Australian Government
Department of Health

Prostheses List Reforms Consultation No. 1

Executive Summary

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Executive Summary

In August 2021 the Department of Health released Consultation Paper No. 1 – *Prostheses List Purpose, Definition and Scope* (the Paper). The aim of the Paper was to canvass stakeholder views on proposed implementation of improvements to the Protheses List (PL) as announced in the 2021- 22 Federal Budget.

A total of 116 submissions were received from stakeholders representing the Medical Technology Sector, Private Hospitals, Private Health Insurers, Clinical Societies, and individual clinicians. The purpose of the Paper was to seek stakeholder views about the Government's decision to better define the PL purpose, definition, and scope, to inform decision-making about implementation activities including amendments to legislation.

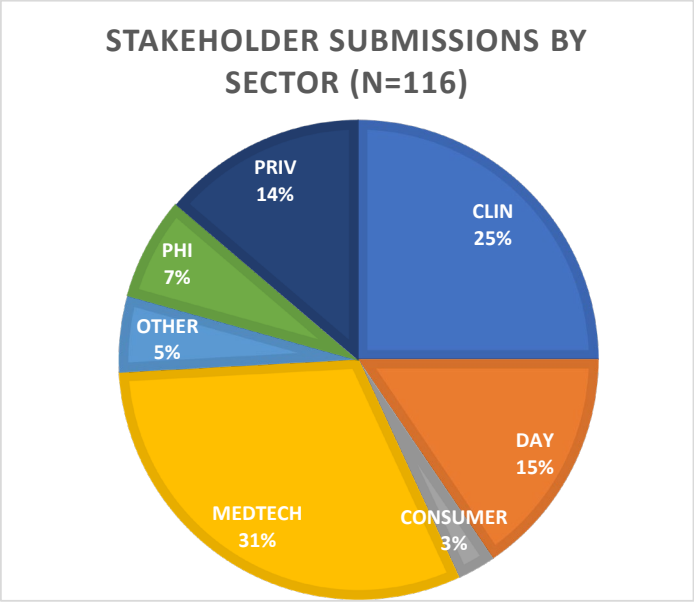
The Paper proposed the definition and listing criteria be redefined to clarify product eligibility for the PL. The implication of this change will result in certain general use products currently listed in Part A, Part B and the General Miscellaneous Category no longer meeting the eligibility requirements. Additionally, there are products, such as skin glues that do not meet the current listing criteria that were flagged for removal.

The Paper presented further proposals for consideration, including an update to the name of the PL to more accurately reflect the products listed, as well as aligning PL terminology to be consistent with terms used by the Therapeutic Goods Administration (TGA) where relevant.

The Prostheses List Reform Taskforce (the Taskforce) have analysed the stakeholder feedback on the Consequences of Changes to the PL as outlined in Attachment A of the Paper. This analysis was provided to the newly established Clinical Implementation Reference Group (CIRG). This Group is made up of clinicians and is tasked with providing clinical guidance on implementation matters to the Department during the life of the Prostheses List Reforms. The CIRG was provided with a broad summation of stakeholder views and asked to provide the Department with clinical advice to help inform implementation decisions. The analysis of this feedback will inform the development of legislative amendments to the *Private Health Insurance Act 2007*, *Private Health Insurance (Prostheses) Rules* and other relevant Acts and delegated legislation.

Stakeholders

Stakeholders from across several sectors are set to be impacted by the proposed changes to the PL. As a result, this consultation received robust and informative responses. The Department received 116 submissions from stakeholders in the Medical Technology Industry (MTI), Private Hospitals (PH), Private Health Insurers (PHI), Consumers, Clinical Societies, individual clinicians and other individuals. Stakeholders were invited to respond via the Department's Consultation Hub to ten questions presented in the Paper. They were also invited to upload documents detailing additional clinical evidence if necessary.



Approach to Consultation

The Department's approach to this consultation activity included release of a discussion paper that outlined the proposed changes to the Purpose, Definition and Scope of the PL. The consultation was publicly available to anyone that registered. The consultation was promoted through the Private Health Insurance Circulars as well as through regular stakeholder updates provided by the Taskforce.

The questions in the Paper were structured to draw feedback about:

- Definition and scope
- Criteria
- Name
- Consequence of changes

The consultation Paper was released on 23 August and closed on 24 September 2021. The Taskforce convened a Webinar attended by a range of stakeholders on 8 September 2021 that focused on changes to the Purpose, Definitions and Scope as presented in the Paper.

Consultation Outcomes

The Taskforce collated and summarised the stakeholder feedback against each question in the Paper. This summary will be used by the Taskforce to inform the decision-making about implementation of the reforms. The summary of feedback on the Consequences of Changes that are outlined in Attachment A to the Paper has been provided to the CIRG for consideration.

Clinical Implementation Reference Group (CIRG)

The role of the CIRG is to support the effective implementation of changes to the PL resulting from the PL Reforms by providing clinical advice to the Department about implementation matters. The CIRG will be a time limited group that will be in place until 30 June 2022. The Department will consider clinical advice from the CIRG in its decision-making about implementation of the reforms.

Outcomes of consultation with the CIRG will be published following each meeting.

Findings and Analysis

This stakeholder feedback has provided sector-based data and opinion on the proposed reforms, particularly drawing attention to how the changes may impact certain sectors.

Stakeholders provided robust responses in their submissions, with many detailing historical issues or inefficiencies. The Department is taking this information into account and using this feedback to inform implementation approaches including amendments to legislation. The feedback will also help shape future consultations.

The following are brief summaries of the feedback received for each question from the Paper. Not all stakeholders responded to all questions, therefore the percentages reflect the portion of stakeholders who did respond.

Q1. Is the proposed approach to the definition of a kind of prosthesis flexible enough to anticipate future technologies while providing sufficient clarity on the scope of PL?

The proposed approach that a device no longer needs to be implanted to qualify for listing was cited by 54 per cent of stakeholders as being a progressive and welcome improvement and agreeing that the new definition would improve flexibility to anticipate future technologies.

Q2. Does aligning terms with established terms used by TGA (such as medical devices and biologicals) improve clarity?

Stakeholders held mixed views regarding an alignment with TGA terms, with 52 per cent of stakeholders in agreement. 40 per cent of stakeholders made their own recommendations or suggestions for alternative approaches. 8 per cent of stakeholders disagreed, asserting that the intention of the PL is very different to that of the ARTG and as such, its own distinct terminology should be retained and utilised.

Q3. Are the proposed listing criteria for Part A fit-for-purpose? If not, what changes are needed?

21 per cent of stakeholders agreed that the proposed listing criteria for Part A is fit for purpose. 73 per cent of stakeholders, primarily stakeholders from the Medical Technology and Day Hospital sectors, were concerned that their most used items would not be included in the new criteria due to limited flexibility, posing financial consequences.

Q4. Should the scope of products eligible for listing on Part B remain unchanged?

42 per cent of stakeholders agreed that the current scope and the existing criteria for Part B is sufficient, with some noting that it should be subject to ongoing review. 58 per cent of stakeholders reserved comment for the upcoming consultation relating to Part B or disagreed with the current scope.

Q5. Should the PL retain an option for the Minister to list items in exceptional circumstances on Part C?

84 per cent of stakeholders agreed that the PL should retain an option for the Minister to list items in exceptional circumstances under Part C. Stakeholders supported this option as when considering production of future items with advanced technology or purpose there is potential for such items failing to meet criteria, purely due to the growth of modern medical technology.

Q6. Are there any other exceptional circumstances factors that Part C should accommodate?

Stakeholders provided broad and in-depth commentary about exceptional circumstances. Many stakeholders expressed views that the current Ministerial discretion to list items on the PL was appropriate, especially regarding new and emerging technologies that do not have a comparable PL entry, for example software as a medical device. However, it was noted that criteria for exemption by the Minister should be kept to a minimum, so the integrity of the process is not compromised. There was overall agreement that the implementation of any changes to this provision should be undertaken in a well-publicised manner that does not disrupt or compromise patient care.

Q7. Please consider the tables at Attachment B and explain which products meet the future criteria for listing and the reasons why?

83 per cent of stakeholders provided feedback on specific products, with some stakeholders choosing to await outcomes of consultation with CIRG. Overall, stakeholder feedback was varied on the items in Attachment B and whether or not they met the proposed future listing criteria.

Q8. Should the name of the list be modernised and, if so, what should it be called?

Stakeholders welcomed a change in name with 73 per cent in agreement. Stakeholders provided suggestions for a new name, such as Medical Device List, Implantable Medical Device List, and Private Health Insurance Medical Device List.

Q9. Does the list of items at Attachment A flagged for inclusion and removal accurately reflect the proposed future criteria for listing?

93 per cent of stakeholders disagreed and strongly recommended changes were subjected to clinical consultation prior to removal. Stakeholders highlighted concerns about specific items, including intra-ocular fluids, haemostatic devices, and other closure devices and presented specific claims of meeting the proposed criteria. Stakeholders strongly argued that the items

identified for removal would have significant impacts on patient outcomes as well as disproportionate financial impact on day hospitals. The Medical Technology and Private and Day Hospital Stakeholders were the most vocal regarding item removal, urging the Department reconsider the removal of these items.

Q10. The removal of items identified at Attachment A is scheduled to commence from February 2022. If a decision is taken to remove these items in tranches, is there a logical bundling of the items at Attachment A that would make staged implementation over time possible? Is the proposed staged removal aligned with PL updates workable? What is the most appropriate timing?

The feedback was consistent across the stakeholder groups regarding the proposed timeframe. 83 per cent of stakeholders disagreed with the proposed February 2022 date for removal. The primary concerns from Private and Day Hospitals that this was insufficient time to establish alternative funding arrangements prior to removal. Stakeholders are concerned about the potential increase in cost to Australian patients, reduced clinical choice and the financial burden on private and day hospitals during the transition period.

Departmental Response

The Department thanks all stakeholders who have contributed to this consultation process. The Department is pleased to announce the establishment of CIRG in recognition of the importance of clinical consultation throughout the implementation of these reforms.

It is important to note that these changes are aimed at delivering structural improvements whilst also streamlining application processes.

The Department has used the feedback from this consultation to inform implementation of the reforms to Purpose, Definitions and Scope of the PL. Specifically, summary of feedback on the Consequence of Changes as outlined in the Paper have been provided to the CIRG for consideration of the clinical implications of implementing these changes.

Further consideration of the feedback from this consultation will be used to inform the development of amendments to the legislation that will support the changes. The amendments to the legislation will be the subject of an upcoming consultation paper.

In consideration of the proposed listing criteria, around 70 percent of stakeholders expressed concerns centred on financial considerations and the continued availability of items flagged for removal from the PL. On this basis, the Department will continue to consult stakeholders about the specific details of the listing criteria as well as the suitable timeframes for implementation. The Taskforce is keen to minimise potential disruption to administration and application assessments where possible.

The Department will consider alignment with TGA terminology, noting that more than half of stakeholders who responded to this question were supportive.

The Department notes the input from stakeholders that any changes to Part B should be subject to ongoing review. The Department will be releasing a consultation paper focussed on reforms to Part B and welcomes input from stakeholders regarding the approach and timeline of these reforms.

The Department notes that most stakeholders agree the Minister retain the power to list items on the PL under Part C. The Department agrees that any changes made throughout the PL reform should be undertaken in a well-publicised manner that does not disrupt or compromise patient care.

The Department will progress the changes to updating the name of the PL so that it better defines the purpose and function of the PL.

The Department acknowledges that removing items from the PL is impactful and that adequate time is essential to ensure alternative funding arrangements are in place.

Next Steps

The Taskforce is in the process of developing subsequent Consultation Papers. Stakeholders will be advised of the release dates of these consultation papers through the usual channels of engagement already established by the Taskforce.

A final list of items to be removed and the timing of removals will be published by the end of November 2021.