Advisory Committee that provides technical advice to its parent committee and to the Assessment Group

Introduction

The Australian Government committed $22 million in the 2021-22 Federal Budget to improve the PL and its arrangements. The Prostheses List Reform Taskforce of the Australian Government Department of Health and Aged Care ('the Department'), working with insurers, hospitals, manufacturers and clinicians, aims to ensure that the List will become more efficient, transparent and current.(1)

Adelaide Health Technology Assessment (AHTA), University of Adelaide were contracted by the Prostheses List Reform Taskforce to propose governance options and assessment pathways for a reformed PL application and determination process.

During the development of the governance structure and proposed assessment pathways, the scope of the project was changed to allow greater stakeholder involvement. This was in response to the signing of a Memorandum of Understanding (MoU), on 14 March 2022, between the then Minister for Health and Aged Care, the Hon Greg Hunt MP and the Medical Technology Association of Australia (MTAA) which set out the final policy parameters for the PL Reforms.(1) As a consequence, AHTA undertook further work with stakeholders to co-design the PL assessment pathways. The findings from multiple stakeholder consultation workshops are contained in a subsequent report. The MoU also sets out the implementation approach to the reference pricing reforms, and notes that regrouping of the PL is not to be "an additional source of savings on top of the overall reference pricing savings". Benefit setting, PL grouping amendments and other aspects of the PL Reforms are out of scope for this report.

This current report contains an outline of a framework and options for governance structures that would align the PL application and assessment process with other HTA activities in the Department.

Objectives

The project objectives and findings in this report relate to the initial scope of work dated 5th December 2021.
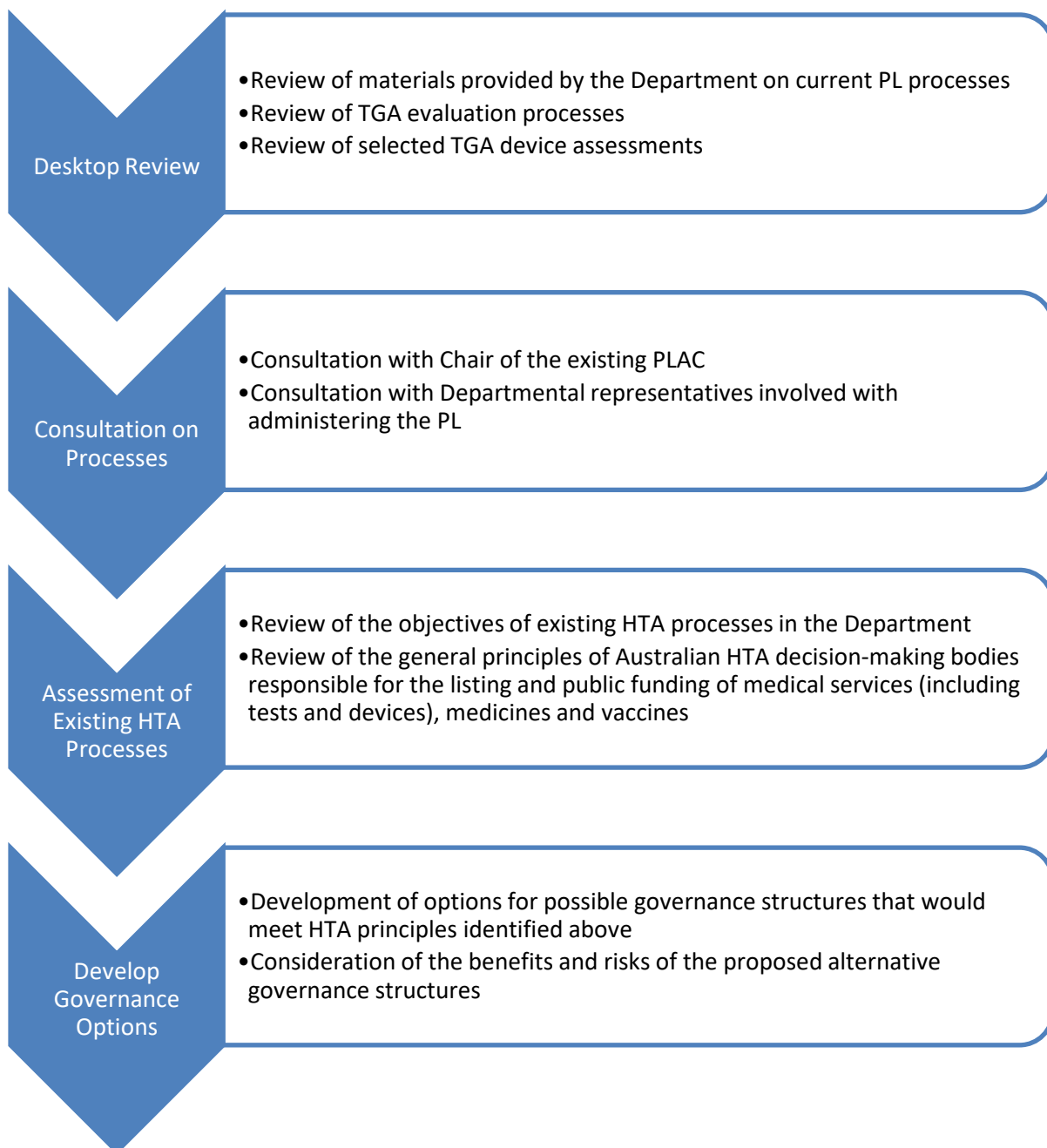
The objectives of the project are to:

1. Develop a pre-listing assessment framework that will support decision making for PL applications that both
   a. Promotes assessment transparency, and
   b. Removes ambiguity in decision making.
2. Develop a governance structure to support the assessment and decision-making framework.

Methodology

To develop the prototype PL pre-listing assessment pathways and proposed governance structures for the prostheses and devices assessment activities we synthesised material from a range of sources, including building upon work already undertaken as part of the PL Reform process.

A schematic of the process that was undertaken is provided in Figure 1.

Figure 1. Methodology for the development of an assessment framework and governance structure for applications to the Prostheses List

Desktop Review
- Review of materials provided by the Department on current PL processes
- Review of TGA evaluation processes
- Review of selected TGA device assessments

Consultation on Processes
- Consultation with Chair of the existing PLAC
- Consultation with Departmental representatives involved with administering the PL

Assessment of Existing HTA Processes
- Review of the objectives of existing HTA processes in the Department
- Review of the general principles of Australian HTA decision-making bodies responsible for the listing and public funding of medical services (including tests and devices), medicines and vaccines

Develop Governance Options
- Development of options for possible governance structures that would meet HTA principles identified above
- Consideration of the benefits and risks of the proposed alternative governance structures

Material that had been developed and submitted as part of the PL Reform process to date was collated and then provided to the consultant by the Department. A list of the material that was reviewed to inform the development of the assessment framework and governance structures is given in Table 1.

Table 1. Materials compiled and evaluated as part of desktop review of Prostheses List processes

Date	Authors	Title
2019	Department of Health	PLAC Terms of References and Operational Guidelines
June 2020	Department of Health	Prostheses List - Guide to Listing
December 2020	Menzies Centre for Health Policy, University of Sydney	Options for a revised framework for setting and reviewing benefits for the Prostheses List
December 2021	Prostheses List Advisory Committee	Meeting minutes of December 2021 meeting
2021, 2022	Department of Health	Consultation papers: No 1: Prostheses List- Purpose, Definitions and Scope (including stakeholder feedback report) No 2(a): Modernisation of Part B of the Prostheses List No 3(a): A modernised fit-for-purpose listing process (Consultation paper 3(a))

In addition to materials provided by the Department, the following sources were consulted:

- Selected recent TGA regulatory assessments of medical devices
- Clinical evidence guidelines for medical devices, Therapeutic Goods Administration (Version 3.0, November 2021)(2)
- Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 5.0, September 2016)(3)
- Guidelines for preparing assessments for the Medical Services Advisory Committee (May 2021)(4)
- One meeting with PLAC chair and departmental PL administrators.

This information allowed a comparison and contrast between the current Prostheses List processes used by the Australian Government and the HTA processes in place for other types of health technologies. These other HTA processes included those employed by the MSAC for the listing of medical services on the MBS, as well as the processes established by the PBAC for the listing of medicines under the PBS. These comparisons between PLAC, MSAC and PBAC processes began with an assessment of the principles underpinning their evaluation of health technologies.

Australian Government HTA Principles

Prostheses List HTA principles

The purpose of the PL, under the *Private Health Insurance Act (2007),* is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs. (5) Devices are included on the PL using a process that is designed to "help to ensure that benefits paid by insurers are relative to clinical effectiveness". (5)

As part of the broader HTA function within the Department, the operation of the PL should adhere to the vision for the Australian Government HTA Policy Framework, namely:

> *"Australians have timely, equitable and affordable access to the cost-effective health technologies needed to manage their health."(6)*

Although the PL is different in some ways to the other schemes that comprise the HTA operations of the Department, such as the Therapeutic Goods Administration (TGA), PBS and the MBS, the objectives of the Australian Government HTA processes are universal:

> *"That Australian Government HTA processes use the best available evidence and efficient methods to inform robust decisions about market entry and the subsidised use of health technologies. The Australian Government HTA system should also continually improve the evidence base for assessment and operate according to agreed principles."(6)*

Specifically, the Australian Government HTA processes should be:

- Sustainable
- Transparent, independent and accountable
- Consultative and reflective of Australian community values
- Administratively efficient
- Flexible and fit-for-purpose
- Informed by robust and relevant evidence (6)

Comparison with other Australian Government processes: PBAC and MSAC

Committee operation and process

It is useful to compare and contrast the operation of two other key HTA processes to the current PL process. Table 2 shows key components of the framework and governance of the PBAC, the MSAC and the PLAC.

Table 2. Comparison of HTA processes within the Department of Health and Aged Care

	MSAC1	PBAC2	PLAC3
Decisions made for the purpose of recommending listing on:	MBS	PBS	PL
HTA undertaken by:	External independent evaluators (DCAR) Applicants/sponsors (ADAR), with commentary by external evaluators	Applicants/sponsors, with commentary by external independent evaluators	Clinical Advisory Groups, Panel of Clinical Experts External independent evaluators
Purpose of committee	"MSAC appraises medical services, health technologies and health programs for public funding through an assessment of their comparative safety, clinical effectiveness, cost effectiveness and total cost, using the best available evidence"	"Its primary role is to recommend new medicines for listing on the PBS. When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments"	"Its primary role is to make recommendations to the Minister for Health and advise the Department of Health [and Aged Care] about the listing of medical devices and their benefits on the Prostheses List. The PLAC's recommendations and advice are to be based on assessment of comparative clinical effectiveness and cost effectiveness of medical devices using the best available evidence"
Sub-committees	Evaluation Sub-committee (ESC) PICO confirmation advisory Sub-committee (PASC)	Drug utilisation Sub-committee (DUSC) Economic Sub-committee (ESC)	Clinical Advisory Groups (CAGs) Panel of Clinical Experts (PoCE)
Reporting pathway	Advises Minister	Advises Minister	Advises Minister (or Delegate)
Committee membership	Clinical and HTA experts	Clinical and HTA experts	Clinical and HTA experts

	MSAC1	PBAC2	PLAC3
	Consumers	Consumers One industry representative	Consumers Representation from: device industry insurance industry private hospitals
Reporting of outcomes	Public summary documents published online; some full HTAs (DCARs) published online	Public summary documents published online	PLAC deliberations and recommendations recorded in meeting minutes (unpublished).

1. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-terms-of-reference

2. https://www.pbs.gov.au/pbs/industry/listing/participants/pbac

3. https://www.health.gov.au/committees-and-groups/prostheses-list-advisory-committee-plac

Key differences in the governance and processes across MSAC, PBAC and PLAC include:

- The expert undertaking the HTA assessment. Both MSAC and PBAC processes may involve industry developed submissions that are subsequently assessed by an expert HTA evaluation group that is independent of the Department. An alternative process for MSAC may involve the development of an assessment report (DCAR) by an expert HTA evaluation group which is informed by an application and input from the entity seeking a new MBS item number or a change to an existing service. In contrast, external independent evaluation is provided to the PLAC on an ad-hoc basis, with the HTA function primarily undertaken by the CAGs and PoCE.

- MSAC and PBAC have designated Sub-committees with stable membership, and clear reporting requirements to the parent committee. The 'Sub-committees' of PLAC, specifically the PoCE, is ad-hoc in nature, and the reporting of deliberations is not well defined.

- While MSAC and PBAC offer the opportunity for stakeholders to engage with the committee through brief presentations or submissions during public consultation, these stakeholders are not present during committee deliberations concerning the public funding of these health technologies. The exception to this is the inclusion of an industry expert with over 20 years pharmaceutical experience who is not currently employed in the sector that sits on PBAC and is bound by the terms of the committee. In contrast, the composition of the PLAC includes stakeholders representing industry (medical technology, private hospitals and private health insurance) as invited guests. There is the potential for these stakeholders to have pecuniary interests or perceived or real conflicts of interest in the outcome of PLAC considerations even if they are invited guests.

Structure and development of reports

In addition to differences in the operation and composition of PBAC and MSAC compared with PLAC, the HTA reports that the committees consider differ in their structure, content and generation. Both PBAC and MSAC applications are based on systematic reviews of clinical evidence to assess the safety and effectiveness of a technology and include economic analyses that may include modelling. The development of these submissions, assessment reports and commentaries are supported by detailed guidelines and templates to guide the sponsors and evaluators in how to develop and assess the dossier of information. In circumstances where reports are created by stakeholders with conflicts or perceived conflicts (e.g. the sponsor of a pharmaceutical, or a professional body), the report is scrutinised by an independent HTA evaluation group prior to consideration by PBAC or MSAC.

It is clear from previous reports and a review of PLAC minutes that the applications received for the PL differ markedly in structure and content from submissions and commentaries that are considered by PBAC and MSAC.

Applications for prostheses to be listed on the PL often contain irrelevant information and lack the synthesis of evidence that enables the committees to effectively and efficiently assess the application and to make recommendations for and against listing. This contributes to inconsistency in the process applied across technologies, resulting in advice being inconsistent and variable in quality and content.

The existing PL assessment framework and processes appears to support many of the Australian Government's HTA objectives. However, there are clear limitations with the current process that

may affect the ability of PLAC to consistently realise the guiding principles set out by the Australian Government.

The Prostheses List Process

Characteristics of a reformed listing process

As discussed previously, to enable the Australian Government's HTA objectives to be better met by the PL process, the PL HTA process should be:

- Sustainable
- Transparent, independent and accountable
- Consultative and reflective of Australian community values
- Administratively efficient
- Flexible and fit-for-purpose
- Informed by robust and relevant evidence (6)

Sustainability means that the process needs to be sufficiently resourced and supported so that it can be sustained in the long term. Transparency, independence and accountability relate to demonstrating to stakeholders and the community that decisions are made consistently and fairly, without prejudice, bias or influence from competing interests, and in a manner that can be reviewed or audited and where clear reasons are given for decisions taken. Stakeholder and community consultation, as well as community values, need to be reflected in the process and in the decisions that are made. The process for assessment and decision-making needs to be efficient for the Department, sponsors and committee members with respect to the time taken and the resources involved in administering and engaging with the process. The process needs to ensure flexibility and that it is fit-for-purpose, to ensure that resources utilised in the process are appropriate to the risk. This could involve triaging evaluations using risk assessment principles, such that low risk devices and prostheses follow a less intensive assessment process, while more complex and risky devices and prostheses follow an assessment process that is calibrated to addressing those risks. To properly assess this risk and the impact of specific prostheses and devices on human health, robust and relevant evidence on the safety and effectiveness (and in some cases cost-effectiveness) of each device is needed.

Several important factors are required for an HTA listing process to achieve these objectives. The frameworks that guide the MBS and PBS processes provide a suitable basis for a Reformed PL Pre-Listing Assessment Framework. Key aspects included in these HTA processes that could be utilised in the PL Pre-Listing Assessment Framework include:

- External evaluation of applications / evidence dossiers by independent HTA experts
- Detailed guidelines and templates for sponsors developing applications / evidence dossiers
- Detailed guidelines and templates for evaluators assessing the applications / evidence dossiers
- Clear and fixed timelines describing the milestones in the process, including:

  - Submission or application dates
  - Evaluation timeframes
  - Dates for feedback and timeframes for sponsors input
  - Committee and Sub-committee consideration dates

- HTA expertise on committees
- Health economics expertise on committees

- Consideration of committee composition, including strategies to capture input while ensuring that decision making occurs without undue influence from real or perceived conflicts of interest
- Published and publicly available committee advice, including the rationale for decisions made
- Structured minuting of committee deliberations that is available for future committee deliberations
- Consumer input into committee deliberations
- Public consultation processes
- Consideration of other relevant information that may impact on the use of the technology (such as equity and ethical concerns)
- Full or partial cost-recovery for listing processes, with clear and considered rules for exemptions, to improve the sustainability of the HTA process.

Some of these aspects are already in place for the PL process, however some could be strengthened and others introduced.

Guidelines and templates

Guidelines provide clear instruction to sponsors regarding the:

- Eligibility criteria for different assessment pathways
- Required content of an application, dependent upon nominated pathway
- Preferred presentation of evidence
- Preferred methods to be used in collating, synthesising or appraising evidence
- A clear explanation of the goal of the report, and the factors relevant to committee decision making

Templates further encourage a consistent approach across all applications, clearly defines the role and requirements of the sponsor and ensures the Department, who is responsible for facilitating or assessing applications through the process, is doing so according to the principles of the *Public Governance, Performance and Accountability Act 2013*. The Department will initially assess and verify all applications to ensure they meet eligibility; the correct pathway is nominated; and the application is complete. Sponsors will be provided limited opportunity to provide further information if their application is incomplete. Likewise, applications with irrelevant material that do not adhere to the template will be rejected.

Currently, the committee is faced with assessing many applications, each running to hundreds of pages, each meeting. The volume of reading, coupled with limited time between paper distribution and meeting, limits the scrutiny applied to each application. Developing guidelines that inform a submission to PLAC (or alternative governance arrangement) would result in improved clarity and synthesis of evidence, consistency across the submissions, increased efficiency of committee deliberation and standardised communication (to sponsors and the community) about the risks and benefits of listing and the basis for the decision taken. This may result in more rapid decision making and reduced time to listing for successful applications.

Guidelines may assist committee members, discussants and evaluators to construct an efficient commentary in response to a submission with the purpose of highlighting uncertainties, major issues and committee deliberation points

The provision of guidelines and templates may assist in the implementation of changes to assessment pathways.

External evaluation

Submissions or assessment reports provided to both MSAC and PBAC have typically been created by independent HTA external evaluators or have been provided by sponsors (sometimes commissioning consultants) and then critically appraised by HTA external evaluators. These evaluators or 'assessment groups' are external to, and function largely independent of, the Department and of the committees. They are usually academic HTA groups or for-profit HTA consultancy groups. An existing panel of independent HTA evaluators engaged by the Department to undertake HTA work would also be suitable to undertake PL work.

The routine use of independent external HTA evaluators for specified PL applications would help in providing procedural fairness. Having applications receive external appraisal ensures that the evaluation process is rigorous and assists in the consistency of reporting of key issues to inform committee deliberations. To ensure procedural fairness, reports developed by external evaluators can be provided to the sponsors for comment. The use of external evaluators should minimise the impact of, or perception of, vested interests influencing PL decision-making.

The precise role of external evaluation in the PL process is an important consideration in the development of PL pathways for prostheses and device applications. To ensure that assessment processes are also flexible, efficient and fit-for-purpose, the use of external evaluators should be proportionate to risk. Briefly, preliminary proposals for the use of HTA external evaluation in the PL process are:

- **Departmental Assessment Pathway:** no requirement for external evaluation support
- **Clinical/Focused HTA Pathway:** Noting that there are likely to be several levels of clinical and technical input into applications using the focused pathway, external evaluation may provide a commentary on a sponsor's submission (produced in accordance with Guidelines) to identify key uncertainties and main issues for committee consideration.

  o This service most resembles the ADAR approach used by some MSAC applicants, and would reflect the most likely pathway taken by sponsors to the PLAC.
  o An alternative approach may be to create a focused HTA report for a device, or a group of related devices, based on an application and an evidence dossier. This approach has some similarities to the externally created DCARs in the MSAC process. However, the approach would be critically dependent upon the provision of adequate data from the sponsor (e.g. the clinical evaluation report and supplementary data) as these data are unlikely to be in the public domain.
  o A final option may be a hybrid report, where the clinical data are provided in a submission by the sponsor for consideration by the CAGs / PLAC, and an economic evaluation is performed by an external HTA group. This may be required if the sponsor is requesting a new device category or a higher reimbursement price and does not have the resources to develop an economic analysis.

- **Full HTA Pathway:** External evaluation, provided through the current MSAC pathway, would provide a commentary on a sponsor's submission (produced in accordance with MSAC Guidelines) to identify key uncertainties and main issues for MSAC consideration and to inform benefit setting.

The scope and complexity of reports to support the Clinical / Focused HTA Pathway will be a key topic for discussion in the development of pathways. It is expected that these reports could be substantially more focused than MSAC DCARs or ADAR commentaries, and may be able to be created in shorter timeframes.

External evaluators can be sourced through the Department's existing HTA panel. However, the evaluation of medical devices and prostheses requires additional expertise, and the structure of the reports will be a departure from MSAC reports. External evaluators may require initial training and the provision of guidelines and templates.

Permitting external evaluators to observe committee deliberations for assessments undergoing a Clinical / Focused HTA Pathway may provide insight into the key concerns held by the committees and assist with building expertise on the evaluation of prostheses and medical devices. This will lead to improvements in the focus of subsequent external evaluation reports to those issues most important to the PL decision-making committee. Further, the external evaluators can clarify issues or omissions in the application, if required.

Committee composition

The PL process would also be strengthened by greater HTA expertise on the committee that formulates the PL recommendations, especially given the new pathways are likely to require a much more HTA focused approach. This can be achieved by ensuring the committee, or relevant Sub-committees, contain several members who are experts in clinical evidence appraisal (understanding of study design, bias and confounding) and economic evaluation.

Guidelines describing the presentation of robust evidence and appropriate economic evaluation methods will also aid committee members who have had less exposure to HTA methods. The inclusion of HTA experts in the committee(s), and exposure to guidelines, along with properly constructed applications and external evaluation reports, will ensure that over time committee members' knowledge of HTA will increase.

Stakeholder representation on PL decision-making committee

A key issue with regard to governance concerns conflicts of interest and the impact of vested interests amongst committee members. To reflect the 'transparent, accountable and independent' principle of Australian Government HTA processes and to align the PL process with other HTA processes within the Department, consideration should be given to the representation on the committee that provides advice about listing. Table 3 compares the committee membership of PBAC, MSAC, ATAGI and PLAC.

Table 3. Membership of various Department of Health and Aged Care HTA committees

Committee	Members	Industry representation
PBAC	21, including doctors, health professionals, health economists and consumer representatives	Yes: 1
MSAC	20, including clinical and methodological experts, consumer representative	No

Committee	Members	Industry representation
ATAGI	15 voting members including clinical experts and consumer representatives; ex-officio members including Department of Health and Aged Care, National Centre for Immunisation Research and Surveillance, TGA and PBAC	No
PLAC	11 expert members including clinical and methodological experts and consumer representative Invited attendees from Australian Private Hospitals Association, Catholic Health Australia, Day Hospitals Australia, AusBiotech, Medical Technology Association of Australia, Private Healthcare Australia and Members Health. Representatives from Department of Health and Aged Care, including TGA and Department of Veteran's Affairs also attend	Yes: 7

PBAC has an industry stakeholder representative, MSAC and ATAGI do not, whilst the existing PLAC membership includes clinician experts and representatives from the hospital, insurance and sponsor sectors in advisory membership or invited attendee roles. The recommendations made by PLAC may have differing financial implications for a number of stakeholders, but it is different to the other committees in that the Government is not the payer. Advisory members do not have any voting rights, however members with vested interests do influence committee discussions, to the detriment of the committee functioning.

All the governance options in this report are based on optimising the operation of the lead committee by removing stakeholders with vested interests, however, it is also recognised that stakeholder input is important to the PL process. Stakeholders would not attend decision-making committee meetings. This would eliminate the distractions referred to above, and allow the expert committee to make listing and review advice without influence from financially interested stakeholders. There are two possible ways to address stakeholder input when they are excluded from PLAC meetings. Firstly, the Department currently convenes a stakeholder forum every two months providing updates on reform activities. The Department intends to continue this forum to engage stakeholders on relevant issues such as policy and innovation. Another approach would be to allow formal stakeholder consultation on each application. A summary of the application, excluding commercial-in-confidence material, could be forwarded to a group of stakeholders and submissions invited using a web-based proforma. This input would be collated, summarised and submitted to the Department to inform their deliberations. The parameters for this, such as which applications are shared, what information is shared and at what stage it is shared, would need to be established.

Reporting and documentation

Structured minutes capturing committee and sub-committee deliberations improve corporate knowledge, and support greater consistency in decision making.

Summaries of PLAC recommendations, including clear and consistent language indicating the key issues pertaining to the decision, will act to increase transparency. Summaries may also act as a feedback mechanism to sponsors, who are provided with information that may improve the quality of subsequent submissions. Depending on the application to the PL and the claim being made, public

summaries may be as brief as an acknowledgment of interchangeability with an existing prosthesis, progressing through to detailed summaries of decision making and justification for benefit setting. These public summaries should reflect the pathway an application has taken.

While improving documentation may require investment in additional resources, some or all of these resources may be offset by expected improvements in committee efficiency, reductions in duplicative discussion, and an overall improvement in the quality of submissions. For the most simple of public summaries, automated generation via the Health Products Portal may even be possible.

Wider committee responsibilities

The proposed additions described above relate to the listing process for the PL. Proposed PL Reforms are considering how PLAC responsibilities such as benefit setting and review of existing benefits should be undertaken in the future.

These considerations fall outside of the scope of this report. However, the following processes may be relevant in a broader consideration of listing requirements or governance. Note that these processes are suggestions only and have not been adopted by the Department:

Mechanisms to limit PL proliferation:

- Post listing reviews
- Triggers for de-listing a device (e.g., based on utilisation)
- Triggers for a review of a category on the PL (e.g., increases in overall utilisation, change in the composition of the category)

Mechanisms for containing cost and ensuring ongoing cost-effectiveness

- Implementation of the planned benefit reductions as per the Memorandum of Understanding between the MTAA and the Department, signed 14th March 2022.
- Consideration of ongoing mechanisms for review of benefits and prices

Mechanisms to limit the number of PL groupings

- Prices of groupings are indexed yearly to reduce the incentive to create new categories with incrementally higher prices. Overall financial implications would be controlled by applying a price disclosure mechanism that would reduce group benefits where the reference price for a device was significantly lower than the group benefit price.

Reporting of market data

- The above mechanisms are supported by regular reporting of up-to-date information on utilisation and costs. PLAC, or a Sub-committee established to provide advice to PLAC, would adopt the role of monitoring changes in utilisation and prices, and to recommend changes to current PLAC listings to ensure the ongoing efficiency and value of the PL.

Governance

This report has proposed four options for governance structures of the PL. Each presented option attempts to address some or all of the key problems identified in previous reports, and to reflect the underlying principle of Australian Government HTA processes.

The proposed options are described in the context of a Departmental Assessment Pathway, Clinical / Focused HTA Pathway and Full HTA Pathway. The eligibility for each pathway, and the evidence requirements for each pathway, are the subject of consultation with stakeholders, and presented in a separate report.

Key to all of the governance options are:

- Optimisation of the PLAC committee, whatever form that takes;
- Removing stakeholders from decision-making committees; adding formal stakeholder consultation to the pathways;
- Streamlining of applications through the new pathways process, eliminating unnecessary committee deliberation on simple applications;
- The provision of guidelines and templates for sponsors and HTA external evaluators, and publication of public summary documents.

Optimisation of the PLAC involves ensuring HTA expertise on the committee, as well as removing stakeholders from the committee. An alternative mechanism for stakeholders to engage with government on broader policy issues currently exists through the stakeholder forums. Removing stakeholders from the decision-making committee means that the inclusion of formal feedback mechanisms into the relevant evaluation pathways should be considered. These mechanisms exist in other HTA processes (such as PBAC and MSAC). A designated time-frame and proforma for stakeholders to provide targeted feedback in the PL process should be developed.

Guidance and templates for sponsors will outline the information that is needed for decision-making and the type of evidence that is required for each pathway. In addition, some form of Public Summary Document (PSD) will be provided for each application. As discussed above, this may be as simple and brief as an acknowledgment of interchangeability with an existing prosthesis, progressing through to detailed summaries of the rationale for decision making and justification for benefit setting, reflecting the pathway an application has taken. This will improve transparency and ensure consistency with the other HTA processes in the Department. Where Public Summary Documents are referred to in the governance options described below, this means a document suitable for publication that reflects the level of scrutiny and complexity of the application to the PL; it does not mean the kind of PSD that accompanies MSAC or PBAC decisions.

Four options have been proposed for the new governance structure. An overview of these options is provided in Table 4. Each option is then described in more detail, including the benefits and risks of each.

Given the importance of clinical expertise in the PLAC process, it is evident that the current Clinical Advisory Groups (CAGs) are essential to the success of the PLAC governance arrangements and the assessment of applications to the PL and therefore need to be included in some format. For this reason, we recommend that Option 1 as the suggested governance structure for the PL.

Table 4: Summary of the governance options proposed for a reformed Prostheses List process

	Option 1 (recommended)	Option 2	Option 3	Option 4
Lead committee	PLAC with expanded refreshed membership to include broader clinical and HTA expertise (CAG Chairs, Consumer Representative, HTA and economics expertise)	PLAC - no change of current membership	MSAC executive with addition of a PL representative b	PL executive committee (up to four key experts in prostheses, HTA and economics)
Lead discussant at committee meeting	Discussants from within PLAC, reflecting clinical specialty	As per current meetings	PL representative	PL executive member
Expert input	CAGs	CAGs and/or PoCE	Panel of PL experts (comprised of former CAG members) a	Panel of PL experts (comprised of former CAG members)a

Notes: PLAC- Prostheses List Advisory Committee; MSAC – Medical Services Advisory Committee; PL – Prostheses List; CAGs – Clinical Advisory Groups; PoCE – Panel of Clinical Experts
a operation of CAGs would be streamlined so more efficient (e.g. used on demand)
b A PL representative to join MSAC and the executive would need to have experience in both prostheses and HTA

Option 1: PLAC remains but optimised with membership expanded and Clinical Advisory Groups remain

In this scenario, the PLAC would be reconfigured and optimised so that its representation is more closely aligned with that of the other expert HTA committees. Members would represent relevant clinical and disciplinary specialties (reflective of the CAG structure), with CAG chairs having membership on the committee. It could be expected that the committee would be larger, with broader representation of clinical areas and HTA specialists. However, committee functioning should be improved, as applications are more streamlined through the process and discussion is more focused at committee meetings. Stakeholders would not be members of this committee, with a regular stakeholder forum providing an opportunity to keep them informed of key outcomes of any issues that arise.

In this scenario, when applications require PLAC consideration, a discussant (Chair of a CAG or a member of a CAG) would be assigned to present the application to the committee for discussion and a final recommendation formulated. Where required, external evaluators prepare the advice in close consultation with the assigned discussant who would be well informed of the pertinent issues and can take the draft advice to the rest of the committee with a focus on the key decision-making matters. Discussant duties are shared and applications allocated to members with knowledge in the disease area. Importantly, in this scenario, only the key issues for decision making need to be discussed at the meeting; thus it is vital that CAGs and/or external evaluators are able to identify and explain these issues to the members. Evaluators could also be present at the PLAC meeting, if it was deemed necessary.

Importantly, membership would be expanded to include HTA and Economic expertise and Consumer Representation would remain.

Figure 2. Option 1 schematic of process and governance
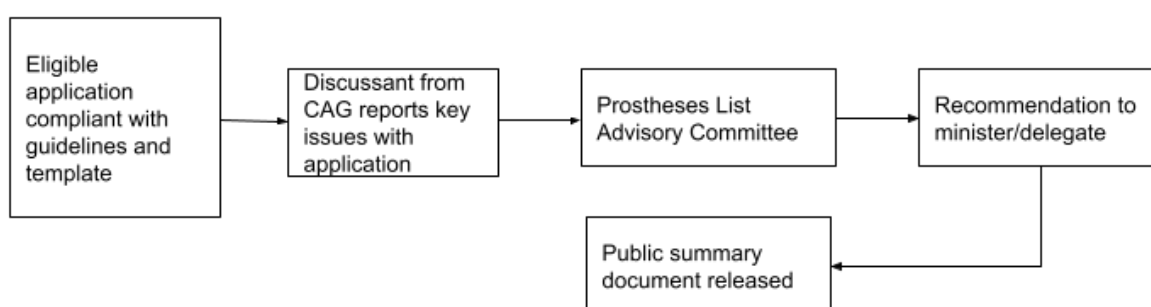
Option 1: Risks

This scenario maintains the expert contribution to PL recommendations whilst streamlining the process, so it is relatively low risk.

Option 1: Benefits

Inefficiencies and issues with conflicts of interest within PLAC would be eliminated with stakeholders removed from the committee, but with a HTA and economic expert included, and a consumer representative remaining. There would be expert contribution to key issues where required via the discussants (CAG Chair or a member of CAG), which will result in more efficient and informed decision making by the committee. There would be less time wasted in meetings as vested interests are minimised, and only key areas of uncertainty need to be discussed (as identified by the discussant and evaluators).

Option 2: Optimisation of current PLAC and Clinical Advisory Group configuration

Noting that many of the issues associated with the PL process would continue to exist if the structure of the PLAC and sub-committees remained the same, there are some steps that could be taken to improve the efficiency of the current process. Sub-committees could remain as the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (PoCE), or the PoCE could be dissolved and only the CAGs act in the sub-committee role.

The composition of the PLAC and role of stakeholders should be reconsidered as discussed earlier. The Departmental pathway will help to ensure that only applications that need to be assessed by the PLAC are considered. The department will initially assess each application when received to ensure it meets eligibility, the correct pathway has been nominated and all information has been provided.

In this scenario, advice could be sought from the appropriate CAGs (or PoCE if it remains) where required. For example, this could occur when clinical guidance is needed by the PLAC on evaluations completed through the focused HTA pathway. To increase efficiency with this process, it is suggested that the CAGs select one or two discussants who can report the key issues to the PLAC, so that the PLAC members are not required to read entire applications. It should be noted that in this scenario, most of the desired efficiency gains would need to be made through the better pathways process, rather than the overall governance of the process.

PLAC membership: committee membership and CAGs (and PoCE if it remains) is changed to take into account the recommendations about committee membership previously discussed i.e. incorporation of HTA expertise and removal of members with vested interests.

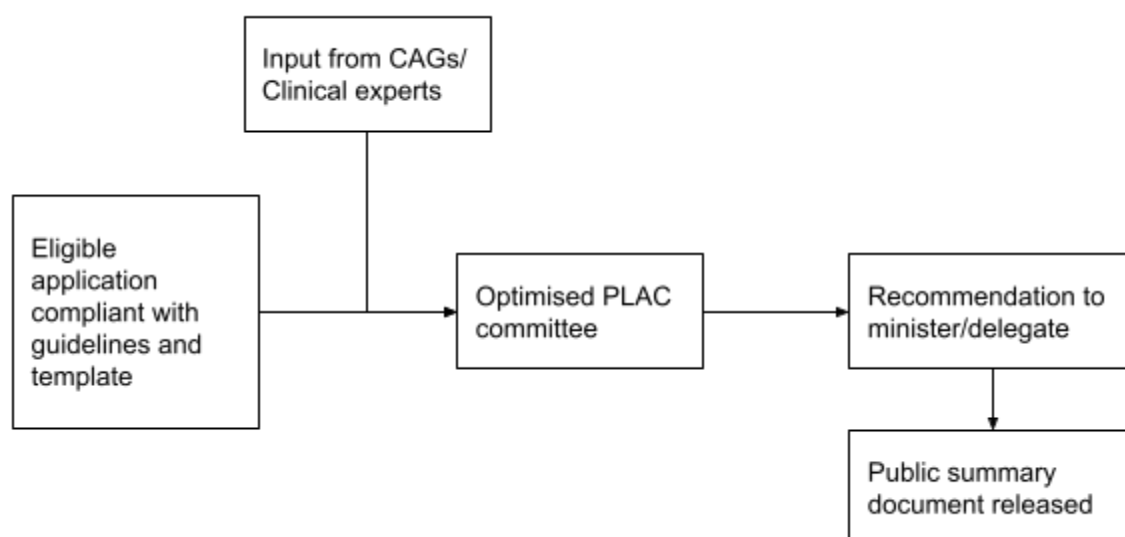**Figure 3. Option 2 Optimisation schematic of process and governance**

Figure 2 notes: CAGs: Clinical advisory groups; PLAC: Prostheses List Advisory Committee

Option 2: Risks

Although some of the HTA principles could be rectified by optimising the composition of the PL committee, formalising guidance for submitting applications, and reporting outcomes of the decision-making process, leaving the PLAC and subcommittees in their current configuration means that some of the issues currently problematic for the listing process will still not be addressed. Independence of the committee will be improved but still largely influenced by the clinical experts. The process would still be administratively inefficient with a range of CAGs needing support, and with a large burden on the committees to do the evaluation of the prostheses and devices (with reference to the Guidelines). The loss of stakeholders from the committee, while reducing the influence of vested interests, would equally also reduce stakeholder consultation.

Option 2: Benefits

The lack of change to the process means that it would likely remain sustainable, as long as the Australian Government keeps it resourced. The inclusion of Guidelines and Templates, provision of PSDs, removal of vested interests from the committee with formal stakeholder consultation built into the pathways, and inclusion of HTA expertise on the committee would improve transparency, independence and accountability. If the proposed assessment pathways are implemented then the full process would also be flexible and fit-for-purpose. If the Guidelines are developed properly then it is likely that more robust and relevant evidence will be presented to the committee.

Option 3: Dissolve the PLAC and subcommittees and form a panel of PL experts who can advise the MSAC executive. Retain optimisation.

This scenario is characterised by the absence of PLAC and associated subcommittees. Responsibility for the transition of applications through the PL process would rest with the Department. A panel of clinical experts would be formed to provide advice to the Department on demand; that is, an appropriate panel member would be called upon when required to provide specialist advice to the Department and/or evaluators. This is similar to a previous structure of MSAC, where the panel of clinical experts (Health Expert Standing Panel, HESP) advised on evaluations that required specialist clinical knowledge.

For the PL process, where an application required it (i.e. any application using the focused pathway), expert clinical or technical advice could be sought and incorporated into the listing advice by the Department. Final approval of the advice, and recommendations, would be the remit of the MSAC executive. As the MSAC executive meets more frequently than MSAC, and there would be fewer and better quality applications to consider under the new proposed assessment pathways, this would be an efficient way for PL applications to be processed with appropriate oversight. The MSAC executive have appropriate HTA experience to consider these applications, and a PL representative could be added to the MSAC executive to lead discussion on items that would be considered. This option would require resourcing the Prostheses section in the Department adequately, as the bulk of the evaluation associated with a prosthesis listing would occur here. The Department could contract out evaluations for the Clinical / Focused HTA Pathway to independent HTA experts/assessment groups, as required.

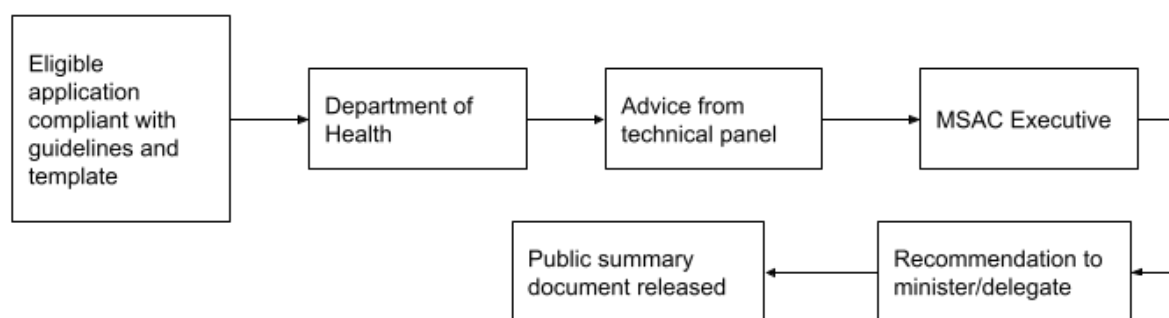**Figure 4: Option 3 schematic of process and governance**

Figure 3 notes: MSAC: Medical Services Advisory Committee

PLAC membership: PLAC and its subcommittees as it currently stands would be dissolved. A panel of experts with relevant clinical and/or HTA experience would be formed to provide advice where required.

Option 3: Risks

Dissolving PLAC and its subcommittees will require the Department to take on a larger role in the administration of the PL, which would likely require upskilling or recruitment of more staff with appropriate evaluation training, and potentially put at risk the sustainability of the revised process.

Option 3: Benefits

The optimisation processes of using Guidelines and Templates and provision of PSDs will assist with transparency and accountability. Inefficiencies and issues with conflicts of interest within PLAC would be eliminated through dissolving the committee and its subcommittees. Expert input is incorporated into the process, without the need for meetings, reading of excessively long documents or irrelevant discussions. Existing mechanisms (MSAC executive) would provide oversight, providing some efficiencies including more frequent meetings. Experts would be used in an efficient and targeted manner, reducing resourcing and workload. Experts would only need to be called upon when a relevant application is received. If evaluations are done externally then the independence of the process would be improved. If the proposed assessment pathways are implemented then the full process would be flexible and fit-for-purpose. If the Guidelines are developed properly then it is likely that more robust and relevant evidence will be presented and evaluated.

Option 4: PLAC and its subcommittees are dissolved and replaced by a smaller executive PL committee

As with Option 3, the Department would be responsible for transitioning the applications through the process. A panel of PL experts would be called upon to provide advice to the Department and evaluators on demand. Applications would be considered by the PL Executive, comprised of three or four key experts in prostheses, HTA and economics, who would provide the final advice. Clinical experts (or external evaluators if required) could attend their item at the PL executive to provide further information. The committee could also include a consumer representative, or consumer feedback could be incorporated via formal feedback mechanisms during the process. This would mean the clinical experts are only used as required, and the PL Executive benefits from the expert input whilst gaining efficiencies from a smaller committee and more targeted discussion around key uncertainties.

Figure 5. Option 4 schematic of process and governance
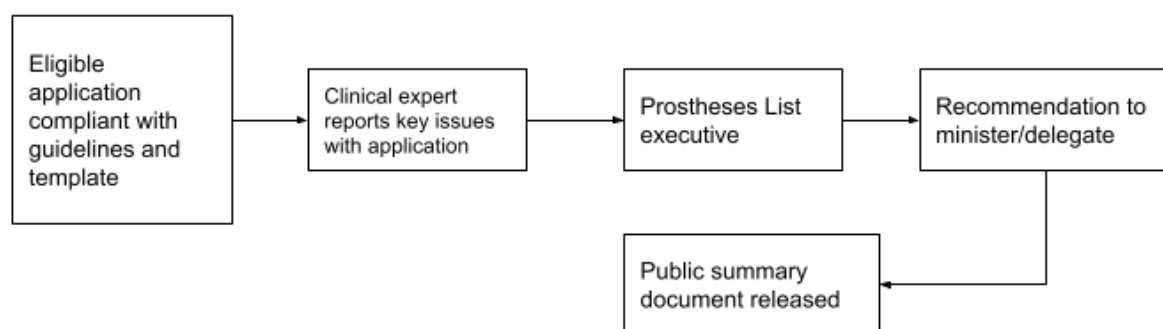
PL Executive membership: this scenario would entail only a small committee, who would need to be carefully chosen to represent the expertise required. Clinical experts (comprised of existing CAG members) or the external evaluators could also attend the PL executive where required, for their specific item. A consumer representative could be included either as a member of the executive, or via formal feedback mechanisms.

Option 4: Risks

This scenario is also relatively low risk, as it still has expert input and oversight. The ability of a PL executive to make suitable recommendations will rely heavily on the quality of the applications and evaluations it received. A small committee making recommendations risks decisions being less consultative and reflective of community values.

Option 4: Benefits

The inefficiencies and issues with the existing PLAC are eliminated. Expert advice is still available via a Panel of PL experts (comprised of all CAG members) and a smaller committee, coupled with the revised pathways, should enable more efficient decision making. Using Guidelines and Templates and provision of PSDs will assist with transparency and accountability. Inefficiencies and issues with conflicts of interest within PLAC would be eliminated with stakeholders removed from the committee. Consumer input could be incorporated through membership on the PL executive, or via the same formal feedback mechanisms available to the other stakeholders.

Conclusions

This report has highlighted the key aspects of a PL framework, and some governance options, that will align the PL process with other HTA processes and ensure that the principles of Australian Government HTA processes are upheld.

Key to the framework is better committee representation, including removing stakeholders from decision-making committees and adding HTA expertise. This applies regardless of the governance structure adopted. The importance of improved guidelines and templates cannot be underestimated, as these enable consistency, the provision of relevant evidence and aid in the passage of applications through the appropriate pathway.

The governance options provided enable the PL process to reflect the underlying principles of HTA to a greater or lesser extent. Some options will require more resources for the Department, which may impact on sustainability, however cost-recovery will aid in this. The use of guidelines and templates, provision of PSDs and the use of external, independent evaluators, where required, will contribute to the process becoming more transparent, accountable and independent. Formal feedback mechanisms which enable all stakeholders to engage in a timely manner ensure that the process is consultative and reflects Australian community values. Aligning the PL process with the other HTA processes and being clear about the evidentiary requirements for each type of listing, will ensure that each decision is informed by robust and relevant evidence.

References

1.   Australian Government Department of Health. The Prostheses List reforms 2021 [April 2022]. Available from: https://www.health.gov.au/health-topics/private-health-insurance/the-prostheses-list/the-prostheses-list-reforms.

2.   Australian Government Department of Health. Clinical evidence guidelines for medical devices 2021. Available from: https://www.tga.gov.au/resource/clinical-evidence-guidelines-medical-devices.

3.   Commonwealth of Australia Department of Health. Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee (Version 5.0) 2016. Available from: https://pbac.pbs.gov.au/content/information/files/pbac-guidelines-version-5.pdf.

4.   Australian Government Department of Health. Guidelines for preparing assessments for the Medical Services Advisory Committee 2021. Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/$File/MSAC%20Guidelines-complete-16-FINAL(18May21).pdf.

5.   Australian Government Department of Health. Prostheses List Guide (Draft). Canberra, Australia: Department of Health; 2020. (supplied)

6.   Australian Government Department of Health. Health Technology Assesment Policy Framework 2022. Available from: https://www1.health.gov.au/internet/hta/publishing.nsf/Content/policy-1.