Australian Government
Department of Health and Aged Care

Reforms to the Prescribed List
Part B: Analysis of stakeholder feedback

October 2024

Abbreviations

ARTG	Australian Register of Therapeutic Goods
ATO	Australian Taxation Office
Department	Department of Health and Aged Care
FP	For-profit
HPP	Health Products Portal
HTA	Health Technology Assessment
JOTSC	Jurisdictional Organ and Tissue Steering Committee
PLRT	Prescribed List Reform Taskforce
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NFP	Not-For-Profit
NHMRC	National Health and Medical Research Council
OBPR	Office of Best Practice Regulation
PHI	Private Health Insurance
PL	Prescribed List of Benefits for Medical Devices and Human Tissue Products
PwC	PricewaterhouseCoopers
TGA	Therapeutics Goods Administration

Introduction

The purpose of this report is to provide an analysis of stakeholder feedback[1] received in relation to the PricewaterhouseCoopers (PwC) - Report and recommendations on the proposed reforms to Part B of the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the PL), and the proposed restructure of Part B – May 2023 (the Report).

The Report was available for consultation between 23 August and 6 October 2023.

The Prescribed List Reform Taskforce (PLRT) in the Department of Health and Aged Care (the department) received 20 submissions from 6 stakeholder groups during the consultation period.

- Insurers (2/20) – 10%
- Eye and Tissue Banks (10/20) – 50%
- MedTech companies (2/20) – 10%
- Hospitals (1/20) – 5%
- State and Territory Governments (2/20) – 10%
- Others (3/20) – 15%

Background

Part B of the PL consists of human tissue products only.

In January 2022, the department released Consultation Paper 2(a) – Modernisation of Part B of the Prostheses List (the Paper). The Paper put forward ideas to improve Part B in line with the changes to the rest of the PL (formerly known as the Prostheses List).

The Paper proposed two initiatives to modernise Part B:

1. a revised classification structure, and
2. introduction of a health technology assessment for human tissue products.

From feedback received, the department determined that further consultation was required to better communicate the details of the proposals; and to address stakeholder concerns.

In December 2022, the department engaged PricewaterhouseCoopers (PwC) to:

- review the Paper, including the 22 stakeholder submissions related to the Paper.
- conduct targeted consultation (via workshops) with key stakeholders on the feasibility of the proposed new grouping structure and listing pathways as detailed in the Paper.
- develop summaries of each workshop, including objectives, issues discussed and outcomes (including any recommended amendments to the proposed new group structure and listing pathways).
- investigate the impact of cost-recovery arrangements on sponsors for Part B applications (including not-for-profit (NFP) public and private banks, NFP organisations and commercial for-profit (FP) entities).

In May 2023, the department accepted delivery of PwC's final report, which included 10 key recommendations and outlined practical and tangible steps to support the proposed reforms to Part B of the PL.

[1] https://consultations.health.gov.au/hearing-and-program-support-division/review-of-part-b-of-the-prostheses-list-pwc-report/

The department has accepted in-principle all the recommendations put forward, with the exception of Recommendation 2 which requires further consideration. The department is working towards implementation of the recommendations.

The feedback received on these recommendations, and the department's response are explored in the following.

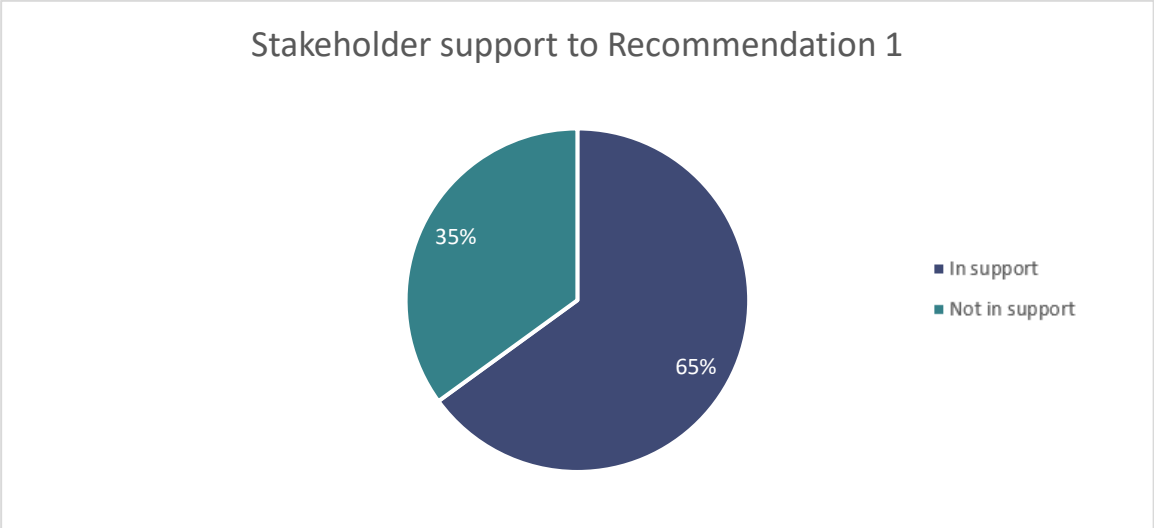
Stakeholder feedback analyses

Recommendation 1 – the department offer stakeholders the opportunity to provide feedback on a proposed definition for Part B products

In line with the Therapeutics Goods Administration (TGA) and the Office of Best Practice Regulation (OBPR), the proposed definition of a Part B product is:

> *Human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law).*

Overall, 65% of respondents were supportive of the proposed definition.



Feedback in support of Recommendation 1

- All sponsors of human tissue products, whether they are NFP, or FP must abide by the same laws.
- All products listed on Part B require a cost recovery method for pricing and, therefore, any definition of Part B products should be focused on whether the product itself is made from human tissue.

Feedback against Recommendation 1

Ethical concerns

- The primary purpose of the *Private Health Insurance Act 2007* is to address benefit and price-setting.
- Imported tissue products should be sourced ethically in line with Australia's stated position on altruistic donation. This requirement should be embedded into the definition to ensure, as far as possible, visibility and adherence to the policy.

Future proofing

- It is important the definition is fit-for-purpose and broad enough to enable innovation and the introduction of new technologies into the Australian market.

Further refinement

- The definition requires further refinement to provide clarity for different stakeholder groups.
- The definition does not acknowledge that highly processed tissue, such as some allografts, is different to minimally processed tissue by a local tissue bank.
- Alternative definitions suggested:

  Human tissue products are regulated under Part 3-2A of the TGA and are substantially derived from altruistically donated human tissue where the tissue has been subject to processing or treatments, and whose supply is governed by state or territory law.

  Human tissue includes products that are substantially derived from human tissue where the tissue has been subject to minimal or more than minimal processing treatments, and whose supply [however described, including trade, sell, distribution at cost, give or gift] is governed by state or territory law.

The department agrees in-principle with the proposed definition in line with the TGA and the OBPR wording. The department acknowledges the proposed definition may be subject to refinement.

Recommendation 2 – the department consider whether the exemption from fees associated with Part B of the PL to be restricted to sponsors of Class 2 biologicals or sponsors who are registered as a not-for-profit entity with the Australian Taxation Office

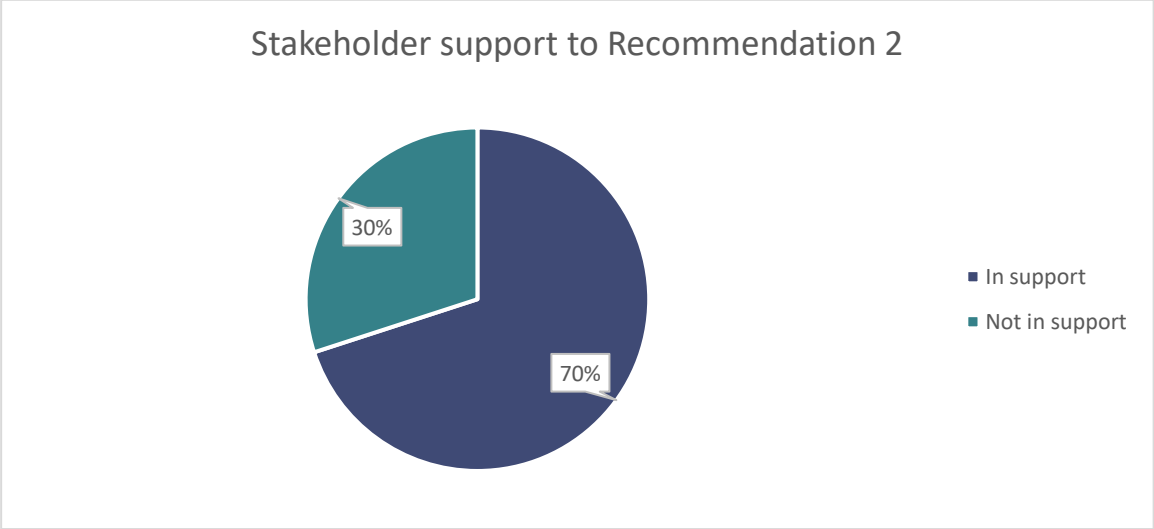
All sponsors of Part B products are currently exempt from fees that apply to other parts of the PL (application, initial listing, and ongoing listing fees).

When Part B of the PL was established, sponsors were predominantly public tissue banks supplying low risk tissue products which had minimal manipulation (Class 2 biologicals). As more highly processed tissue products appear on the PL and involvement by commercial sponsors increases, the appropriateness of this exemption is being reconsidered.

Some FP commercial manufacturers or sponsors have the resources to pay the appropriate listing fees, as assessment of applications for highly processed tissues can be time intensive. If these more highly processed products remain in Part B, a delineation could be made between:

- sponsors based on registration status with the Australian Taxation Office (ATO); or
- sponsors of Class 2 biologicals, and sponsors of Class 3 and Class 4 biologicals.

The recommendation received general support that commercial sponsors should not be exempt from fees. It may be problematic to determine the appropriate criteria for exemption.



Feedback in support of Recommendation 2

- The exemption will keep prices of allografts lower.
- Potentially the exemption should also include other Australian publicly funded facilities such as government departments and public hospitals.

Stakeholder suggestions for Recommendation 2

- Whether specific NFP tissue banks should be exempt and commercial sponsors or sponsors of Class 3 or Class 4 biologicals should not be exempt?

Feedback against Recommendation 2

- All tissue banks should pay fees.
- Fee structures should be uniform across Part B with a standardised costing model applied to all tissue banks.
- Primary funding source needs to be considered – however Class 2 only banks will only have a few listings and need to be separated from tissue banks with multiple listing and larger activity.
- Implementation of fees is inappropriate for Part B listings as it is based on the 'cost of supply' principle and will increase the PL benefit, potentially being passed on to payors.

The PLRT will consult with the department's cost recovery and legal areas, to ascertain if/how this recommendation can be implemented, including any subsequent improvements identified as part of this consultation process. This work is in the early stages and the sector will be informed of any developments.

Recommendation 3 – the department update and refine the groupings proposed by hereco, incorporating the stakeholder feedback on 'Groupings'.

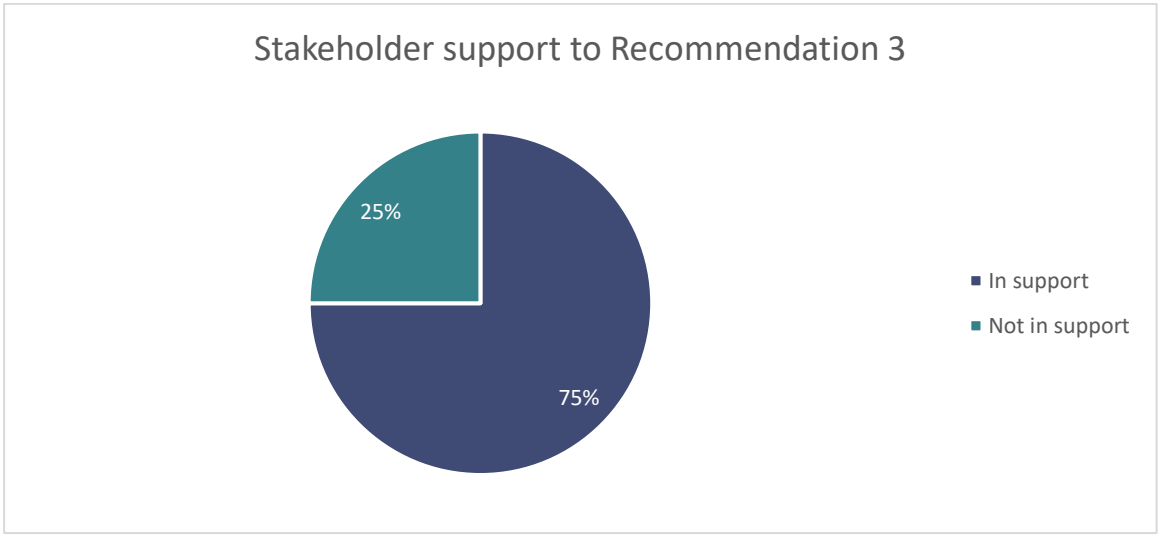
The Analysis of the Australian Tissue Sector[2] conducted by PwC in the 2016 for the Organ and Tissue Authority, as well as consultations with stakeholders outlined that Part B, propose significant reforms. These reforms are to acknowledge the changes in use, supply, and clinical utilisation of human tissue products over time. The department proposed a revised grouping structure to:

- extend the amendments to Part A groupings and bring appropriate and rationalised clinical logic to groupings across the entire PL;
- clarify where Part B products belong;
- determine the appropriate assessment pathway of products and track substantially similar products; and
- use as a reference point for future work on determining benefits.

In 2019, an external contractor was commissioned to propose a new grouping structure for Part B, including a rationale to support the proposed categories.

The proposed new grouping structure retains the four existing categories on Part B (Cardiothoracic, Ophthalmic, Orthopaedic and Dermatologic).

It is also recommended that the Dermatologic Category be renamed to Plastic and Reconstructive.



[2] https://www.donatelife.gov.au/sites/default/files/2022-05/pwc_-_analysis_of_the_australian_tissue_sector_-_final_d16-1267056_2.pdf

Feedback in support of Recommendation 3

- The Part B listing has been substantially reworked following feedback from clinicians in the consultation process to better suit the sector.
- Respondents recommended that regular reviews should be undertaken.

Feedback against Recommendation 3

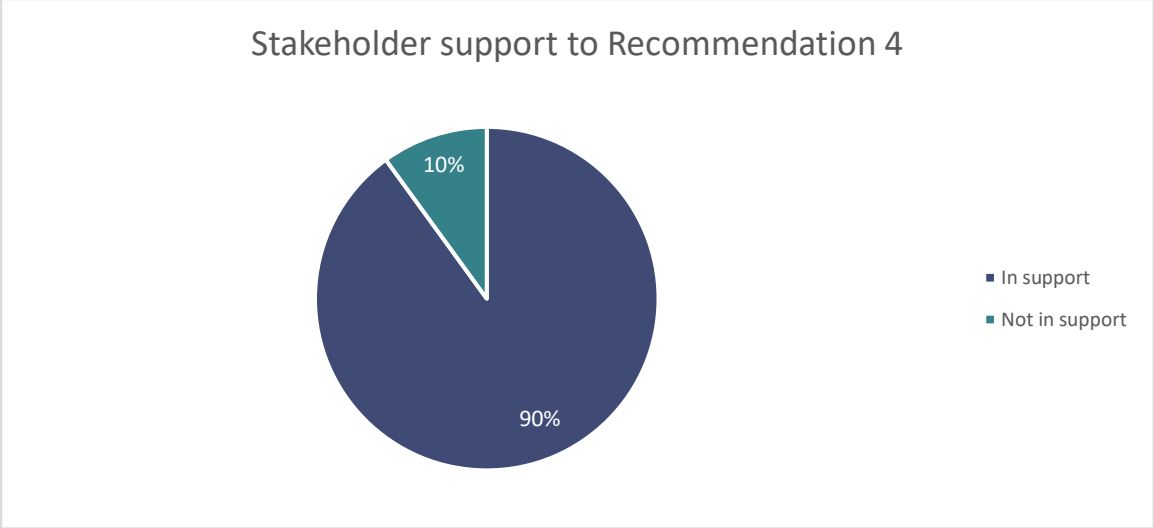
- The new grouping has been designed to replicate Part A and fit into the listing process on the Health Products Portal (HPP), without consideration of the nuances of Part B.
- An alternative option is to reconsider using tissue type - musculoskeletal, skin, ocular etc.

The department agrees with the recommendation and will finalise the proposed Part B structure to reflect the feedback received. Any changes will be shared with stakeholders and consulted on after implementation to ensure there are no unintended consequences.

Recommendation 4 – the department establish a regular review process on the Part B groupings.

There is an opportunity for the department to establish a regular review process on Part B grouping which would ensure continued engagement with the sector and provide the opportunity to gather views and feedback as the reform process continues.

Most stakeholders were in support of this recommendation.



Feedback in support of Recommendation 4

- Regular reviews are essential to ensure the new grouping structure does not result in any unintended or adverse impacts on patient outcomes, clinical choice, or services offered by private hospitals. Additionally, regular reviews will ensure any changes align and achieve intended outcomes and that Part B remains fit-for-purpose as technology and clinical practice evolve.
- Reviews may need to be more frequent in the early establishments of the groupings, as this can help to resolve any inconsistencies in the product listings.

Feedback against Recommendation 4

- The current review of the PL has been ongoing since 2020 and most issues around the listing of Part B products will be resolved when completed so there will be no need for regular review in this format.
- Regular reviews impose an additional burden on sponsors.
- Reviews should be confined to instances where a specific issue requires attention.
- Further consultation would be needed to understand what kind of process is required and any implications it may have.

The department agrees to this recommendation. The department will advise stakeholders of the intended changes before implementation to ensure there is an opportunity to identify unintended consequences.

Recommendation 5 – the department proceed with implementing the three assessment pathways which mirror the pathways for Parts A and C of the PL.

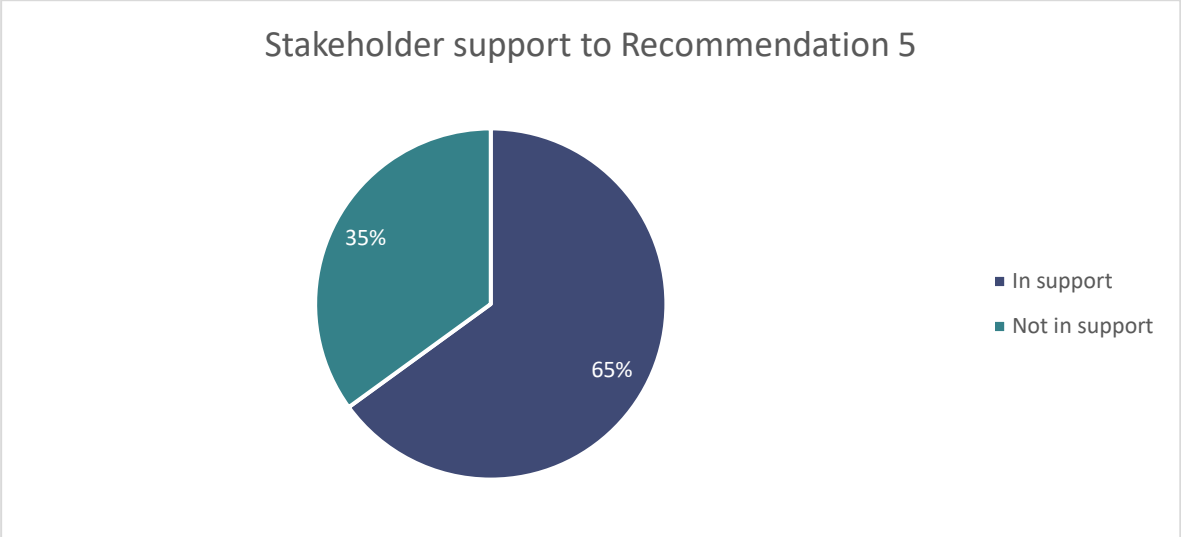
The department's original proposal was that the assessment pathways for Part B should mirror those for Part A and C. These pathways include:

- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical/Focused Health Technology Assessment (HTA) Assessment Pathway
- Tier 3: Full HTA Assessment Pathway (Medical Services Advisory Committee - MSAC)

Stakeholders who manufacture Class 2 biologicals will use Tier 1 and may use Tier 3 pathway on occasion.

For Class 3 and Class 4 biologicals, which are highly processed, sponsors should be able to provide the clinical evidence required for the Tier 2 and Tier 3 pathways, as this evidence would have been provided for the TGA application to support registration of these products on the ARTG (Australian Register of Therapeutic Goods).

However, TGA evidence requirements for Class 2 biologicals generally rely only on literature, and in some instances expert clinical opinion. Apart from corneal tissue, which is tracked through the Australian Corneal Graft Registry, most manufacturers of Class 2 biologicals do not collect objective long-term evidence as to the clinical effectiveness of their products including through registries. Class 2 biologicals are considered low risk as they have been subject to only minimal manipulation and are only for homologous use.



Feedback in support of Recommendation 5

- This approach is more user friendly, less complex and avoids duplicative efforts for sponsors.
- Any claims for superior performance (and therefore higher Tier) attributed to specific processing methods must be subjected to rigorous HTA.

Stakeholder suggestions for Recommendation 5

- Adjustments may be required to choose between the three assessment pathways to make them suitable for use by sponsors applying to Part B.
- A 'note' or 'exception' could be added within the pathway requirements, rather than developing a new Part B pathway, to maintain consistency and limit complexity.
- The department and TGA should work closely together to review evidence requirements for the proposed assessment pathways and classification of biologicals.
- Tier 2 should be limited to class 2 biologicals with a valid ARTG where the sponsor requests a higher PL benefit based on superior clinical performance.
- An additional fee is only appropriate where clinically relevant benefits can be demonstrated with evidence of real-world patient/public health outcomes. As small tissue banks are unlikely to submit items that require substantive analysis, this is where genuine commercial products are treated differently to tissue banks who may not have the competency to draft complex submissions to obtain an increased benefit.

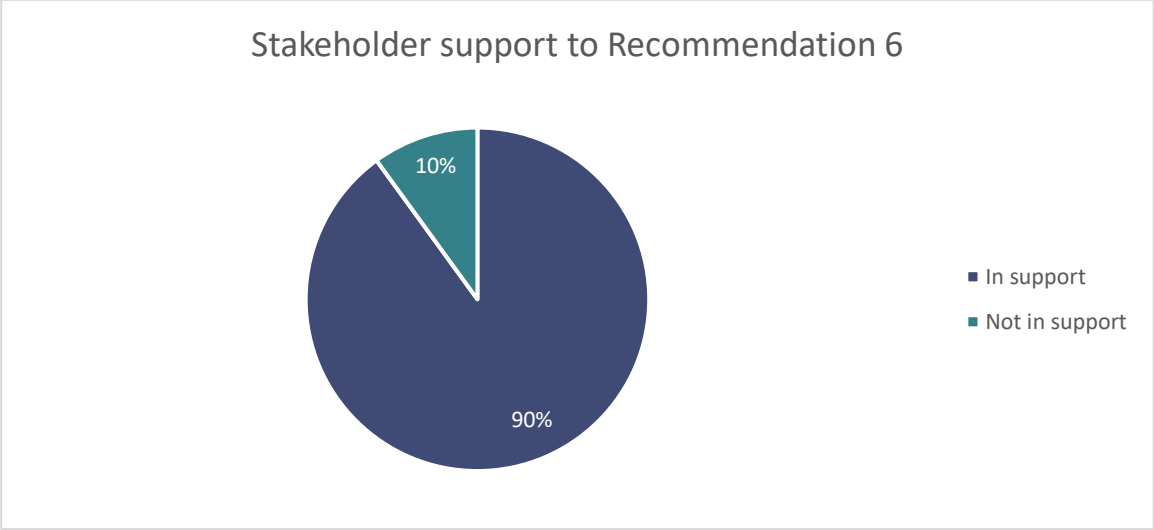
Feedback against Recommendation 5

- Non-commercial and low volume banks are unlikely to be able to deliver the documentation and HTA analysis required to submit adequate evidence for Tier 2 or Tier 3 applications.
- There is a concern that if sponsors of tissue products are unable to produce the data, innovation will be stifled and overtaken by international sponsors.
- The requirements and capability in response from sponsors needs to be better road-tested.
- The three pathways should be presented in more detail to stakeholders, with potential difficulties explored in face-to-face workshops.

- There is disagreement about what HTA methodology is applicable to human tissue products, as the cost effectiveness approach to benefit setting is incompatible with legislative requirements for human tissue items. However, there is agreement that the tiered pathways are suitable for administrative processing of comparator applications.
- Concern was expressed about the difference between Class 2 and Class 3 products – a definition about what constitutes being subjected to 'only minimal manipulation' would be useful.
- Manufacturers need to be supported to meet any new requirements to avoid reliance on imported allograft, which not only erodes Australian advanced manufacturing and innovation, but also reduces the opportunity to donate in Australia.
- There needs to be clarity on how consistency can be assured to support accessibility to tissue banks. Consultation between the department and States/Territories would be useful.

The department notes the recommendation and feedback. Prior to requiring Part B products to use the three assessment pathways the department will undertake further consultation with relevant stakeholders. Any amendment to the HPP for Part B products in relation to the three pathways will occur after additional consultation.

Recommendation 6 – the department provide additional support and guidance for sponsors of Class 2 biologicals to navigate HTA pathways.



Feedback against Recommendation 6

- Limiting future support to only sponsors of Class 2 biologicals (most likely NFP) to navigate the three pathways (if Recommendation 5 is implemented) may hinder innovation or competition in the market and that guidance should be provided for all sponsors and for all classes of biologicals.
- Concern there will be limitations in relation to the quantity, quality, timeliness to produce data substantiating HTA pathways for the national supply sources in comparison with international counterparts.

Stakeholder suggestions for Recommendation 6

- The three pathways should be presented in more detail to stakeholders, with potential difficulties explored in face-to-face workshops.
- Specific support should be prioritised for state-owned services.
- Clear guidance is required in relation to new technology allografts.

The department agrees in-principle to this recommendation, noting that it is dependent on implementation of Recommendation 5.

Recommendation 7 – the department undertake further work on the methodology for pricing including the development of costing standards

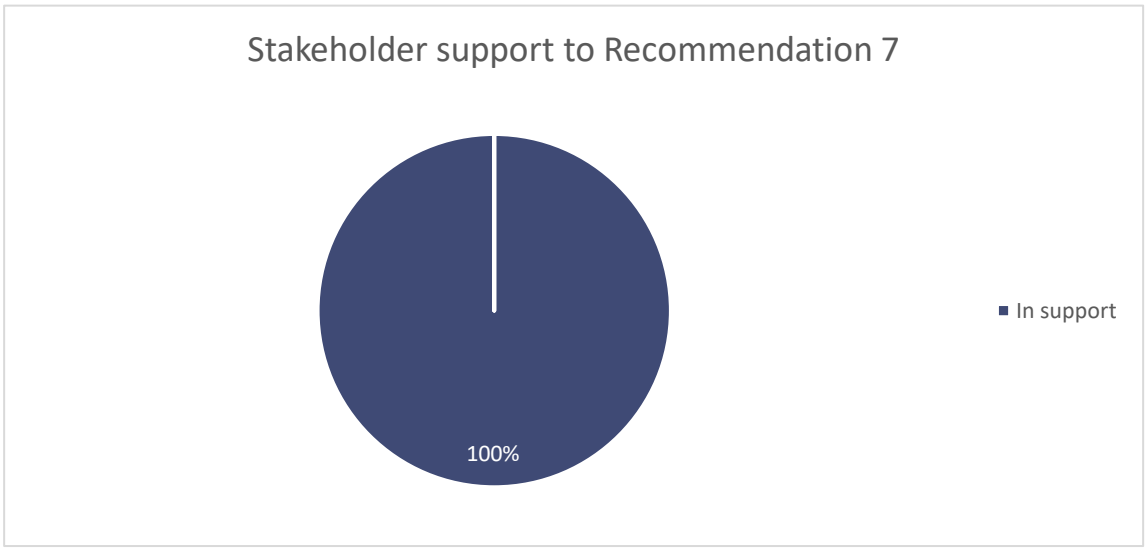
Part B of the PL currently operates on a cost-recovery basis. This cost-recovery fee includes costs associated with departmental staff processing the application, including undertaking assessments in relation to evidence provided, reviewing current requirements and processing invoices.

Anecdotally, the PL benefit acts as the *de facto* cost of the product used by the sector to determine the price charged to public hospitals and uninsured individuals.

While costing and benchmarking work was identified out-of-scope for the purposes of the Report, feedback received during the consultation processes highlighted the relationship between the HTA pathways, proposed groupings and benefit setting to be inter-dependant.

The department leads policy responsibilities to review and investigate the development of a costing methodology through the Jurisdictional Organ and Tissue Steering Committee (JOTSC).

Any form of cost-recovery activity will need to abide by Australian state and territory legislation. Further regulation and compliance should be considered in the context of the NHMRC ethical guidelines on cell, tissue and organ donation and transplantation.

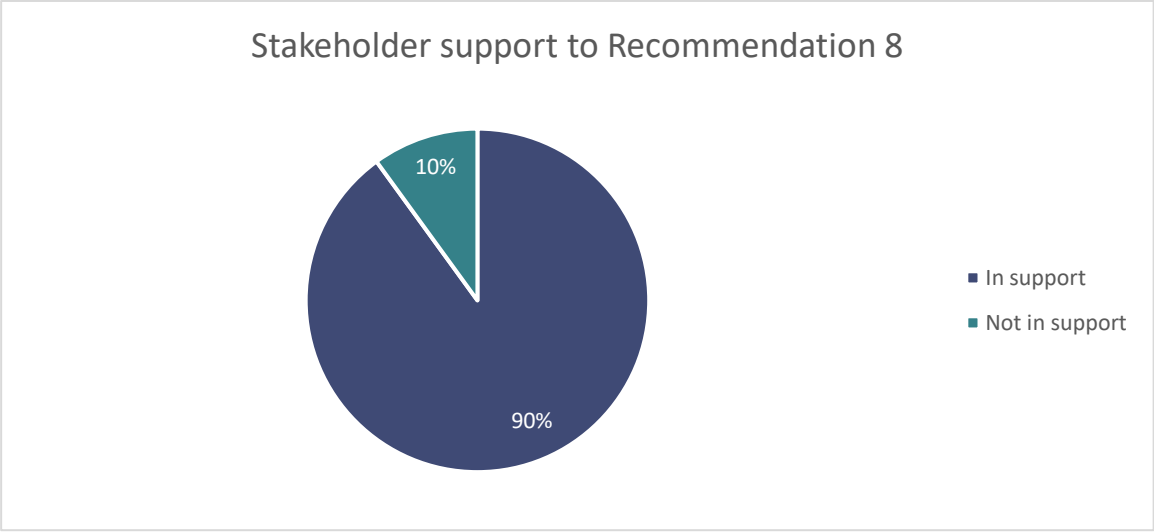


Stakeholder suggestions for Recommendation 7

- Concerns that the JOTSC do not have a large enough sample of tissue banks to undertake an industry benchmarking exercise.
- Not all JOTSC members have been in communication with tissue banks in their area. The department needs to be careful not to threaten the financial viability of regional banks who do not have access to testing, as closure reduces the overall capacity to supply across the country.
- Further activities which could be considered for inclusion:
  - Low turnover tissue products that stay on the shelf or expire.
  - Tissue banks incurring storage costs and not being reimbursed unless the product is used.
  - Regulatory and licencing costs (could come under administration costs). Operational realities and business models are quite different among the diverse facilities and within jurisdictions.

The department agrees in-principle to the development and implementation of pricing methodology. This will require working with state and territory governments to ensure any pricing standards to be used as part of the PL application process, aligns with state and federal legislative requirements and principles of the NHMRC Ethical Guidelines. Stakeholders will be consulted on the development and planned implementation of any pricing methodology.

Recommendation 8 – 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



Feedback in support of Recommendation 8

- There is strong support to maintain ethical and legislative considerations in regard to trading and profiting from the sale of human tissue, particularly if tissue is sourced from overseas.

Stakeholder suggestions for Recommendation 8

- The department harmonise and simplify existing legislation and regulations (commonwealth, state and territory) to ensure a consistent approach. Currently there are different requirements placed on state-based and commercial sponsors.
- In all states and territories, tissue manufacturing should be undertaken on a cost-recovery basis. However, some tissue banks accept returns for distributed allografts that aren't used by surgeons.
- Any review should clarify how each state or territory legislation applies to the supply and benefits of highly processed human tissue products.
- A review could look at:
    - The business structure of sponsors and any manufacturing proxy arrangements.
    - The full process to determine what is produced locally and what is imported, including multiple layers of processing to increase benefit yield.
    - The relevant differences between products – particularly whether derived from locally donated tissue or human tissue sourced from overseas – must be accounted for and wastage considered.
    - That it does not impose ongoing additional burden on sponsors in the form of repetitive consultations.
    - A review does not necessarily mean that the prohibition in trading will be removed.

Feedback against Recommendation 8

- As the department has no power over state and territory legislation and it is not the role of the PLRT to develop policy or legislation in relation to human tissue products, the review should be clearly defined, and stakeholders should be clearly advised of the parameters of the review and the PLRT's powers.

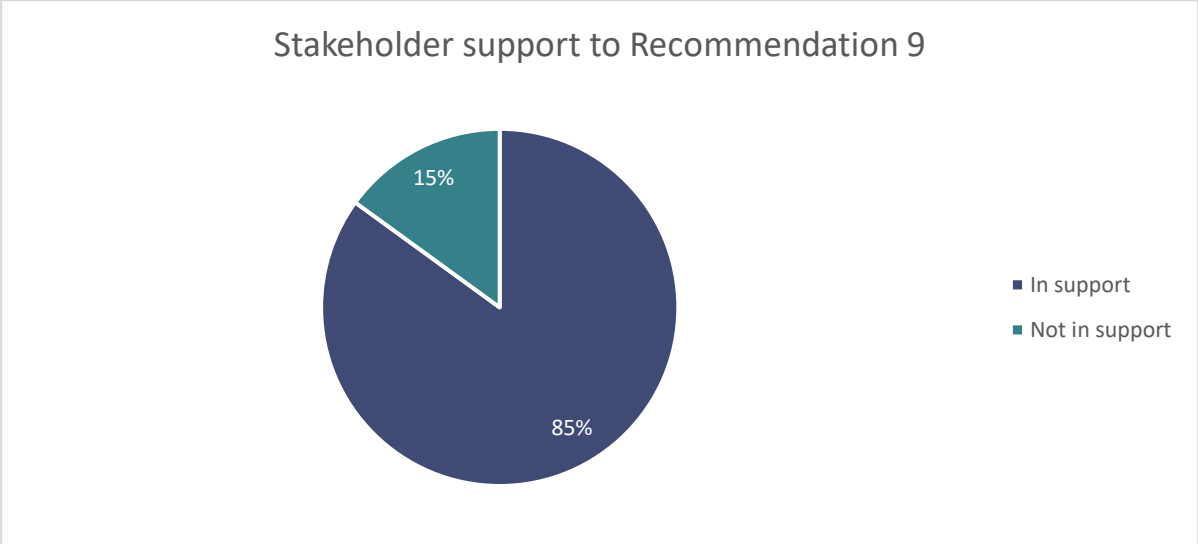
The department agrees in-principle to this recommendation.

On 15 August 2024, an Australian Law Reform Commission inquiry into human tissue laws was announced to determine whether legislative reform is required to harmonise laws across the nation.

The department's response to Recommendation 7 further addresses this recommendation.

Recommendation 9 – the department retain the Prescribed List items for autologous skull flaps and femoral heads

The PL Guide should define and clarify whether autologous products are eligible for listing and, if ineligible, that autologous skull flaps and autologous femoral heads are removed from the list.



Feedback in support of Recommendation 9

- If the products remain clinically safe and effective and there is a clinical use this will ensure there is a set minimum benefit.
- Currently, there are no autologous femoral heads listed.

Feedback against Recommendation 9

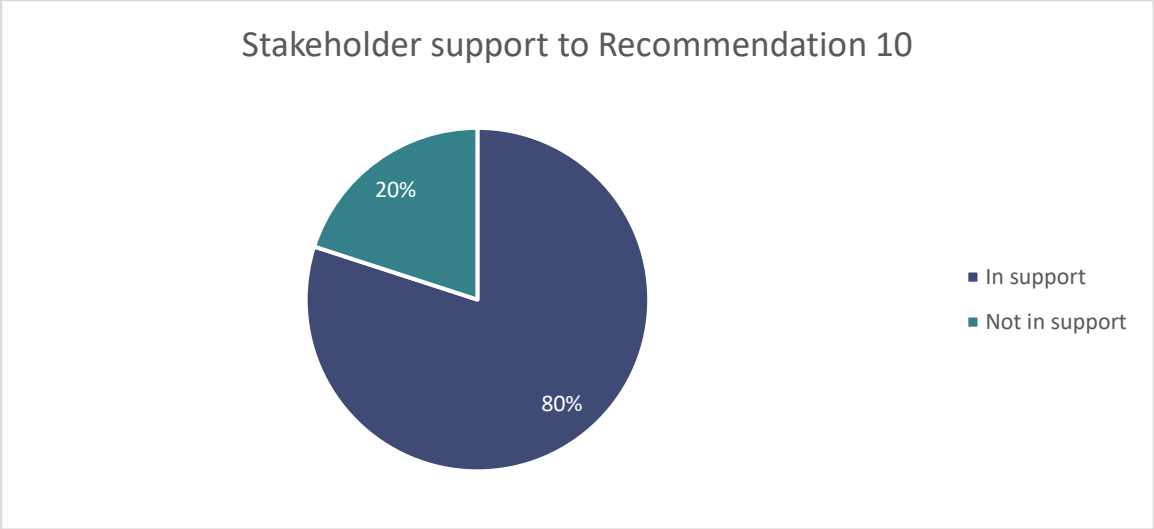
- These products are excluded from TGA regulation and therefore not listed on the ARTG, so they are ineligible for PL listing.
- Even though there is a cost in taking an autologous skin flap and retaining it, this is not a prostheses or a third-party tissue item and should be funded outside the PL.
- There is a very low utilisation so the retention of the items is likely to have no commercial impact to PHI funds, but it may set up a later precedent that will be of concern.

Under the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024*, human tissue products must not be listed in Schedule 1 unless it is included in the Australian Register of Therapeutic Goods maintained under section 9A of the *Therapeutic Goods Act 1989*. As listing of human tissue products in Schedule 1 provides the ability for appropriate benefits to be set, the department will engage in further consultation regarding Recommendation 9.

Recommendation 10 – the department does not pursue restricting the use of Part B items to specific MBS items at this time

That Part B products undergoing HTA assessment have an agreed list of appropriate Medicare Benefits Schedule (MBS) items assigned to them to enable their use to be restricted to specific clinical indications.

Support has been shown for the mandatory use of appropriate clinical registers to track usage and performance data. This will increase the availability of data on human tissue products and can improve the evidence base on clinical safety and cost-effectiveness when used for specific clinical indications. It would also discourage inappropriate use of human tissue in some settings.



Feedback in support of Recommendation 10

- The department should be consistent in the approach to any limitations of use across the PL. As this is not being applied to Part A and C products, it should not be applied to Part B products.
- Many allografts can be used for multiple purposes and, therefore, should not be limited.
- Hospitals support maintaining clinical autonomy and choice.

Stakeholder suggestions for Recommendation 10

- The department should conduct a HTA review to compare patient outcomes after comparable spinal surgeries where an allograft is used in one surgery and not the other. This will assist to determine the true value of each.

Feedback against Recommendation 10

- There is no policy justification to treat medical devices differently to pharmaceuticals where the government restricts use to clinically relevant and cost-effective indications.
- The department should review the rapid rise in the use and consequent billing of human tissue products and the increase in commercial suppliers and take action in relation to this.
- Some stakeholders strongly supported linking the use of Part B items to specific clinical indications, MBS, Australian Refined Diagnosis Related Groups (AR-DRG) and Australian Classification of Health Intervention (ACHI) codes to actively promote quality use, clinical and cost effectiveness.

The department will confirm if it does not pursue restricting the use of Part B items to specific MBS items and inform the sector of the outcome.

Other questions

Do you support the proposed restructure of Part B?

Most respondents referred to their response to Recommendation 3 (75% in support).

Feedback against the proposed grouping structure for Part B

- A grouping structure for Part B is not necessary for ophthalmology.
- A grouping structure has no purpose except to benchmark prices, which is counterproductive in a cost-recovery environment.

Stakeholder suggestions

- Stakeholders proposed any grouping structure should include grouping like-to-like items and tissues, so it is easier to identify differences in cost for similar cadaveric tissue locally sourced and prepped, along with imported or heavily engineered tissues.
- Any grouping structure should enable assessment of comparator items and comparative HTA.
- It is important to sustain viable donor tissue banks and clinician access to these, but they are different from commercial endeavours.
- Stakeholders suggested that promotional practices by commercial sponsors should be investigated.
- Stakeholders suggested conducting a targeted review for the Orthopaedic listings.
- They also recommend further review in relation to:
    - 03-Orthopaedic: Long Bone, Distal, Proximal and Proximal with Soft Tissue (03.01.01.03.05) to determine the appropriate subgroups, and
    - 04–Plastic and Reconstructive: Split Skin (04.01.01) to determine the appropriate subgroups.
- Stakeholders requested more detailed consultation or feedback on product level groupings for musculoskeletal products is likely to be useful before these are finalised. Examples include:
    - products listed under 03.01.02.015 Wedge includes tricortical wedges, which are better aligned to 03.01.01.0X Hemipelvis, Part.
    - Likelihood of possible overlap or refinement across listings 03.01.02.01 Block and 03.01.02.03 Block, Custom Shape, 03.01.02.011 Spacers, Cervical, and 03.01.02.015 Wedge.
- Autologous skull flaps should be under Orthopaedic- osseous- intact bone, whole or part skull flap.
- Billing code RNB02 is missing for the Hunter New England autologous skull flaps in the paper.
- Product TBV08 Cancellous Wedge is in an incorrect subgroup 03.01.02.06 Plug when it should be in subgroup 03.01.02.015 Wedge.
- Product TBV65 Tendon - Patella with Quadriceps is missing from the list. It should be listed in 03.02.04.05 Patellar Tendon with Bone.
- Subcategories 03.01.01.09 Whole bone, and 03.01.01.010 Whole Bone with Soft Tissue should be combined into 03.01.01.03 Long Bone, Whole +/- soft tissue, otherwise they reflect duplication.
- New inclusion since structure updated - 02.01.03 Cornea, Patch Graft, LAB01 Cornea Frozen, Lions Eye Institute Limited (LEBWA).
- 03-Orthopaedic: Ligament, Medial (03.02.03.01) - questions the addition of ligament patch, spinal given the suggested removal of ligament, medial.

Additional comments received

- There is strong interest in timelines and updates regarding next steps, including consultation.
- Legislation in the trading and use of cost recovery principles in human tissue is universal.
- Separating cost recovery assurance from PL benefit determinations would remove the need for a standardised costing template while ensuring assessment of all providers. Removing the need to forecast and instead regularly demonstrate cost-recovery operation may be more easily navigated by sponsors and the department.
- It is a challenge to overcome the breadth of services offered by commercial sponsors/manufacturers.
- There was a strong objection to benchmarking that assumes public entities have similar abilities and costs as each other to supply tissue, if that price is below the cost of all the inputs for the tissue supplied by that bank. Zero profit margins mean they are affected by the inevitable rises in major costs.

Out of scope

Several issues were raised by stakeholders that were outside the scope and were not included in the analysis above. These included:

- Part B and the PL Guide
- Commercial FP vs NFP entities (NFP public and private banks, NFP organisations) on Part B.
- Whether highly processed human tissue products are better suited to Part A of the PL
- Clarification on the terminology of ‘benchmarking’ and what that will include.
- The parameters of any review of state and territory legislation and the power of the department to make changes in relation to this legislation or Federal legislation.

Next steps

The department will work towards the implementation of each recommendation before the end of the PL Reform period.