Australian Government
Department of Health and Aged Care

# Prostheses List Reforms –

## Pre-Listing Assessment Framework and Governance Structure

# Contents

# Summary

In January 2022, the Department of Health and Aged Care (the Department) released *Consultation Paper 3(a) – Prostheses List – A modernised fit-for-purpose listing process*. The aim of the paper was to canvass stakeholder views on the proposed three-tiered approach to the assessment of Prostheses List (PL) Part A and Part C applications.

A total of 34 submissions were received from stakeholders representing the medical technology sector, private hospitals, private health insurers, clinical societies and individual consultants.

The paper did not explore the review of governance arrangements associated with the PL listing process, however, the Department recognises many stakeholders did provide feedback including, but not limited to, the future role of the Prostheses List Advisory Committee (PLAC), Clinical Advisory Groups (CAGs) and their membership.

As part of the reforms to improve the PL and its arrangements, a review of the role, function and membership of the PLAC and its sub-committees was carried out by EY who provided advice in July 2021 (Attachment A).

Building on the EY review, in 2022, the Adelaide Health Technology Assessment Group (AHTA), within the School of Population Health at the University of Adelaide, were engaged to develop Options for a Reformed Prostheses List Pre-Listing Assessment Framework and Governance Structure which would align the PL with the other health technology assessment processes conducted by the Department.

The development of the Final Report (Attachment B) has been informed by research and engagement with the PLAC Chair and Departmental representatives and provides information on each of the following four options, highlighting issues, risks and benefits:

- Option 1: PLAC remains but optimised with discussants, and CAGs remain
- Option 2: Optimisation of current PLAC and CAG configuration
- Option 3: PLAC and sub-committees are dissolved and replaced by a panel of PL experts who can advise the Medical Services Advisory Committee (MSAC) Executive, whilst retaining optimisation
- Option 4: PLAC and its sub-committees are dissolved and replaced by a smaller executive PL committee.

Aligning the prices set for medical devices in the private system with those paid in the public system, thus improving the affordability and value of private health insurance for Australians is key to the PL reforms. Important messages the Department has received from stakeholders include the need for flexibility in the process; clear guidance material; transparency; elimination of repetition; and consistency of messaging.

Given the increase in the number of applications considered by PLAC and its sub-committees, and the complexity and variety of applications being reviewed, the reforms will refresh the current process and structure, and modernise the current governance arrangements. This includes increasing the efficiency of the process by improving co-ordination and streamlining access to medical devices to support the sustainability of the PL.

# Existing arrangements

Since its inception in 1985, the PL has been reviewed numerous times, with reviews identifying issues and challenges, including acknowledging a lack of independence in the assessment process due to the involvement of key stakeholders in the application assessment process and the potential for conflicts of interest.

The principal role of the PLAC is to provide recommendations and advice on the clinical effectiveness and cost-effectiveness of devices, and other matters related to the PL to the Minister for Health and Aged Care and the Department, about the listing of devices on the PL and the benefits payable by private health insurers.

Membership of the PLAC comprises of a Chair, experts in orthopaedic surgery, spinal surgery, epidemiology, cardiology, thoracic medicine, bioengineering, and vascular medicine, the MSAC Chair, and a consumer representative. Additionally, stakeholder invited attendees represent private hospital associations, the medical technology industry and private health insurance attend each meeting. Representatives from the Department (including the Therapeutic Goods Administration) and the Department of Veterans' Affairs also attend PLAC meetings.

While there are currently 13 categories of devices listed on the Prostheses List Part A and C, the PLAC is supported by CAGs covering only eight of these categories (comprising in excess of 50 members with relevant subject matter expertise). The CAGs provide advice throughout the health technology assessment by considering the comparative clinical function and effectiveness of devices to be considered for listing on the PL. The eight CAGs are as follows:

- Cardiac Prostheses Clinical Advisory Group
- Cardiothoracic Prostheses Clinical Advisory Group
- Hip Prostheses Clinical Advisory Group
- Knee Prostheses Clinical Advisory Group
- Ophthalmic Prostheses Clinical Advisory Group
- Specialist Orthopaedic Clinical Advisory Group
- Spinal Prostheses Clinical Advisory Group
- Vascular Prostheses Clinical Advisory Group.

Other categories of devices (Ear Nose and Throat; General Miscellaneous; Plastic and Reconstructive; Urogenital; Neurosurgical) are assessed by the Panel of Clinical Experts (PoCE), comprising of over 25 clinicians.

The difference between the CAGs and the PoCE is that CAGs have meetings three times per year to discuss their assessments, while individual clinicians from the PoCE are approached to provide their independent assessment of an application in their field of expertise.

Assessments and advice from the relevant CAGs and PoCE are formulated and provided to PLAC for consideration (along with any further information provided by the applicant). These documents are used to inform PLACs discussions and subsequent recommendations to the Minister regarding the clinical effectiveness of the device compared with other similar devices listed on the PL, or other available treatments.

# Departmental response to EY Report

The Department considered the EY review and recommendations that found the current governance structure and membership composition was preventing PLAC from effectively fulfilling its purpose, recommending significant enhancement of PLAC.

The Department suggests stakeholders read the EY Report (Attachment A) in conjunction with the report by AHTA (Attachment B) and advises the EY Report reflects the views and perceptions of stakeholders at a particular point in time (i.e. July 2021) which may have changed over time. The Department's views were not represented in this report and there has been progress and changes made in the space since.

# Departmental response to AHTA Report

The Department has considered the Final Report and the options suggested by the AHTA.

The Minister for Health and Aged Care, the Hon Mark Butler MP, has used this report to inform an initial judgement on a way forward, to deliver improvement, assist with streamlining processes and allow for reasonable workloads, while delivering high quality advice to sponsors. With this in mind, Minister Butler considers Option 1 is the most appropriate option moving forward as it will improve the efficiency of the current process, particularly with the adoption of improved application forms and revised guidance materials for sponsors and external evaluators, however, with some continuity as a well-established structure remains. This will be aided with Professor Terry Campbell (AM), who has proven to be a highly effective Chair of the PLAC, agreeing to be reappointed as Chair.

The key points of difference proposed from the existing governance design are:

- The PLAC is modernised with a change of name, the Medical Devices and Human Tissue Advisory Committee (MDHTAC)
- Representatives from the Medical Device, Private Hospitals and Private Health Insurance industries will be removed from the committee to reduce any perceived or actual conflict of interest within the committee membership
- The existing CAGs and PoCE will be re-structured into six Expert Clinical Advisory Groups (ECAGs), with up to ten members residing on each ECAG
- The MDHTAC will comprise of the six Chairs from each of the ECAGs who will provide not only clinical expertise but also a connection between the MDHTAC and the respective ECAG. Additionally, a consumer representative; a health economist; and up to two clinical / health technology assessment experts who are not on an ECAG
- Revised guidance material will be developed for each of the three-tiered pathways processes and an enhanced application form via the Health Products Portal (HPP)
- Applications will be assessed against the requirements for eligibility for listing on the Prostheses List, however under Tier 1, there will be limited opportunity to amend or provide further information in the application
- Applications that require Tier 2 or Tier 3 assessment are assessed by the relevant ECAG and external health technology experts or MSAC where required

- The assessments, including advice from external assessors, are presented to the MDHTAC. This can be presented by the Chair of ECAG or one of the clinical experts (discussants).

## Optimising the current PLAC – proposed structure of the MDHTAC

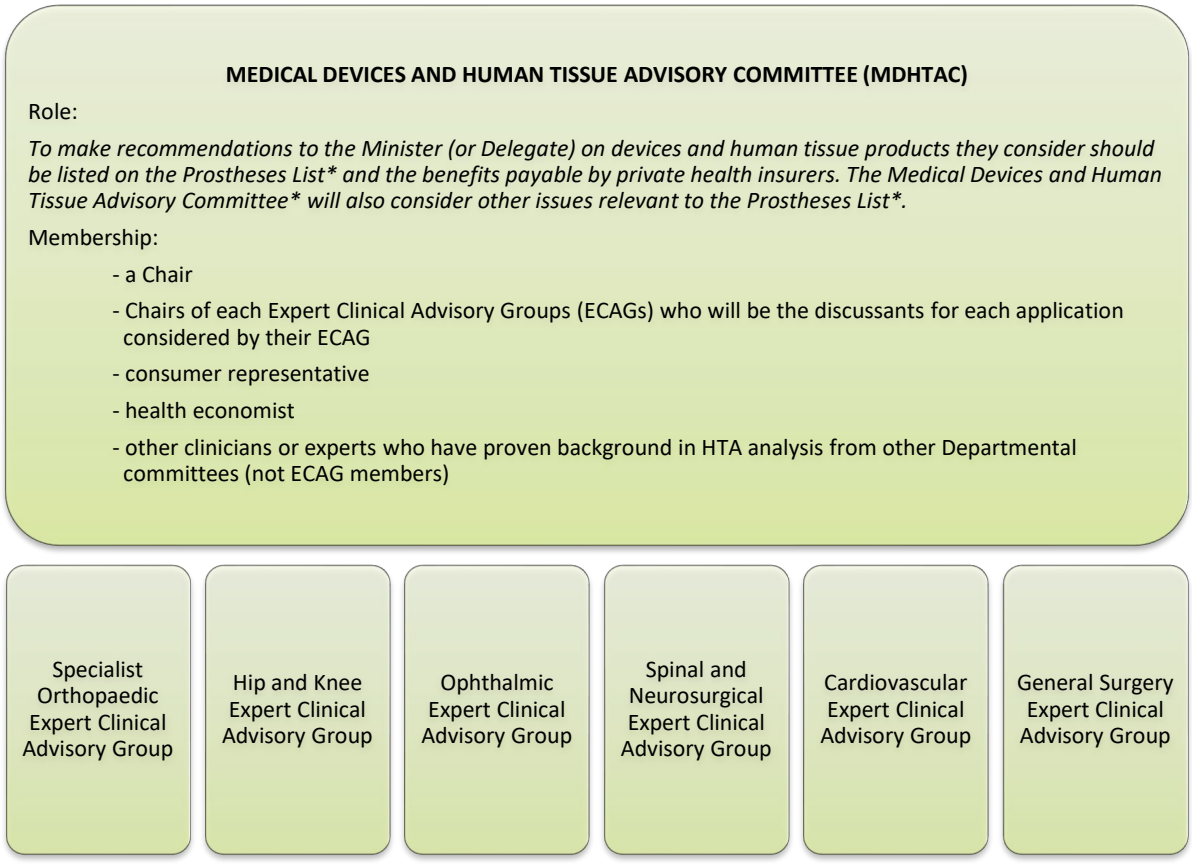
The Medical Devices and Human Tissue Advisory Committee (MDHTAC) will continue to make recommendations to the Minister (or Delegate) on whether the devices for listing on the PL they consider should be listed on the PL, the benefits payable by private health insurers, and other issues relevant to the PL.

The Chair of each ECAG will be appointed by the Minister for terms of two-years, up until 30 June 2025. Members will be departmentally appointed.

It is expected additional clinicians may be required to provide advice on occasion, however, to avoid reinventing the PoCE, it is proposed the Department should approach the relevant medical society to engage expertise, where relevant and as required and practicable to do so.

The proposed structure of the MDHTAC and each ECAG are at Figure 1 and Table 1.

**Figure 1: Proposed structure of the MDHTAC**




*these naming conventions are subject to change to align with updates to the legislation taking place as part of the reforms

**Table 1: Proposed structure of the ECAG models**

| ECAG | Areas of Specialty (Advice) | Replacement of Current CAG / PoCE |
|---|---|---|
| Specialist Orthopaedic | – Shoulder<br>– Ankle<br>– Foot, Upper limb, Skeletal Reconstruction | – Specialist Orthopaedic (SOCAG) |
| Hip and Knee | – Knee<br>– Hip | – Knee Prostheses (KPCAG)<br>– Hip Prostheses (HPCAG) |
| Ophthalmic | – Ophthalmic | – Ophthalmic Prostheses (OPCAG) |
| Spinal and Neurosurgical | – Spinal<br>– Neurosurgical | – Spinal Prostheses (SPCAG)<br>– Neurosurgical PoCE |
| Cardiovascular | – Cardiac<br>– Cardiothoracic<br>– Vascular | – Cardiac Prostheses (CPCAG)<br>– Cardiothoracic Prostheses (CTPCAG)<br>– Vascular Prostheses (VPCAG) |
| General surgery | – Ear, Nose and Throat<br>– Plastic and Reconstruction<br>– Urogenital<br>– All other general surgery devices | – ENT PoCE<br>– Plastic and Reconstructive PoCE<br>– General Misc and Urogenital PoCE |

# The role of Industry representation

The Department acknowledges that there is some concern from stakeholders the removal of industry representation from the committee (i.e. observers from the private health insurance and medical device industries).

Stakeholders will be able to raise concerns once an item has been listed. Any interested stakeholder is able to write to the Department (as the decision maker) to raise their concerns (including providing evidence) regarding the listing of any item on the PL.

Additionally, key stakeholders will be kept abreast of issues through the regular stakeholder forums and through the post-listing review process.

# Publication of Committee Outcomes

It is acknowledged consultation on a sponsors application is the preference of some stakeholders, including the publishing of a Public Summary Document which provides the critical thinking on an outcome. The Department recognises there is commercially sensitive information contained in an application and for this reason, the Department is not proposing to disseminate applications for comment and does not plan to publish Public Summary Documents on each application. Further, the Department receives over 700 applications per cycle and the publication of these documents are resource intensive. The likely resources required to produce this output is not feasible.

Recognising concern while also addressing transparency, the Department is considering the production of a high-level meeting outcomes document of applications considered by the

MDHTAC. Information to be released will include the device name, its use and high-level outcomes (including grouping where an application has been approved) and negative recommendations where applicable. The Department acknowledges concerns related to the publishing of high-level meeting outcomes and will monitor any unintended consequences of its implementation.

**Health.gov.au**

All information in this publication is correct as at December 2022