PL REFORMS CONSULTATION PAPER 3(B) – PATHWAYS SUBMISSION RESPONSES ANALYSIS

Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received in response to the Prostheses List Reforms *Consultation Paper 3(b): Pathways for Applications to the Prostheses List*. The submission period for responses to this paper occurred between 16 September and 28 October 2022. A total of 18 submissions were received and accepted by the submission deadline (**Figure 1**). Evaluation of the submissions considered responses to the proposed 3-tiered application pathways and cost recovery proposal of the Prostheses List (PL) Reforms.

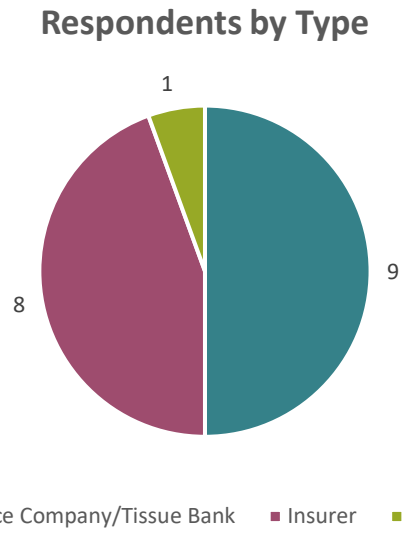

Figure 1: Number and type of respondents to Prostheses List Reforms Consultation Paper 3(b).

Key concerns raised on pathways

Concerns raised centred largely around the following issues: lack of payor scrutiny in Tier 1 applications, Class III device ineligibility for Tier 1 Pathway and a lack of reduction in the timeframe from application to listing . Additionally, feedback was provided on the glossary of terms and the comparative table by stakeholders.

Key feedback from cost recovery proposal

In response to the positive impacts of implementing cost-recovery for PL applications:

- 11% of respondents are expecting no positive impacts,
- 39% are expecting some positive impacts.
- 17% responded neutrally with a ‘wait-and-see’ approach
- 22% provided no comment
- 11% provided feedback specific to possible future cost recovery from a Part B perspective

The positive respondents are anticipating greater transparency and integrity in the PL application process as a result of cost recovery implementation measures., while some stakeholders reasoned any potential positive impacts through increased savings would likely be offset by increased costs elsewhere.

When considering the potential negative impacts brought forward by the cost recovery proposal:

- 56% of stakeholder submissions expect there to be negative impacts
- 33% either did not comment or did not raise any potential negative impacts related to cost recovery
- 11% of submissions provided feedback specific to cost recovery from a Part B perspective.

An overview of stakeholders feedback on the Pathways and cost recovery proposal, as well as the Department's response to the feedback is summarised in **Table 1** below.

Outside the scope

Several issues were raised by stakeholders that were outside the scope of Consultation Paper 3(b) and were not included in the analysis above. These included (in no particular order) but are not limited to:

- Part B pathways and cost recovery associated with Part B
- Part C application process
- Key performance indicators to evaluate Prostheses List Reforms
- Post-listing reviews

These issues will be considered as part of future Prostheses List Reforms.

Table 1: Key concerns about the Pathways and cost recovery fee proposals raised by stakeholders and the Department's accompanying response to address stakeholder concern.

Issue	Stakeholder feedback	Department response
Payor Scrutiny / Public Consultation	Some stakeholders raised their concerns regarding a lack of transparency in the PL listing process with 28% of submissions concerned about a lack of payor scrutiny. A further 22% of submissions sought clarification and/or raised concern about formal public consultation during the assessments phases of PL listing.	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. As was advised in the Consultation Paper, key industry stakeholders will be kept abreast of issues through the regular stakeholder forums and through the post-listing review process. **Tier 1 and Tier 2 assessments** The Department will not share commercially sensitive information. The Department is, however, considering the publication of high level meeting outcomes which documents applications considered by the Prostheses List Advisory Committee (PLAC). Information to be released would include the device name, its use and high level outcomes (including grouping where an application has been approved). **Tier 3 assessments** It should also be noted that applications submitted via the Tier 3 Pathway, are subject to the processes outlined by the Medical Services Advisory Committee (MSAC), which includes formal public consultation.
Class III device ineligibility in the Tier 1 Pathway	Some stakeholders expressed disappointment that all Class III devices were ineligible for Tier 1 Pathway with 28% of submissions raising this concern.	The Department acknowledges Sponsors are disappointed with Class III devices being reviewed via the Tier 2 Pathway, however, the Therapeutic Goods Administration (TGA) assess safety, quality and performance of an application. The PLAC will continue to assess Class III devices in order to assess comparative clinical and cost-effectiveness of the prostheses. The Department understands these concerns and will monitor this pathway before consideration is given for these devices to be considered under the Tier 1 Pathway.

Timelines	28% of submissions raised concern that despite the streamlined pathways, the timeline to listing remained the same.	Concerns raised by stakeholders in response to the timelines not changing are understood, however, due to the significant number of applications received per cycle and the significant resource intensive requirements of health insurers and hospitals to update their systems, the number of PL updates will remain the same and thus the timelines for device applications will remain the same.
3 Tier-Pathway Proposal	The first question posed by the Department was in regard to whether there were any significant concerns with the proposed pathways as outlined in the consultation paper. This question was not addressed by 17% of submissions. From the submissions that did provide a response, 44% had a positive response and/or did not raise any significant concerns with the proposed pathways while 39% had a negative response and raised their concerns with the proposed pathways. Furthermore, feedback from Tissue Bank stakeholders was they preferred to withhold feedback until further consultation occurred with regards to Part B specifically.	The Department thanks all stakeholders for the feedback provided with regards to the 3 Tier-Pathway proposal. The Department has considered the feedback received with key concerns addressed in this response. Part B stakeholders will likely be consulted in the first half of 2023.
Glossary of Terms	The glossary terms outlined in the consultation paper were largely well received with 56% of submissions agreeing the terms were well defined. 22% of submissions did not provide any comments while a further 22% provided comments and suggestions to redefine certain terms. The terms “Comparator” and “Well-established Technology” were the most commonly raised with stakeholders suggesting the terms are potentially ambiguous and in need of clarification.	The Department is grateful for feedback provided on the Glossary of Terms and the Comparison Table. These two documents will be updated to reflect feedback, specifically further clarity being required on some of the definitions, and some fields in the comparison table requiring consideration. The Department will consider these and incorporate this information in the new PL Guide which will be available on the Consultation Hub for feedback in the first half of 2023.
Comparison table	Table 2 in the consultation paper, which is to be used to demonstrate interchangeability (one device can be substituted for another device), was seen as adequately suitable by 28% of submissions. 17% of submissions did not provide any comment while 56% of submissions provided further comments and suggestions regarding its suitability and advising of potential improvements, eg. information on a comparator device was not always publicly available for sponsors to enter into the table.	
Cost recovery fee	***Positive*** • Stakeholders expect these measures will ensure appropriate levels of resourcing within the Department, with staffing efficiencies in processing PL applications and	The Department acknowledges concerns of stakeholders regarding the flow on effects of the introduction of cost recovery fees. However, the new cost recovery proposal is aimed to ensure the Department’s activities are consistent with the Australian

	better accessibility and responsiveness of Departmental staff. Medical device and product sponsors in particular anticipate additional capacity and increased efficiency, accuracy and resourcing for PL listing processes. ***Negative*** • Cost recovery fees may act as a barrier to sponsors, particularly smaller local sponsors being unable to invest in the submission for inclusion on the PL, raising risks of limiting prospective patient access. • Additional costs from cost recovery fees may be passed on from device manufacturers to customers, which may result in increased costs borne by the suppliers. • The proposed cost recovery fee associated with list management services is expected to increase the costs of keeping billing codes up to date • Fees associated with compliance and related activity costs should not be charged in entirety to sponsors and should be shared amongst all stakeholders that directly or indirectly derive some form of commercial benefit through the PL listed items.	Government Charging Framework (the Charging Framework) and the Cost Recovery Guidelines introduced in 2015, which requires that non-government entities using PL services pay the minimum efficient costs of these activities.The PL cost recovery model has been developed by calculating these minimum efficient costs for administering the PL. The Department notes that sponsors will be liable to pay a cost recovery levy for each billing code on the PL.These levy implications should be taken into account in considering the incentives for sponsors to make list management applications for deletion of inactive billing codes or transferring billing codes. This is likely to ensure a more efficient, transparent and current PL.
Transparency	• The need for detailed criteria for the new pathways to be clear, transparent, and mutually exclusive in order to enable industry to plan and prepare their applications accordingly. This includes information about the indicative fees for categories not covered in the consultation paper. • Agreed key performance indicators should be captured to measure the impact of cost recovery, and the PL reforms more broadly for enhanced stakeholder knowledge.	The Department will publish a Cost Recovery Implementation Statement (CRIS) annually explaining key information on how cost recovery for the PL is implemented and reports on how the activity is performing on an ongoing basis, consistent with the Charging Framework. The Department will maintain and update the CRIS as required until the activity or cost recovery for the activity has been discontinued to allow for appropriate scrutiny of government activities, decisions and processes. The Department will review the PL cost recovery arrangements following implementation. In addition, the Department will conduct periodic reviews of all existing and potential charging activities within the PL application and listing process at least every five years, in accordance with the published schedule of portfolio charging reviews or at other times agreed by the Finance Minister.

Guidance and education for sponsors	• Stakeholders request more details regarding simple administrative tasks such as a change of product code, change of product name, change to Australian Register of Therapeutic Goods (ARTG) number etc. Further, these simple administration tasks should be performed at zero cost to the supplier. • More guidance and education material should be developed for the benefit of the stakeholders, particularly, to provide more information on application and assessment pathways, the parallel processing of submissions to MSAC, proposed Risk Sharing Agreement and transitional arrangements.	The Department acknowledges that more information has been requested by respondents regarding the cost recovery proposal and interactions with the application and assessment pathways, as well as other reforms. The Department will provide stakeholders with access to detailed information and guidance to support sponsors and industry in understanding of new processes prior to implementation.