Australian Government
Department of Health and Aged Care

Prostheses List Reform Consultation Paper 4(a) and 4(b) – Stakeholder Feedback Report

Legislative Amendment webinars and Exposure Drafts

Contents

Introduction 3

PL reform webinars – proposed legislative amendments 3

Webinar overview 3

Figure 1 Number of questions and responses from the webinars 1-3 from SLIDO 4

Webinar responses 4

Figure 2 Webinar 1 5

Figure 3 Webinar 2 5

Figure 4 Webinar 3 6

Exposure Drafts 8

Legislative Amendment Tranches 8

New Terminology 9

Purpose of Exposure Drafts 9

Status of the bills 9

Exposure Drafts for legislative amendments to the Private Health Insurance Acts to support the PL reforms. 11

Figure 5 Recurrent themes and concerns raised by respondents to Consultation Paper 4(b) - Exposure Drafts 11

Name change 12

Definitions 12

Structure of cost recovery levies 13

Australian Government Charging Framework (AGC Framework) 14

Out-of-scope from Consultation 4(b) – Exposure Drafts 15

Next Steps 16

Conclusion 17

Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received from:

- the three webinars (the webinars) the Department held in September 2022, which outlined the proposed legislative amendments in their entirety, and
- the written responses to the Prostheses List Reforms *Consultation Paper 4(b) – Exposure Drafts for legislative amendments to Private Health Insurance Acts to support the PL reforms* (the paper), which included three draft bills incorporating the first tranche amendments and an Explanatory Memorandum.

PL reform webinars – proposed legislative amendments

Webinar overview

The three webinars that were delivered in September 2022 provided an overall cover of the proposed changes to the PL. Stakeholders were given the opportunity to pose questions on the proposed changes through 'SLIDO'. The webinars were divided into three sessions:

- Webinar 1 - Name change, definitions and listing criteria
- Webinar 2 - Application process, removal of devices and new cost-recovery arrangements
- Webinar 3 - New data sharing and compliance powers.

The webinars facilitated a total of 171 questions asked by stakeholders across the three sessions.

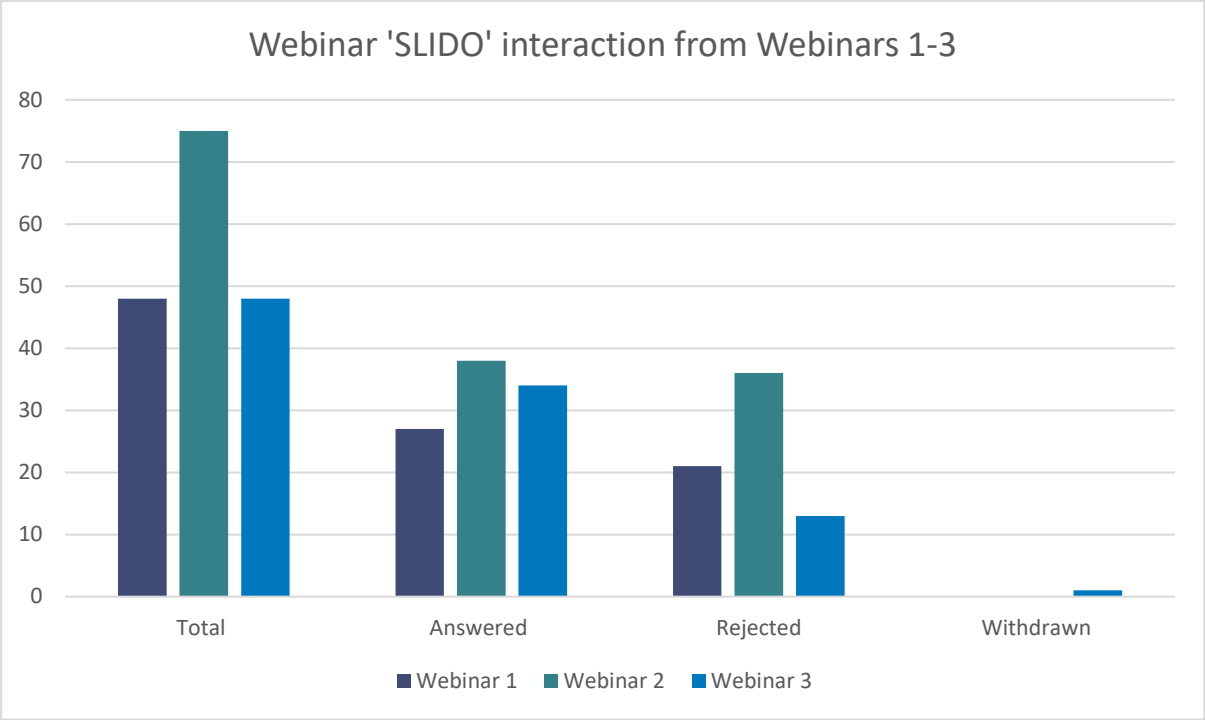

Figure 1 Number of questions and responses from the webinars 1-3 from SLIDO

Webinar responses

Figure 1 demonstrates that webinar 2 featured the highest engagement levels, most likely due to concerns about the potential effect of changes to the application process, removal of devices and new cost-recovery arrangements on industry sectors.

The highest proportion of questions from webinar 1 were about listing criteria for Parts A, B, and C. This work is yet to be completed, with Parts A and C to be completed prior to Part B. Consultation about the listing criteria will be conducted early 2023.

Work on the new data sharing and compliance powers as discussed in webinar 3, are currently underway with further consultation scheduled throughout 2023.

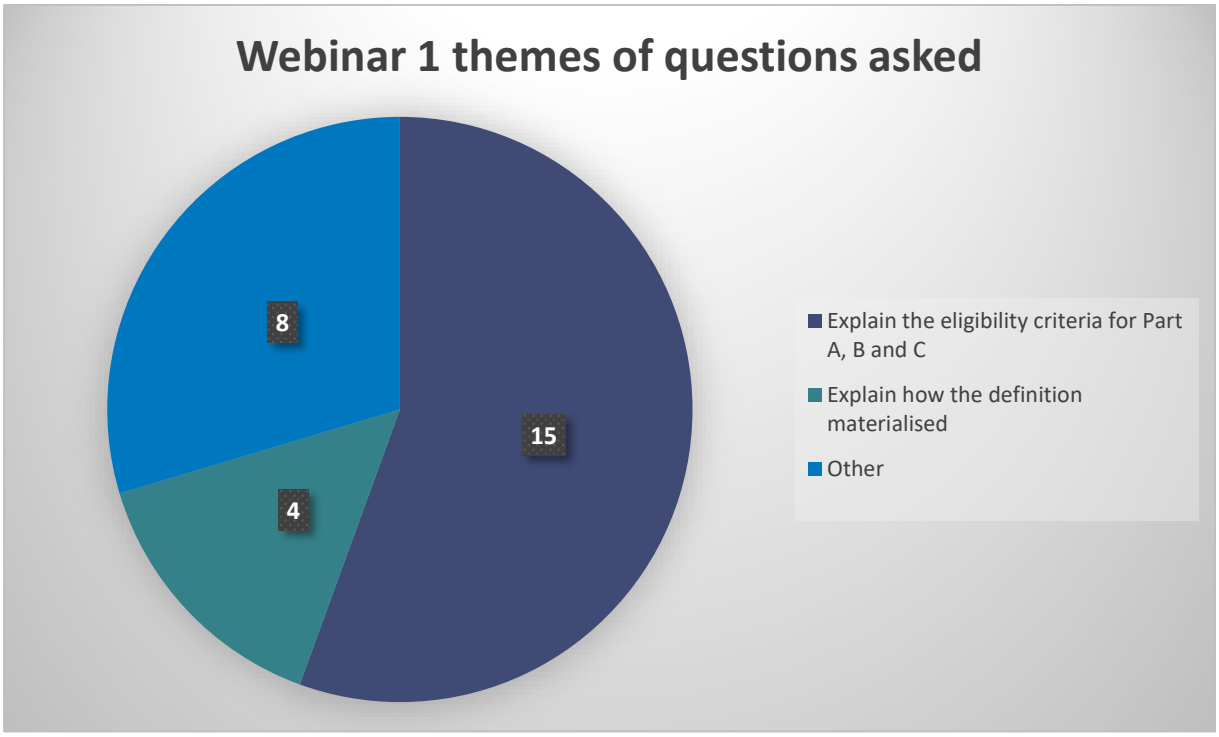

Figure 1 Webinar 1: Themes of questions asked

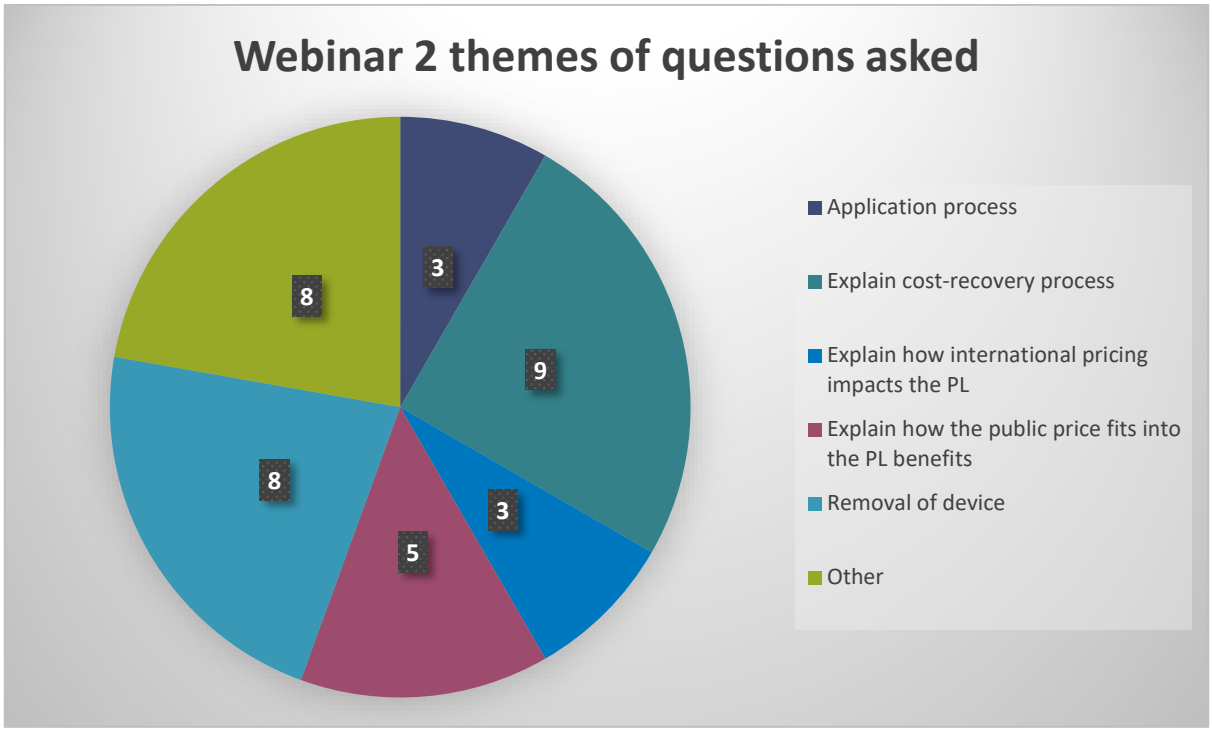

Figure 2 Webinar 2: Themes of questions asked

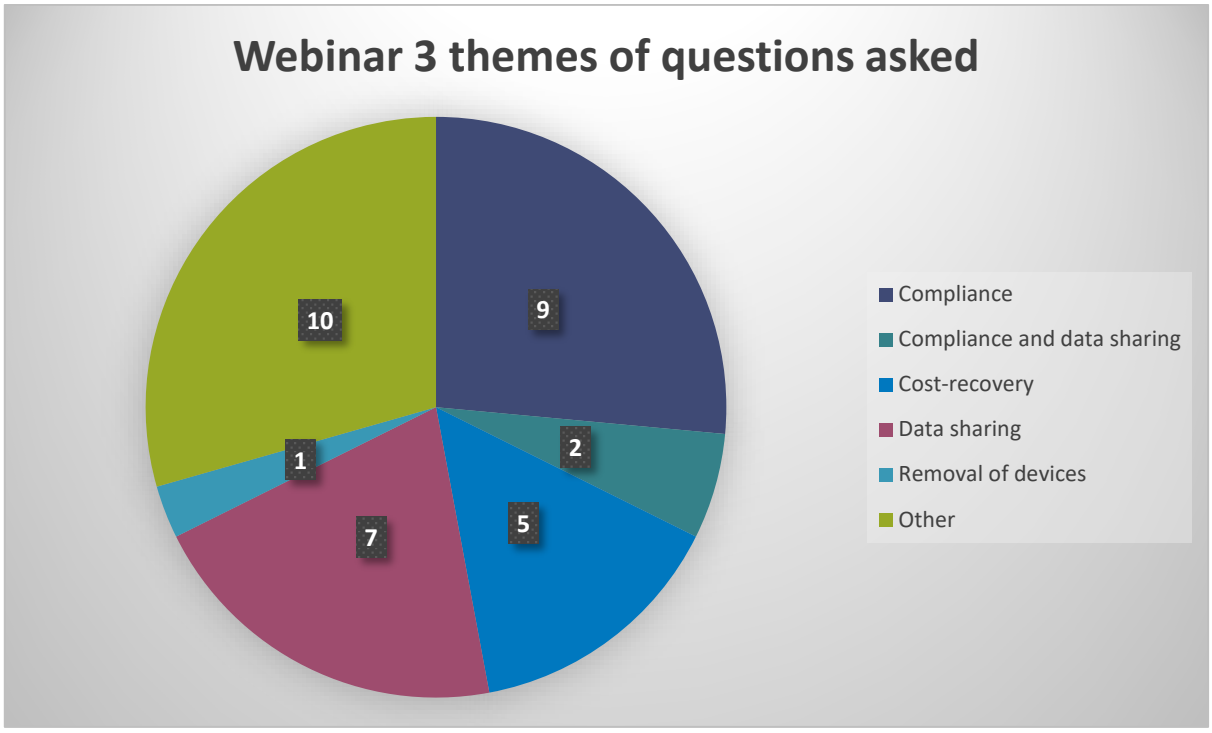

Figure 3 Webinar 3: Themes of questions asked

The main concerns raised across all three webinars were about:

- eligibility criteria of Parts A, B and C
- cost-recovery
- compliance
- data sharing

Questions in order of popularity of upvote	Webinar 1	Webinar 2	Webinar 3
First	Paper 1 asked if the definition of prostheses was flexible enough to cover future change in technology. But proposed leg definition is more restrictive. Why?	The MOU refers to a 7% gap between public price and PL benefits. Why are new applications being asked to be at or below public prices?	Has DoHA modelled whether this proposed compliance framework will delay products being introduced and patient access in the private market?
	Can you confirm that non-implantables could be eligible for Part C?		

Questions in order of popularity of upvote	Webinar 1	Webinar 2	Webinar 3
Second	The paper currently seems to propose two different definitions (p.5-6). What does the Department think is the difference between these if any?	There is no single public price, so how does this work? Weighted by jurisdiction utilisation? Adjusted for bulk-purchase pricing? Additional private services?	Some of these requirements appear to duplicate TGA - e.g., concerns with safety. - is this correct?
	Is the intent that Part C would still require discretionary Ministerial activation on DOH advice? Or automatic if it meets categories (e.g., HTA) outlined.	The Prostheses List arrangements benefit PHI and hospitals as well as industry. Why is the levy not applied to PHI and hospitals?	Paper states "sponsors may be required to reapply for listing every five years". Why? Will this require a cost recovery fee at each reapplication?
Third	Criteria 5. "The use of the products is limited to the product's intended purpose ..." Is this referring to ARTG exempt items specifically or off-label use too?	"public price or less". Why "or less"? Why offer to provide a private entity (insurers) a preferential subsidy to the public health system?	The requirements to notify the Department of new information that may affect different factors are very open ended - how can this be feasibly expected?
	In the feedback from Consult No.1, 54% of stakeholders supported that a device no longer needs to be implanted, why has this feedback now been ignored?	Please provide further information for the rationale for international pricing references - including market referenced	
		The device industry does not benefit from post-listing reviews or compliance activities. Why is the device industry being charged for these?	

Exposure Drafts

The paper was open for consultation between 4-11 November 2022. A total of 9 written submissions were received, with one submission that was received after the consultation period. This submission was accepted and considered along with submissions received within the consultation period.

Written submissions were received from the following entities:

- Australian Medical Association
- Australian Private Hospitals Association
- Catholic Health Australia
- Day Hospitals Australia
- Edwards Lifesciences
- Medical Technology Association of Australia
- Medtronic Australasia
- Members Health Fund Alliance
- Private Healthcare Australia

The feedback received will be used to help inform the content and design of future amendments to the Act(s) and the subordinate legislation (i.e. Rules and Regulations) that will underpin the Prostheses List (PL) reforms.

Legislative Amendment Tranches

There are currently three tranches of legislative amendments planned to support the PL reforms. As the reforms progress, further tranches are expected.

1. First tranche Act amendments
    - the bills recently introduced into Parliament, amends the Private Health Insurance (PHI) Acts to insert new definitions, amend the name of the legislative instrument, and establish the authority for new fee for service cost recovery arrangements.
2. Second tranche legislative instrument amendments
    - amend the legislative instruments to give effect to the measures in the first tranche bills. These amendments will include the name change, updated listing criteria for Parts A and C, cost recovery provisions and associated fees, and other changes as they are required to support the reforms. Drafting of the second tranche amendments will commence early 2023. Stakeholders will have an opportunity to comment on these separately.
3. Third tranche Act amendments
    - amend the Private Health Insurance (PHI) Act to include data sharing and compliance provisions. Drafting of the third tranche Act amendments will commence early 2023. Stakeholders will have an opportunity to comment on these separately.

New Terminology

The first tranche Act amendments provide authority for the current Private Health Insurance (Prostheses) Rules to be re-named the Private Health Insurance (Medical Device and Human Tissue Product) Rules. The schedule to the renamed Rules will be known as the Prescribed List of Benefits for Medical Devices and Human Tissue Products, the 'PL' for short – previously the Prostheses List.

Previous terminology	**Proposed new terminology**
Prostheses	Medical Device Human Tissue Product
Private Health Insurance (Prostheses) Rules	Private Health Insurance (Medical Device and Human Tissue Product) Rules.
Prostheses List (PL)	Prescribed List of Benefits for Medical Devices and Human Tissue Products (PL)

Purpose of Exposure Drafts

The purpose of the Exposure Drafts (ED) was to introduce the:

- Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022
- Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022
- Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022.

These bills will amend the *Private Health Insurance Act 2007*, the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*, *the Private Health Insurance (National Joint Replacement Register Levy) Act 2009* and the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007*.

These amendments will:

- insert definitions of 'medical device' and 'human tissue product',
- change the name of the legislative instrument to better reflect its scope, and
- establish the authority for new fee for service cost recovery arrangements that are consistent with the Australian Government Charging Framework (AGC Framework).

The purpose of consultation paper 4(b) was to ask questions of stakeholders solely focused on the ED and the Explanatory Memorandum (EM).

Status of the bills

The overall feedback from this consultation was supportive of the measures included in the bills and therefore the bills were not amended prior to their introduction to Parliament. The primary concerns raised by respondents related to the lack of detail available. The Department notes that this detail will be included in the second tranche of legislative instrument amendments to be drafted in 2023, and stakeholders will have an opportunity to comment on these separately.

The bills were introduced by Assistant Minister Ged Kearney MP in the House of Representatives on 1 December 2022, with debates adjourned to 2023.

Exposure Drafts for legislative amendments to the Private Health Insurance Acts to support the PL reforms.

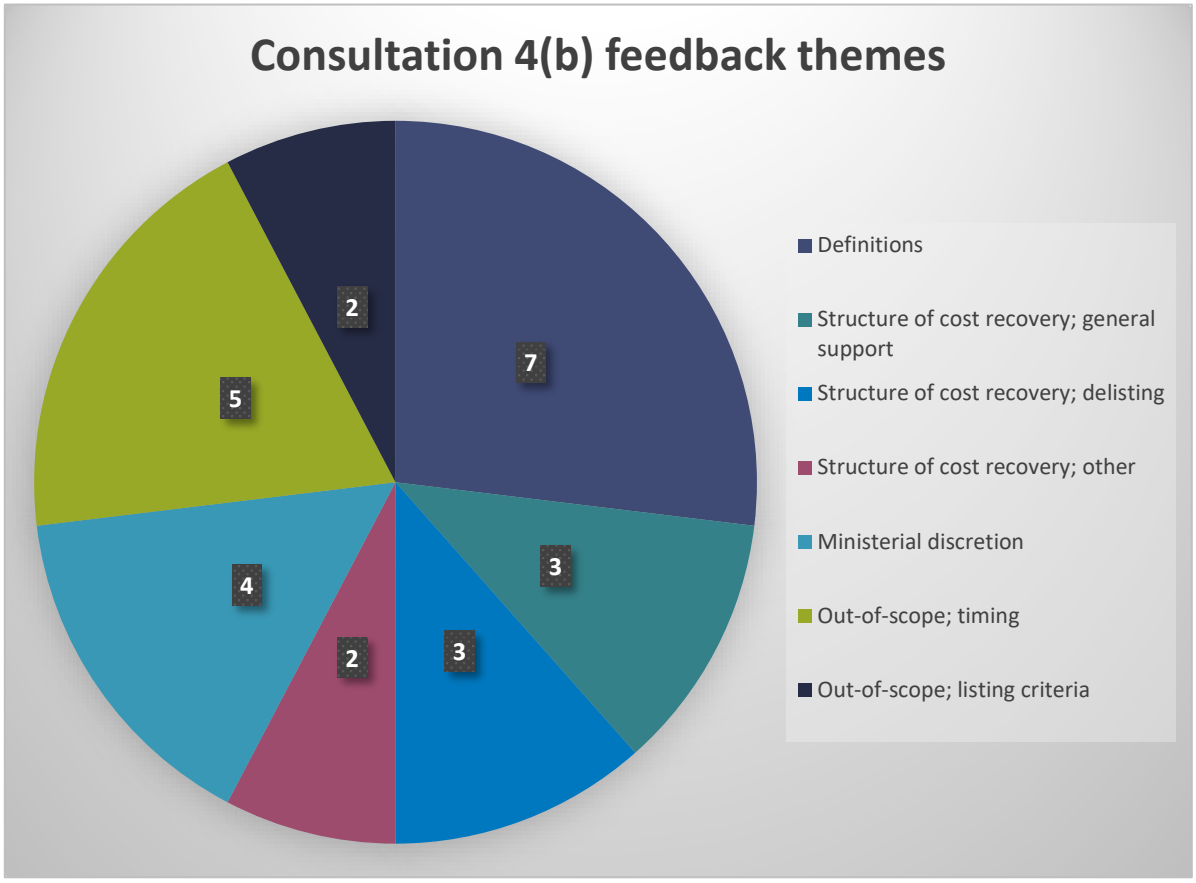

Figure 4 Recurrent themes and concerns raised by respondents to Consultation Paper 4(b) - Exposure Drafts

Figure 5 represents the number of responses that relate to the key themes and concerns raised from the feedback received. The key themes are:

- Definitions
- Structure of cost recovery
- Ministerial discretion
- Delisting of items from PL
- Timing

Name change

Question asked: Do you have any significant concerns with the proposed name change of the legislative instrument from the Private Health Insurance (Prostheses) Rules to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules? If so, what are they and/or what would you change?

Overall, stakeholders did not have concerns with the proposed name change and therefore is not included in information presented in Figure 1.

Department response:

The Act amendments provide for new terminology being ‘medical devices’ and ‘human tissue products. The term ‘prostheses’ has been omitted from the Acts and will no longer be used. The current Private Health Insurance (Prostheses) Rules will be named to the Private Health Insurance (Medical Device and Human Tissue Product) Rules. The schedule to the renamed Rules will be known as the Prescribed List of Benefits for Medical Devices and Human Tissue Products, the ‘PL’ for short – previously known as the Prostheses List. This new terminology will help modernise the PL arrangements and be reflective of the items that are eligible for inclusion on the list.

Definitions

Question asked: Are the proposed definitions of 'medical device' and 'human tissue product' appropriate and relevant to the effective operation of the (future) renamed Prescribed List of Benefits for Medical Devices and Human Tissue Products (formerly the Prostheses List)? If not, please indicate what you believe needs to change. Please note that to determine eligibility of products for listing, these definitions will be used in conjunction with an updated listing criteria to be included in consequential changes to the remade Private Health Insurance (Medical Devices and Human Tissue Products) Rules. A draft proposal will be consulted on in the first quarter of 2023.

Seven respondents found the proposed definitions appropriate and aligned with the definitions provided by the Therapeutic Goods Administration (TGA). Two responses raised issues that retrospective application of the new definitions could mean existing items on the PL would no longer meet the new definitions and would therefore be removed from the PL.[1] Also the term ‘main equipment’ is not explicitly defined, and should be amended to included flexibility in the scope of exceptional purposes and innovations to devices and products.[2] This respondent also noted that that the term ‘accessory’ was taken to mean that it must always be used with a device and can be seen as exclusionary, and limiting clinically satisfactory outcomes.

Department response:

[1] Response to question 2 of response: ANON-24YC-6S4X-Q.
[2] Response to question 2 of response: ANON-24YC-6S4Y-R

The current legislation does not include a definition of a ‘prosthesis’. The legislation states that ‘the prosthesis is ‘a product of a kind’ that is listed in Schedule 1 of the Prostheses Rules’. The Department has rectified the ambiguity caused by this lack of a clear definition in the Act, by the insertion of clear definitions for ‘medical devices’ and ‘human tissue products’. Where products meet these new definitions, they will also need to meet the proposed updated listing criteria which will be outlined in the Private Health Insurance (Medical Device and Human Tissue Product) Rules. The listing criteria can be amended as required to reflect new or emerging technologies that may otherwise not be captured. These two parameters being used in conjunction will give better clarity about items that are appropriate for listing.

Structure of cost recovery levies

Question asked: Do you have any concerns with the proposed legislative structure of the new cost recovery arrangements, including cost recovery fees-for-service and a cost recovery levy? Please note these arrangements are separated into two bills. These bills establish a new statutory authority for cost recovery to ensure compliance with the Australian Government Charging Framework. (The actual amount of the fees/levies will be included in consequential changes to legislative instruments, as Rules and/or Regulations, under each amended Act). The Department is currently considering stakeholder responses to Consultation Paper 3(b). Further consultation will be conducted prior to the commencement of the new fees and levies.

Stakeholders provided feedback in relation to this question on cost recovery levies which included responses relating to compliance with the Australian Government Charging Framework (AGC Framework) and ministerial discretion regarding removal from the PL for unpaid fees.

One respondent expressly noted it was premature to comment on the cost-recovery framework as subordinate legislation was not out for consultation yet and another respondent noted that cost recovery is not clear, there is insufficient guardrails on the objectives and scope of cost recovery.3

Department response:

The Department notes that the amendments outlined in these bills provide a statutory authority for a new cost recovery framework only. As stakeholders have correctly noted, the content of the new arrangements such as the amount of the fees/levy, when fees/levy are to be paid and other matters relating to the fees and levy will be outlined in specific detail in the new Rules and Regulations (with the fees being amended in the second tranche, and the levy in future tranches). These have not been drafted yet, and stakeholders will be given ample time to comment on these once they are finalised.

[3] Response to question 3 of response: ANON-24YC-6S4B-1

Australian Government Charging Framework (AGC Framework)

Stakeholders are supportive of the position that compliance with the legislated framework is fundamental and necessary. While the legislated framework work is yet to be completed, it has been explicitly supported by stakeholders, who have commented that it will produce a positive financial outcome for consumers.4

Department response:

The amendments outlined in the bills support the new cost recovery arrangements that align with Australian Government Charging Framework (AGCF). Implementing these cost recovery arrangements will ensure that the Department can administer the new list in a financially sustainable and compliant way.

Ministerial discretion

There were 3 responses with concerns that the 'Ministerial discretion' is too broad. These concerns were directed towards the Minister's discretion generally (i.e., relating to listing and delisting). However, the current Bills refer to the establishment of the statutory authority for cost recovery arrangements as the Bill provide for. As such, the Department has separated the feedback on Ministerial discretion into two streams: in scope (see response below); and out of scope (refer to the Out-of-scope from consultation 4(b) – Exposure Drafts; Delisting section below to see feedback regarding the Minister's discretion relating to listing criteria amendments).

Department response:

The Ministerial discretion referred to in consultation 4(b) relating to the cost recovery amendments aligns and adheres to similar cost recovery projects undertaken by the Department. If a stakeholder has not paid the required levy to enable their product to stay eligible for listing, the Department will firstly work with the stakeholder to come to an appropriate solution to prevent their product from being removed from the PL.

[4] Response to question 3 of response: ANON-24YC-6S4W-P

Out-of-scope from Consultation 4(b) – Exposure Drafts

Stakeholders raised several issues that were outside the scope of consultation paper 4(b). The Department would like to reassure stakeholders that their concerns regarding these issues will be considered for future tranches of legislative amendments to both the Acts and the legislative instruments. These out-of-scope issues included:

Timing

Stakeholders raised that a seven-calendar-day consultation period (4-11 November 2022) was an inadequate amount of time for stakeholders to properly digest and provide feedback on the exposure drafts prior to their introduction into Parliament.

Department response:

The Department acknowledges that this short timeframe was challenging for stakeholders to fully consider the content of the bills and will endeavour to provide adequate timeframes for upcoming consultations in 2023. In addition to the feedback received through this consultation, the Department also incorporated feedback from previous forums (including webinars and consultation papers) into the first tranche bills.

Regrouping

Stakeholders are awaiting final advice on the regrouping of the PL. The regrouping is not affected by the measures in the bills.

Delisting

Respondents raised concerns on Ministerial discretion for delisting of items in circumstances other than delisting measures for unpaid cost recovery levies. Some stakeholders noted that the delisting of items from the PL does not only disadvantage the listing company who may be the intended recipient of 'punishment'[5], but also patients and hospitals.

Department response:

The current legislation does not provide for specific delisting powers. The courts have recognised the Minister's ability to de-list kinds of prostheses from the Prostheses List based on s 333-20 of the PHI Act, together with s 33(3) of the Acts Interpretation Act 1901 (AIA). The Department may consider the inclusion of specific delisting powers in future legislative amendments and will consult with stakeholders in due course.

[5] Response to question 3 of response: ANON-24YC-6S4X-Q

Criteria for listing to be introduced through Legislative Instruments

Stakeholders also provided feedback regarding the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022, specifically, that that by allowing "other criteria" to be specified in a legislative instrument, it would not be subject to sufficient scrutiny.[6]

Department response:

Where products meet the new definitions of medical device or human tissue product, they will also need to meet the proposed updated listing criteria which will be outlined in the Private Health Insurance (Medical Device and Human Tissue Product) Rules. The listing criteria can be amended as required to reflect new or emerging technologies that may otherwise not be captured. These two parameters being used in conjunction will give better clarity about items that are appropriate for listing. The Department acknowledges concerns that the updated listing criteria will not be subject to sufficient scrutiny and advises that clinical input will be sought to set appropriate listing criteria, which will be updated from time to time and in exceptional circumstances.

These 'out of scope' issues will be considered as part of future tranches of legislative amendments.

Next Steps

The Department acknowledges stakeholders' time and effort to help shape the legislative amendments. All feedback received from stakeholders through the webinars and consultation papers has been reviewed and taken onboard for the first-tranche legislative changes (when relevant) or recorded for next tranches of legislative changes.

The Department intends to consult with stakeholders on the next tranches of legislative amendments (tranches 2-3) in early in 2023. This will include amendments to the renamed Rules being the Private Health Insurance (Medical Device and Human Tissue Product) Rules (formerly the Prostheses Rules) to include the updated listing criteria and cost recovery fee amounts along with other provisions to support reform measures. These changes are scheduled to take effect in 2023.

The Department will also consult with stakeholders on the draft bills for further PHI Act amendments that will incorporate compliance and data sharing provisions.

[6] Response to question 2 of response: ANON-24YC-6S4X-Q

Conclusion

Overall, the feedback received indicated in-principle support for the first tranche legislative amendments.

Stakeholders highlighted the need for the Department to provide timely stakeholder consultation on future legislative amendments. The Department agrees and is incorporating additional timeframes for stakeholders engagement and feedback on future legislative amendments planned in 2023. Stakeholders also indicated a strong desire for more clarity and flexibility in the legislative provisions to allow for innovation in medical technologies as well as ensuring inclusion of adequate consumer protection mechanisms. The refreshment of the legislation and associated instruments aim to address both concerns by supporting new and novel technologies as well as ensuring that consumers will bear no additional out of pocket costs as a result of the reform measures.

All concerns and submissions in the next stages will be thoroughly considered and reviewed; either through enquiries, formal consultations, or webinars. The Department is committed to supporting and engaging with stakeholders and industry partners through the implementation of the PL reforms.

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All information in this publication is correct as at December 2022