Prostheses List Reforms -

Reforms to Part B of the Prescribed List of Benefits for Medical Devices and Human Tissue Products\* (PL)

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# Summary

In January 2022, the Department of Health and Aged Care (the Department) released **Consultation Paper 2(a) - Modernisation of Part B of the Prostheses List\*** (the paper). The paper put forward ideas to improve Part B in line with the changes that will apply to the rest of the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the PL), formerly known as the Prostheses List. Specifically, it proposed two initiatives to modernise Part B:

* A revised classification structure, and
* Introduction of a health technology assessment for human tissue products.

The department received 22 submissions from various eye and tissue banks, sponsors, hospitals and insurers. A high-level analysis of the submissions was undertaken, with varying levels of support for the proposals outlined in the paper.

A common theme identified in the responses was that eye and tissue banks were unsure of how they could remain viable if the initiatives outlined in the paper were implemented. This represented a significant risk both for patients and the eye and tissue sector as whole. The Department needed to gain a better understanding of these issues to ensure the implementation of the reforms can progress as planned.

The Department determined that further targeted consultation was required to fully understand stakeholder concerns and trepidations regarding the regrouping and new assessment pathways. The consultation process would also allow the Department to both better communicate the details of the proposals, and address stakeholder concerns.

In December 2022, the Department engaged PricewaterhouseCoopers (PwC) to undertake a scope of work including the targeted consultation. This scope of work included:

* Reviewing **Consultation Paper 2(a) - Modernisation of Part B of the Prostheses List\***, including the 22 submissions received as part of the PL review consultation process.
* Attending a scoping meeting with the Department to further define the scope, parameters, and objectives of the targeted consultation.
* Conducting targeted consultation, including a minimum of two workshops, with key stakeholders to collect pertinent information and more detailed feedback regarding the feasibility of the new proposed new group structure and listing pathways as detailed in the consultation paper.
* Developing summaries of each workshop, including objectives, issues discussed and outcomes (including any recommended amendments to the already proposed regrouping and listing pathways).
* Investigating the impact of cost-recovery on organisations that submit Part B applications – including not-for-profit organisations and commercial manufacturers.

In May 2023, the Department accepted delivery of PwC’s final report ‘*Reforms to the Prostheses List\* Part B – May 2023*’ (the report) which makes 10 key recommendations and outlines practical and tangible steps forward to support the proposed reforms to Part B of the PL. The Department’s initial response to PwC’s report is outlined in **Table 1** below.

# Departmental response to the PwC Report

The Department is currently considering the recommendations made in the report and invites stakeholders to review and make comment on both the report (at Attachment A) and the Department’s initial response to the recommendations, as outlined in **Table 1** below.

**Table 1: Department’s initial response to PwC’s report recommendations**

|  |  |  |  |
| --- | --- | --- | --- |
| **Recommendation** | **Recommendation Accepted****Yes / No** | **Dept Ownership area** | **Next Steps** |
| **1.** that the Department offer stakeholders the opportunity to provide feedback on the proposed definition for Part B products. | Yes | PLRT+ | * PLRT is reviewing the proposed Part B definition and is seeking feedback from the sector, via a survey on the Department’s Consultation Hub.
 |
| **2.** that the Department consider whether the exemption from fees associated with Part B of the PL be restricted to Sponsors of Class 2 biologicals or Sponsors who are registered as a not-for-profit entity with the Australian Taxation Office. | TBD | PLRT | * PLRT will consult internally with relevant areas, including cost recovery and legal branch, to ascertain if/how this recommendation can be implemented, including any subsequent improvements identified as part of this consultation process.
* PLRT will identify a proposed way forward and undertake targeted consultation with key stakeholders prior to implementation.
 |
| **3.** that the Department update and refine the groupings proposed by hereco, incorporating the stakeholder feedback contained in Table 1 and Table 2. | Yes | PLRT  | * PLRT is updating the PL for the Part B structure as part of this consultation process and has incorporated stakeholder feedback as detailed in Tables 1 and 2 of the PwC report (pgs. 9&10).
* PLRT is seeking feedback from the sector, via a survey on the Department’s Consultation Hub, prior to finalising the regrouping structure.
* Once stakeholder feedback has been reviewed, the PLRT will finalise the proposed Part B structure and distribute via a PHI Circular.
 |
| **4**. that the Department establish a regular review process of the Part B groupings | Yes | PLRT | * PLRT will consult internally with relevant areas to determine next steps and implementation timeframes once a new grouping structure has been finalised.
* PLRT will seek feedback from the sector prior to finalising the proposed review process for Part B products.
 |
| **5.** that the Department proceed with implementing the three assessment pathways which mirror the pathways for Parts A and C of the PL. | Yes | PLRT | * PLRT will update the appropriate reform documents to reflect the three new pathways for Part B products.
* PLRT will continue to work with the Health Products Portal (HPP) transition team to reflect the new changes for Part B products
* PLRT will continue to engage with the sector prior to implementing the three assessment pathways for Part B products.
 |
| **6.** that the Department provide additional support and guidance for Sponsors of Class 2 biologicals to navigate HTA pathways. | Yes | PLRT | * PLRT will identify relevant guidance documentation to be drafted/updated.
* PLRT will map out potential be-spoke pathways for stakeholders when preparing Part B Class 2 biological PL applications.
 |
| **7.** that the Department undertake further work on the methodology for pricing including the development of costing standards. | Yes | OTPPS# | * OTPPS will manage and progress this work in consultation with PLRT and other relevant areas of the Department.
* OTPPS is investigating the development of a costing methodology through the Jurisdictional Organ and Tissue Steering Committee (JOTSC). The NSW Tissue Bank have provided their costing methodology, which is currently with JOTSC members to consider whether the methodology is appropriate for their jurisdiction and what changes could be made to improve its suitability.
* OTPPS will undertake consultation with stakeholders to seek their feedback on the outcome of the JOTSC discussions.
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| **8.** that the Department undertake a review of state and federal legislative requirements which prohibit trading in human tissue and its application to determining benefits for Part B. | Yes | OTPPS | * OTPPS will manage and progress this work in consultation with PLRT and other relevant areas of the Department and in consultation with stakeholders.
* JOTSC has asked jurisdictions to review their existing legislation and identify activities that are cost-recoverable in accordance with it. This may assist in understanding the costs of the retrieval and manufacturing process, and where funding from government is already provided. JOTSC will provide their findings to the OTPPS.
* OTPPS will consult with stakeholders once the outcomes of the JOTSC discussions are known.
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| **9.** that the Department retain the PL items for autologous skull flaps and femoral heads. | Yes | PLRT | * PLRT will consult with the Department’s Executive to confirm whether PL items for autologous skull flaps and femoral heads be retained on the PL.
* PLRT will inform the sector of the outcome of these discussions.
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| **10.** that the Department does not pursue restricting the use of Part B items to specific MBS items at this time. | Yes | PLRT | * PLRT will consult with the Department’s Executive to confirm it will not currently pursue restricting the use of Part B items to specific MBS items.
* PLRT will inform the sector of the outcome of these discussions.
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**\*** On 1 July 2023, the Prostheses List was renamed to the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the PL)

+ **PLRT** - Prostheses List Reforms Taskforce

# **OTPPS** - Organ and Tissue Policy and Programs Section

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All information in this publication is correct as at August 2023