



Prosthesis List Reforms Consultation Paper 6(a) – Proposed Listing Criteria – Stakeholder Feedback Report

28 June 2023

Introduction

The purpose of this report is to provide a high-level analysis of stakeholder feedback received in response to the [Prostheses List Reform Consultation Paper 6a - Listing Criteria](#). The submission period for responses to this paper occurred between 20 March 2023 and 1 May 2023, with a total of 12 submissions received by the Department (**Figure 1**).

The Department of Health and Aged Care (the Department) held a webinar to address stakeholder questions on 3 April 2023, covering both the listing criteria and proposed cost recovery arrangements (consulted on in [Consultation Paper 6b Cost Recovery Arrangements](#)). Stakeholders were given the opportunity to pose questions. This webinar remains accessible on the Department's website [here](#). The responses to these questions were compiled in a '[frequently asked questions](#)' document published 21 April 2023.

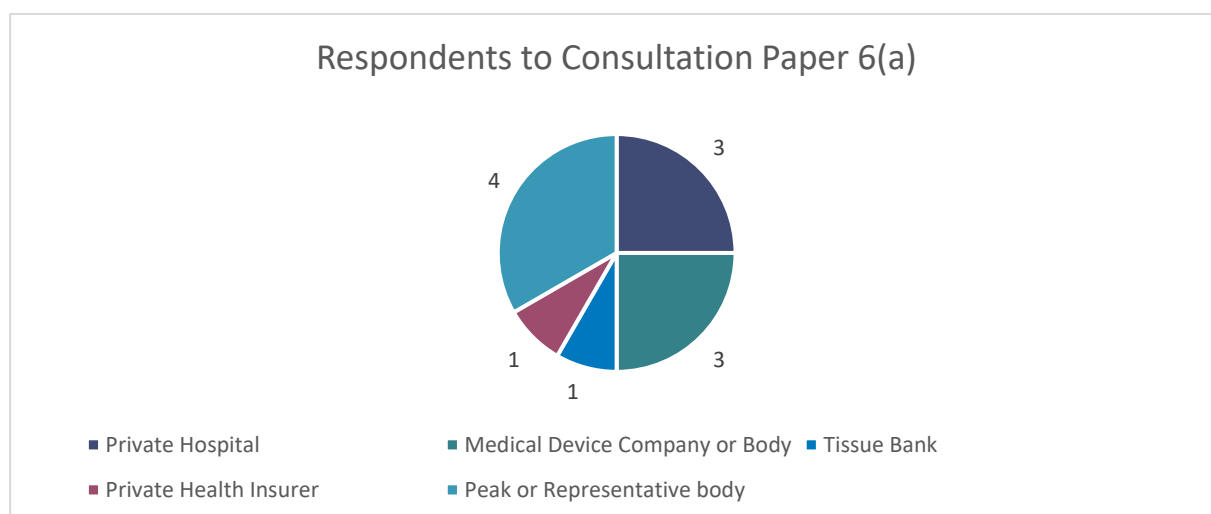


Figure 1: Number and type of respondents to Consultation Paper 6(a)

Important context

It is important to note that at the time of release of the Listing Criteria (LC) consultation paper, the Department could only provide examples of text from the existing (publicly available) Prostheses List (PL) Guide to support the proposed LC. As stakeholders are aware, the Department is currently revising the PL Guide and will be consulting on the document soon. For this reason, this response document will not focus on feedback provided in relation to strengthening existing LC text within the PL Guide, as this will be captured through the PL Guide consultation period.

Next steps

All the submissions to the consultation paper will be considered by the Department along with other feedback received from stakeholders.

Acronyms

- 'PHI Act' – *Private Health Insurance Act 2007*
- 'TG Act' – *Therapeutic Goods Act 1989*
- 'TG Regulations' – Therapeutic Goods (Medical Devices) Regulations 2002
- 'ES' – Explanatory Statement
- 'LC' – Listing Criteria
- 'PL Guide' – Prostheses List Guide

Stakeholder Feedback Evaluation

Evaluation of the submissions considered responses to the four key matters outlined in the consultation paper, namely the:

- Impact of each proposed criterion
- Suggested inclusions to the LC
- Frequency of revision of the LC
- Inclusion of notes in the legislative instruments

The following sections summarise the key feedback against these four matters.

Impact of the proposed Listing Criteria

- All submissions that included a response to this question agreed that the proposed LC largely reflected administrative practices as currently operate and would not result in major impacts to pursuing listing on the PL. There were many minor caveats provided for each response, with the most common request being for further clarity around each criterion to be included in the next iteration of the PL Guide (currently under development).
- A handful of submissions appear to have confused the intent of the LC to govern how and when an item listed on the PL can be used, rather than its actual intent of outlining the eligibility that must be met in order to be listed on the PL.

Part A – Criterion 1(a) – implantable medical device and active implantable medical device

Definition of 'implantable' or 'implantable device'

- The definition of 'implantable/implantable device' was raised in several submissions. Respondents view that the proposed definition is misaligned with TG regulations, with several raising that 'active implantable medical devices' need to be included.

Duration of the implant

- Several respondents were concerned that this criterion does not provide a timeframe for how long a device should remain implanted and one submission noted that there should be an expectation that the implantable device is essential, and not an aid.

Department response:

Implantable/implantable devices: The Department acknowledges the need for inclusion of 'active implantable medical devices' and will expand Criterion 1(a) to include a reference to 'active implantable medical devices' as well as 'implantable medical devices' in line with the TG Regulations. This provides that wherever the criteria apply to an 'implantable medical device' it will also apply to an 'active implantable medical device'.

Duration of implant: Criterion 1(a) uses the definition of 'implantable medical device' from the TG Regulations, which includes duration requirements under those regulations.

Part A – Criterion 1(b) – essential to and specifically designed as an integral single-use aid for implanting a medical device in (a) above, which is only suitable for use with the patient in whom the medical device is implanted

Inclusion of 'essential'

- Respondents agreed that the inclusion of the term 'essential' was welcomed, but further clarification was required.
- Further clarification was requested that 'essential' should be taken to mean that the product will (in the opinion of clinicians) in some cases deliver better outcomes for the implant or the implanting process.

Department response:

The inclusion of 'essential' is used in the same way as in TG Regulations. The Department will consider providing additional context in the ES (e.g. 'Devices are essential where they deliver better health outcomes for insured persons, including improved surgical accuracy, reductions in operating time and reduced incidence of revision surgery').

Part A – Criterion 1(c) – critical to the continuing function of the surgically implantable medical device to achieve (a) above and which is only suitable for use by the patient in whom the medical device is implanted.

- There was no major feedback about this criterion other than a common theme that there is uncertainty of its historical application, which is noted by the Department.

Part A – Criterion 2 – not used for diagnostic, prognostic or predictive purposes

- Respondents noted that the wording for this criterion as posed would rule out devices for diagnostic, prognostic or predictive purposes and outlined that it is therefore important that alternative payment arrangements are considered.

Department response:

The Department considers that the wording for this criterion as proposed is appropriate and reflects the eligibility criteria for listing on the PL as defined under the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023* that comes into effect from 1 July 2023. Further, this criterion

confirms the Government's commitment to remove ineligible items currently listed on the PL (e.g. General Use Items).

Following the stakeholder feedback received through the recent [Prostheses List Reforms - Consultation Paper 5 - Bundling of Benefits for General Use Items](#) consultation, the Department is considering the next steps for these items and will provide further advice to the sector in June 2023.

Part A – Criterion 3 – specific treatment and indication

- Respondents indicated that there may be confusion about a 'specific treatment' and 'multiple conditions' for which that treatment is used, as the criterion applies to 'treatments' not 'conditions' for which the treatment is used.

Department response:

The Department acknowledges the confusion raised and will consider how it can strengthen this criterion either through reframing of the criterion itself and/or additional context in the ES.

Part A – Criterion 4 – comparison of clinical effectiveness and benefit proportionality

- Respondents noted this criterion is consistent with what is applied administratively currently, and the wording is appropriate as posed, which is noted by the Department.

Part B – Human Tissue Products

- Respondents noted this criterion is consistent with what is applied administratively currently, and the wording is appropriate as posed, which is noted by the Department.

Part C – General

- Generally, respondents welcomed this criterion as an avenue for innovative technology.
- A handful of submissions outlined reservations about 'exceptional circumstances' and questioned whether Ministerial invitation to submit an application would be required.

Department response:

The concept of 'exceptional circumstances' is commonly used through the Commonwealth. The Department will consider how it can strengthen this criterion either through reframing of the criterion itself and/or additional context in the ES.

Part C – Criterion 1 – ineligible for Part A

- Respondents noted that the wording as posed for this criterion is acceptable, however, many suggested that additional context against this criterion should be included under the PL Guide. This includes clarification that eligible devices must be single use or patient specific to avoid any impression that multiple use devices or capital equipment are likely to be considered.

Department response:

The Department notes that the wording for this criterion as posed is appropriate and will consider whether additional context can be incorporated within the ES.

Part C – Criterion 2 – comparison of clinical effectiveness and benefit proportionality

- Respondents noted the wording for this criterion is appropriate as posed, which is noted by the Department.

Part C – Criterion 3 – exceptional circumstances

- Respondents were broadly supportive of the examples of ‘exceptional circumstances’ that are provided for this criteria, however, additional examples including ‘serious conditions’ and ‘orphan indications’ were proposed.
- A further suggestion was made that Criterion 3(d) should be reworded to clarify that the lower cost of the device applies to the wider healthcare system and not necessarily the device itself.

Department response:

The Department will consider whether the suggested additions to this criterion are appropriate, either through reframing of the criterion itself and/or additional context in the ES.

Suggested inclusions to the Listing Criteria

Several additional recommendations were provided by respondents to be considered for inclusion in the LC. In addition to those already outlined in this response paper, this includes (but is not limited to):

- Part C - Criterion 3 - Benefit should only be payable once the device has actually been used.
- Additional listing criteria that ask device manufacturers to declare there will not be extra charges for the device beyond the PL price.
- Development of a secondary set of criteria which differentiate General Use Items from other items of the PL.

Department response:

The Department will consider all suggestions provided by respondents when finalising the LC.

Frequency of revision of the Listing Criteria

- Respondents agreed that the LC should be cyclically reviewed to keep up with medical and technical advancements (including outcomes of specific Post Listing Reviews).

Department response:

The Department acknowledges that the listing criteria represents an important transparency measure and will be reviewed regularly and if necessary, updated whenever improvement is required, including as a result of specific Post Listing Reviews.

Inclusion of notes in the legislative instruments

- The majority of respondents agree that notes in the legislative instruments should be included for the sake of clarity and to avoid differing interpretation.

Department response:

The Department will include notes (where able) within the legislative instruments to increase ease of interpretation and clarity of terms. Where relevant, additional clarity around the listing criteria will also be included in the ES.

Outside the scope of the consultation paper

While technically outside the scope of the consultation paper, several submissions provided alternative options for consideration by Government to achieve the policy objectives of the reform. The Department would like to reassure stakeholders that their concerns regarding these issues will be considered either in future consultation papers, or educational materials provided by the Department. These issues included (in no particular order), but are not limited to:

- Concerns about the pathway for reviewing or challenging a decision about (in)eligibility for listing is inadequate, resulting in increased funding uncertainty and access issues for private patients.
- Using the existing PL Part D but with:
 - collection of utilisation data to inform clinical practice
 - a sliding scale of benefits reductions to incentivise contracting
 - efficient prices rather than public sector prices to incentivise more cost-effective utilisation.
- Centralised procurement of general use items by the Commonwealth to reduce inequities in pricing across hospitals and between the Australian and overseas markets.
- Requested revisions to existing content of the PL Guide and seeking advice on when the PL Guide will be released for consultation.