**Table 1: PwC REPORT RECOMMENDATIONS - REFORMS TO PART B OF THE PRESCRIBED LIST OF BENEFITS FOR MEDICAL DEVICES**

**AND HUMAN TISSUE PRODUCTS (PL)****\* - May 2023**

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| --- | --- | --- | --- |
| **Recommendation** | **Recommendation Accepted****Yes / No** | **Dept Ownership** | **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
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| **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
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| --- | --- | --- | --- |
| **Recommendation** | **Recommendation Accepted****Yes / No** | **Dept Ownership** | **Next Steps** |
| **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 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