



## Webinar 8 September 2021 - Participant's Questions

### Consultation Paper No 1 – PL purpose, definitions and scope

The Prostheses List Reform Taskforce (the Taskforce) received 110 questions regarding Consultation Paper No 1 – Prostheses List (PL) purpose, definitions and scope. As some stakeholders have asked similar questions, the queries have been grouped into themes represented by an example question.

### Funding Items scheduled to be removed

The Taskforce received 17 questions related to the funding of items proposed for removal from the Prostheses List. How is the Government proposing these items to be funded, would the cost be passed to consumers and how would the Government protect smaller providers from being taken advantage of in the negotiations.

#### **Example question: Will the insurers not shift the cost of these devices being removed to the taxpayer essentially?**

The consultation paper states: 'The Government has an expectation that for those items removed insurers and private hospitals will reach an agreement on a market based alternative funding arrangement and one that does not involve out of pocket costs for the consumer.' The Department of Health will continue to support insurers and hospitals to reach an arrangement.

### Removal of Items from the Prostheses List

Thirteen questions concerned the items proposed to be removed from the Prostheses List.

#### **Example question: Does the Department contemplate that individual products currently listed on the Prostheses List within existing categories might be deemed as no longer eligible for listing on the basis of the proposals outlined in the Consultation Paper? -If so when and where, how and by whom will these products be identified and when and where will details be published? Will there be further consultation processes about these products?**

All products proposed for removal are listed on Attachment A tables 1 and 2. No other product has been identified for removal. The Clinical Implementation Reference Group will analyse comments provided in submissions before a finalised list is published in November 2021.

The Prostheses List is a benefit setting system only. Removing an item from the PL does not limit commercial access to that product, and it is expected that these devices will be reimbursed under alternative funding arrangements. It is not the intention of the reforms to question the clinical need for the devices that are an accessory, a consumable, or a general-purpose item. The intention is to ensure that only items that fit the proposed definition of a

prosthesis and meet the criteria for listing are listed on the PL and funded through this mechanism.

**If you strongly feel you can make a case for an item not to be removed, we encourage you to put it in writing in your submission.**

## TGA and ARTG aligning terminology

Fifteen questions were received regarding the proposal to adopt the TGA terminology, including the information entered on the ARTG (on the intended purpose and, where applicable, functional description of the device, or indication) being consistent with the information entered on the PL (product name, description, purpose, and grouping).

**Example Question: How will referencing the terms “medical device” and “biological” as defined under the Therapeutic Goods Act 1989 change the scope of devices eligible to apply for listing on the Prosthesis List?**

The consultation paper proposes the alignment of the terminology used in the *Therapeutic Goods Act 1989* and respective regulations with the terminology used in the Prosthesis List.

It means that if certain terms are defined or described in the therapeutic good legislation, when the same terms are used for the products listed on the Prosthesis List, the meaning of these terms will be the same.

## General Listing Criteria Technical Questions

The Taskforce received 19 questions that referred to the future listing of specific items on the PL; some were of a highly technical nature and are expected to be raised in your submissions to the consultation paper.

**Example Question: The exemptions to Part A mentioned in the paper specifically mention devices for general purpose i.e. a wide range of procedures intended to assist inserting sutures in the body. Should devices used for a small range of highly specific procedures intended to assist inserting sutures be kept on the PL?**

General items that are used as an adjunct to the procedure such as sutures, will no longer be funded through the PL. Respectively the devices that are used for implantation of a suture, also will not be eligible for listing on the Prosthesis List.

If your example refers to a product that is not a general item, you may provide further information in your submission to be considered as part of the consultation.

**There is an opportunity to substantiate any claims for an item to remain on the Prosthesis List in your submission.** All Submissions will be analysed by the Taskforce and the Clinical Implementation Reference Group, which includes expert clinicians in the medical fields related to the PL.

## Hypothetical Scenarios Outside the scope of current consultation:

Fifteen questions were received that are hypothetical scenarios outside the scope of consultation paper #1 and ask clarification regarding other stages of the four-year reform, which are still in planning and therefore have not been consulted on yet.

**Example question: If there is an existing public price for a new listing, is the Department expecting it will still need to undergo clinical and cost-effectiveness review or will it be assumed to be cost-effective by virtue of its existing public price set by competition?**

Future consultation papers will address proposed new processes and governance arrangements and there will be an opportunity for stakeholder comment when these papers are released. However, it is anticipated that the assessments of comparative clinical effectiveness and cost-effectiveness will remain features of the system.

## Accessories, Consumables and Bundling

Several questions were received regarding accessories and consumables, specifically, if some of the proposed items to be removed will be bundled with those devices they will be used with.

**Example question: Does the Department consider that any of the devices in the categories listed in Table 1 and Table 2 in Attachment A will be funded as a bundled item on the Prostheses List (i.e. bundled into the cost of the device they are intended to be used with)?**

No, it is intended that general items listed in Table 1 and Table 2 will be removed from the PL. Also, where a general item is supplied and used as part of a system or procedure pack containing another device that meets the criteria for listing, the cost of the general item will be bundled into the cost of the eligible device they are intended to be used with, or funded under a different funding mechanism.

## Consequences of Changes

The Taskforce received 10 questions that refer to the measures planned by the Australian Government to ensure clinicians will have access to medical devices.

**Example question: How will Government ensure that doctor's in private facilities have access to optimal equipment when required, and that substitution with cheaper, less reliable products will not occur?**

The Prostheses List is a benefit setting system only. Removing or including items on the PL does not limit or increase access to medical devices. The products not eligible for listing on the Prostheses List need to be funded under alternative funding arrangements.

The Review of the General Miscellaneous Category of the Prostheses List was undertaken to investigate whether benefits payable for products in this category were appropriate and whether the products meet the criteria for listing on the PL.

Hospitals and private health insurers have commenced discussions on alternative funding arrangements for the general items being removed from the Prostheses List. **The government is supporting all parties in this negotiation process.**

## Miscellaneous Questions

- 1. Will the government monitor any impact on outcomes as a result of products being removed from the PL?**

Yes, within the PL reform plan, there is a comprehensive evaluation review scheduled for 2023.

- 2. How seriously will submissions on this portal be taken by the Department of Health in its consideration of revising things if required?**

The Government takes stakeholder consultation very seriously and the Taskforce will take all submission into consideration before finalising the list of items for removal.

- 3. In view of the relative speed of MedTech innovation and the real risk of the MSAC process becoming overwhelmed as a result, is there a plan to introduce/explore a more nimble, fit-for-purpose, HTA process for timely assessment and PL listing?**

Yes, The PL improvements are part of a major multi-year reform to the Health Technology Assessment (HTA) processes within the Department of Health to address capability limitations and position HTA for future needs.

- 4. Would the clinical implementation committee reference group include representative from clinical societies for each related category specialty?**

The Clinical Implementation Reference Group will include independent clinicians from a variety of clinical specialities.

- 5. Will there be an opportunity to comment on an exposure draft of the proposed legislation and/or regulatory changes used to implement decisions taken as a result of this consultation. What will be the timelines for any decisions arising from this consultation and any further consultation on exposure drafts?**

Yes. The Taskforce will publish a consultation paper in the next few months.

- 6. Can the Department provide further detail on the clinical advisory group? Who is in the group? How will the assessments take place? What is their framework for decision-making? What data will be provided to them?**

Once members have been appointed, details on the Clinical Implementation Reference Group will be published.

- 7. The Australian Government factsheet Modernising and Improving the Prostheses List (Provided at the stakeholder meeting on 12 May 2021) states the intention of “removing products from the Prostheses List, that are better funded through direct contractual engagement between parties”. On what basis have you concluded the items listed in Table 1 and Table 2 in Attachment A are better funded by contractual engagement between parties and what evidence have you used to reach this conclusion?**

In preparing the content of the consultation paper, the Prostheses List proposed definition (p 5 greyed area) and criteria for listing (p 6-8) have been applied. Based on these

criteria and definition, the items in Table 1 and Table 2 do not fit within the scope of the PL and normal purchasing arrangements should apply to them.

- 8. 'In relation to the ARTG entry, it is proposed that this criterion will be clarified so that the information entered on the ARTG entry [on the intended purpose and, where applicable, functional description of the device, or indication] is to be consistent with the information entered on the PL [product name, description, purpose, and grouping]; this will clarify that the price is payable for the prosthesis as authorised for supply by the TGA. Does this mean that only one billing code will be allowed per ARTG? What other implications are there for listing on the PL?**

No, but it will achieve better transparency and accountability, and ensure a clear link between the PL and ARTG entries.

- 9. Are you proposing that the changes in terminology are applied retrospectively to current products listed on the PL? Or do you remain open to a proposal whereby this is adopted for newly listed products only?**

We expect that the proposed alignment of terminology will be equally applicable to the products already listed on the Prostheses List and any future applications for listing products on the Prostheses List.

- 10. Can the Department please provide further details on what the Department plans to do when it says “introducing, as a part of PL application process, a declaration by companies that there will not be extra charges for the products beyond the PL price, with penalties for false declaration, to ensure no out-of-pocket expenses for consumers.”**

- a. Does this mean at the time of lodging an application?**

Yes

- b. What happens if no benefit currently exists for a device at the time of lodging?**

There will still be a declaration at the time of application.

- c. What sort of penalties does the Department foresee?**

This will be canvassed in future consultation papers.

- d. Does this require primary or secondary legislation?**

A consultation paper regarding legislative requirements will be available for consultation at the end of this year.

- e. What is the timeline for this to be introduced? 1 July 2022?**

The timeline is still to be confirmed.

- 11. Will temporary implants still be included under this definition?**

Yes, if they meet other Part A criteria for listing, they will be eligible for listing on PL.

- 12. The consultation paper says that its purpose is to “clarify details of the government’s decision to better define the Prostheses List purpose, definitions, and scope and explore how this might be implemented in delegated legislation and guidance”. However, the paper doesn’t seem to say very much about the purpose**

**of the Prostheses List. What is the purpose of the Prostheses List? And where is this currently defined and documented?**

Section 1.2 of the Prostheses List Guide outlines: 'What is the Prostheses List? The purpose of the Prostheses List is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs.'

Under the Private Health Insurance Act 2007 (the PHI Act), private health insurers are required to pay benefits for prostheses that are included on the Prostheses List:

- for which an insured person has appropriate cover
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment
- for which a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

**13. p.3 'Clarifying the decision to better define scope' – has the decision been taken to narrow the definition already?**

No, the consultation process has not concluded, and the existing Prostheses List criteria has not been changed yet.

However, applications for devices that do not meet the existing criteria for listing are not being recommended for the PL, even if such measure is not entirely consistent with some decisions made in the past.

**14. Should the scope and definition change considerably e.g. removal of all service components from the definition criteria incl. freight and loan sets, will all benefits then be subject to review under such an approach, how, and also will it be incorporated into the benefit differentials in the public/private comparisons?**

The proposed scope, definition and listing criteria are those outlined in the consultation paper. IHPA has developed the Consultation Paper on a Methodology for Determining the Benchmark Price for Prostheses in Australian Public Hospitals to seek feedback from stakeholders on the proposed approach for establishing the benchmark price for prostheses.

This consultation paper seeks public comment on a number of key aspects in relation to IHPA's work in this area, including data sources, benchmark price calculation and legitimate differences between the public and private sectors that should be accounted for in setting the benchmark price.

The submission period is open from Monday 6 September 2021 to 5:00 pm AEST on Friday 1 October 2021.

**15. Can you please explain how the proposed scope, definitions and exclusions outlined in the Consultation Paper have been applied to identify each of the categories listed in Table 1 and Table 2 in Attachment A and differentiate these from the categories listed in Table 3 in Attachment A?**

As outlined in the consultation paper, it is proposed to redefine a kind of prosthesis and criteria for listing, with the listing criteria referring to a specified therapy. This change

means that certain general use products (mainly listed in Part A of the General Miscellaneous Category) will no longer be eligible for listing on the PL.

Table 1 and Table 2 in Attachment A provide a list of general use devices flagged as falling into the abovementioned group.

The devices in Table 1 have also been previously identified in the Review of the General Miscellaneous Category of the Prostheses List report.

Further background on these items and how they have been identified is detailed at question 17.

**16. p.5 Would hernia repair or some other procedure where tissue closure was the main intervention to address the patient's condition be an example of a medical procedure where the intent was to use the device to remedy the condition even if one of the wound closure products now targeted for removal was used? For example, dynamic wound closure devices?**

YES, hernia surgical meshes are usually considered as the devices intended for the treatment of specific conditions. As such, these devices are taken as miscellaneous items rather than general use products intended to support a range of different types of surgical procedures.

**17. Why is the department evoking the recommendations of the EY report, specifically to delete products from the PL, when the EY report failed to consider any clinical evidence or patient outcomes?**

The Review of the General Miscellaneous Category of the Prostheses List was undertaken to investigate whether benefits payable for products in this category were appropriate and whether the products meet the criteria for listing on the PL.

The Review did not question the clinical need of the products but rather looked at whether the general products meet the Prostheses List criteria for listing and whether efficiencies could be gained by removing low-cost high usage general use items from the PL and funding them through alternative mechanisms.

**18. p.9 What factors will determine the Department's thinking about what will be removed from the PL in the first stage vs later rounds?**

This is part of the consultation paper. Please submit your views.

**19. Table 4 p.13 Can the Department explain why these products specifically were considered in doubt for the PL?**

Table 4 provides a list of different products, some of which meet, and others do not meet the existing PL criteria for listing on Part A. The consultation paper invites stakeholders to comment on which of the provided examples will be meeting the revised Part A criteria for listing. You may also provide further examples to test the proposed listing criteria.

**20. Would you be able to send a list of PL entries that will be excluded?**

Tables 1 and 2 in attachment A outline the items that are proposed to be removed from the Prostheses List.

**21. Table 5 p.14 If a part of a system needed replacing or needed to be ordered individually, if the product only had a benefit for the single system, how would the Department propose handling this?**

The items in table 5 have been put out for consultation to our stakeholders. Please submit your views.

**22. If a product is registered as a system or procedure kit under the TG Act will it have to be listed as a single billing code going forward?**

YES, if a system or procedure pack is included in the Australian Register of Therapeutic Goods (ARTG) under one ARTG entry, it is expected that this collection of products is intended to be always supplied and used together, and respectively should be covered under one Prostheses List billing code.

**23. If there is a product that does have a specific use in some cases, and a general use in others, how would this be handled?**

The primary intended use of the product will need to fit the definition and listing criteria of the Prostheses List.

**24. How will you bundle but allow use of accessories access for mix/match technologies or spare parts surgery? This was a key issue in NJJR measuring component clinical performance.**

It is expected that accessories intended to be always supplied and used together with an implantable or surgically invasive device will no longer be separately funded through the Prostheses List. Those accessories that do not meet the revised definition and criteria for listing but are not supplied together with the main device, may need to be funded through alternative mechanisms.

These matters will be considered as part of the regrouping work and a consultation paper is planned in the coming months.