Prostheses List Reforms Consultation Paper 6(b) – Proposed Cost Recovery Arrangements – Stakeholder Feedback Report

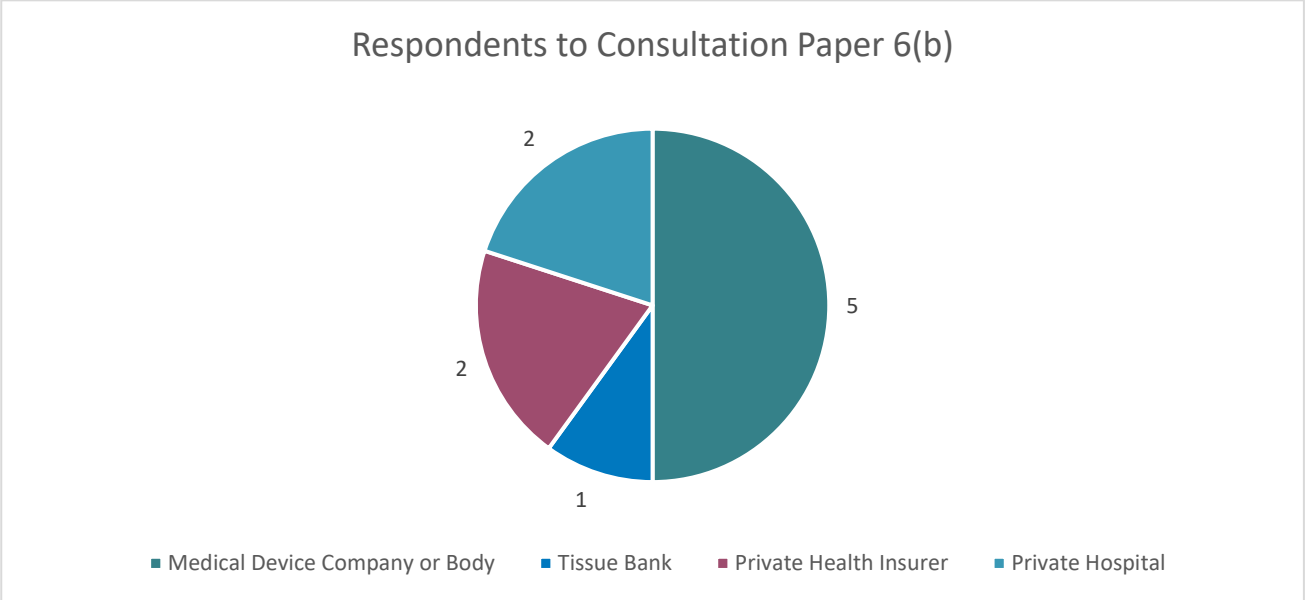
June 2023

Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received in response to the Prostheses List Reform Consultation Paper 6b Cost Recovery Arrangements. The submission period for responses to this paper was 20 March to 1 May 2023. A total of 10 submissions were received by the submission deadline, with the number and type of respondents outlined below (**Figure 1**).

The Department of Health and Aged Care (the Department) held a webinar to address stakeholder questions on 3 April 2023, covering both cost recovery and listing criteria (consulted on in Consultation Paper 6a - Listing Criteria). 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(b)



Stakeholder Feedback and Department Responses

The Department notes general feedback from stakeholders regarding the principles of cost recovery. The Department highlights that the new cost recovery arrangements are aligned with the Australian Government Charging Framework, which means that:

- In line with the Australian Government's Cost Recovery Guidelines (CRGs), all cost recovery charges must have a statutory basis and be underpinned by specific legislation or legislative instruments. There are both Rules and Regulations for fully implementing the cost recovery proposal, including the fees and the levy. Consistent with this approach, the Prescribed List of Benefits for Medical Devices and Human Tissue Products (PL) cost recovery fees and circumstances where the fees will be payable will be specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.
- Cost recovery charges reflect the minimum efficient costs of providing the cost recovered services to industry – this means that revenue is equivalent to expenditure – and this is reported on each year through the Cost Recovery Implementation Statement (CRIS);
- Minimum efficient costs of the activities completed by the Department in managing the PL are based on an activity based cost model – the cost model is made up of direct costs (staffing, committee costs, supplier costs), indirect costs (overheads for staff) and capital costs (including IT systems); and
- In some cases, where an activity is listed against multiple fees, this may be because multiple steps are occurring, for example, invoicing occurs both at the initial application stage, and for some applications throughout the assessment process.

List Management – Deletion and Transfer Application Fees

Stakeholders propose the removal of fees for Deletion applications on the basis that Deletion applications do not require any health technology assessment. Stakeholders suggest that the Therapeutic Goods Administration in their cost recovery arrangements currently do not charge for Deletions.

Stakeholders advised that the transfer applications are complicated due to two potential parties who may be charged the fee. Stakeholders comment that the Therapeutic Goods Administration in their cost recovery arrangements currently do not charge cost recovery fees for Transfers.

Department response:

The Department accepts stakeholder feedback regarding fees charged for Deletion Applications and Transfer Application fees. The Department advises stakeholders that these List Management services will no longer be subject to separate cost recovery fees from the 2023-24 financial year.

As these services are still performed by the Department as part of general management and maintenance of the PL, these will be cost recovered under the cost recovery levy. This is likely to result in a very small increase to the anticipated levy amount. A cost recovery levy is payable once annually for each billing code the sponsor has listed on the PL. The levy will commence in the 2024-25 financial year. Details relating to the cost recovery levy will be available on the PL website and through the Cost Recovery Implementation Statement.

Fees payable for variations to listing, including amendments to Australian Register of Therapeutic Goods (ARTG) details

Overall, respondents expressed uncertainty over the payment of fees for applications relating to variations of existing listings.

- Respondents noted that some applications for variations to an existing listing may not require advice from HTA committees or contract external HTA experts.
- Respondents advised that amendment applications are often made to update PL billing code details to keep them current. Stakeholders advise that substantially high-cost fees associated with making variations to existing listings may act as a disincentive to actively maintain up-to-date listing details. Medical device companies are in the view that charging such high fees to update ARTG details reflected on the PL (which are already reflected on the ARTG) will discourage sponsors from updating the ARTG details in a timely manner.

Respondents suggested that a lower fee should be considered in instances of variations of existing listings.

Department response:

The Department can confirm that there are likely to be no changes to the proposal in relation to amendments of an existing billing code, including amendments to ARTG details of billing codes. The Department advises that amendment applications must be submitted under one of the assessment pathways (Tiers) and will be charged the relevant fees. It is anticipated that the majority of applications relating to variations of existing listings will be considered in Tier 1. Applicants are encouraged to review the PL Guide for further information.

The Department can confirm that the Non-Refundable application fee reflects minimum efficient costs for the initial assessment of the application by the Department. This Department assessment is required even when an application does not require further clinical or economic assessment.

Waiver and Exemption Criteria

Medical device companies proposed that the Department should have the ability to waive fees in cases where applications are made for very niche products that provide for a small population with high clinical need. Tissue Bank stakeholders welcomed the waiver for human tissue products on Part B of the Schedule as state and territory legislation govern the use of human tissue products.

Department Response:

The Department has not proposed any broad fee waivers based on the financial unviability criteria which will apply to all applications.

The Department proposed in the Consultation Paper 6(b) that an application relating to listing a human tissue product on Part B of the Schedule will be provided with a fee exemption. Following further consideration, the Department instead proposes that applications relating to a human tissue products on Part B of the Schedule will not be subject to any cost recovery fees, and will not be required to submit a request for fee exemption or waiver.

Medical Device System Applications

Medical device companies expressed that there was a lack of information relating to so-called device systems. Respondents wanted to know the the cost recovery fees should be applied for system applications which include a combination of devices that have different risk classifications (e.g. both Class III and Class IIB or lower).

Respondents recommended that where applications relate to a system, they would be subject to a single clinical assessment or economic assessment fee.

Department response:

The Department agrees with respondents that it is appropriate, where a set of medical devices can be assessed together for clinical assessment or economic assessment, a reduced fee is payable.

Practically, in these cases, the applicant must advise the Department that multiple billing codes form part of one system, and the Department must agree that the application can be assessed together for clinical or economic assessment. A reduced clinical assessment fee or economic assessment fee will be payable.

Note that a separate Non-Refundable Application Fee is payable for each billing code.

Refund of fees and withdrawal of applications

Stakeholders expressed lack of clarity regarding how refunds will operate. Stakeholders suggest that if error results in non-listing for the target listing cycle the full fee should be refunded.

Sponsors also advise that it is unclear whether sponsors are able to withdraw applications for Tier 2a, Tier 2b and Tier 3 within 28 days and only be charged for the original application fee.

Department response:

The Non-Refundable Application Fee must be paid when the application is submitted and before any work commences on the application. For all other fees, the fee must be paid within 28 business days of an invoice being issued by the Department. The applicant will be able to withdraw applications at any point in the application process following the payment of the Non-Refundable Application fee. Subsequent fee invoices will not be issued until it is confirmed that the relevant health technology assessment is required.

Following stakeholder feedback, the Department has considered that the appropriate circumstances for refunds will be:

- In cases of over-charging;
- In cases of over-paying; and
- In exceptional circumstances as determined by the Minister or the Minister’s delegate.

Following stakeholder consultations, the Department can confirm that a refund will not be offered in all cases where an application does not result in a listing by the targeted listing date. This is because, unless in the case of exceptional circumstances, cost recovery fees will be consistent with the services received to assess and manage the application.

Impact of higher cost recovery fees to small to medium companies

In order to mitigate the impact on small to medium companies particularly, sponsors believe that there should be a phased introduction to these substantial fee increases.

The Department acknowledges stakeholders concerns regarding the flow on effects of the introduction of cost recovery fees.

The Department currently has not proposed a temporary fee exemption for small to medium companies, or a phase-in approach to cost recovery for this group of sponsors.

The new cost recovery proposal is aimed to ensure the Department's activities are consistent with the Australian 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 the minimum efficient costs for administering the PL.

The Department will note this feedback and review any unintended implementation effects as part of the review of cost recovery arrangements to be undertaken approximately 18-24 months following implementation.

Training and Formal Pre-Submission Meetings

Sponsors raised concerns about the non-refundable application fees in case of selection of an incorrect pathway, and suggested that the Department provide additional training, formal pre-submission meetings and clear guidance for industry is required to prevent avoidable rejections and wasted resources from all parties.

Department response:

At present, the Department does not propose to offer formal pre-submission meetings. If the Department were to offer any formal pre-submisison meetings in the future, those would be subject to fees which are included in the cost recovery arrangements similar to other Health Technology Assessment committees.

Medical device companies will continue to be able to contact the Department to seek any further information regarding their application. Additionally, the Department will publish the PL Guide for stakeholder consultation. The PL Guide will provide information to assist applicants to prepare an application to list an eligible medical device or human tissue product on the PL, or to amend an existing PL billing code. The Department will provide educational material to support

implementation of the cost recovery arrangements. This may include more webinars to communicate changes to all stakeholders.

Transparency

Medical device companies recommend that key performance indicators are developed with input from sponsors and mutually agreed upon for the new PL application arrangements. Stakeholders suggested that these performance indicators and metrics could be published three times per year in accordance with the updates to the Rules.

Department response:

The Department notes that the publication of key performance indicators of assessment outcomes is out-of-scope of cost recovery arrangements. The Department will note and consider this feedback and advise stakeholders if this information will be made publicly available.

In relation to cost recovery, the Department publishes a range of cost recovery performance indicators, primarily in regularly publishing a Cost Recovery Implementation Statement (CRIS). The CRIS is published at a minimum of once annually to explain 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 draft CRIS 2023-24 is available here to consult with industry on the changes to the cost recovery arrangements for the Prescribed List of Benefits for Medical Devices and Human Tissue Products.

A review of the cost recovery arrangements will be undertaken by an independent, external reviewer following implementation in financial year 2024-25.

In addition, the Department is committed to conducting 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.

Out-of-scope of proposed new cost recovery arrangements:

Several issues were raised by stakeholders that were outside the scope of Consultation Paper 6(b) and were not included in the analysis above. The Depart would like to reassure stakeholders that their concerns regarding these issues will be addressed in future consultation papers and educational materials provided by the Department. Timing of Consultation on the PL Guide

Stakeholders raised concerns that the PL Guide had not yet been provided for consultation. The Department notes that the PL Guide will be provided for consultation and stakeholders will be notified when this is available.

- Training requirements
    - The Department notes that educational materials will be provided to stakeholders, however, sponsors making applications should review all supporting documents and familiarise themselves with the cost recovery arrangements and the IT platforms which support applications to be made.
- Evaluation of the PL Reforms
    - Evaluation of the PL Reforms as a whole is out-of-scope of this paper. As outlined above, however, cost recovery will be evaluated following implementation by an independent, external reviewer.
- Mode of payment
    - The Department notes that first fee must be made before application can be assessed. The subsequent fees will be invoiced, with the standard 28 business days for payment.
- Unique Device Identification (UDI) in Australia
    - The Department is aware of the UDI project currently being undertaken by the Therapeutic Goods Administration.The Department will consider feedback from stakeholders and will provide further advice.
- Risk Sharing Arrangements
    - The Department notes that a policy on risk sharing arrangements is out of scope of cost recovery consultation. However, the Department will consider whether risk sharing can be operationalised in the PL context.