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SUBMISSION

Friday, 6 October 2023

PwC Report on Reforms to Prostheses List Part B

AMA submission to Department of Health and Aged Care on the PwC report on reforms to Prostheses List Part B

Via email to prosthesesreform@health.gov.au

Introduction

The AMA appreciates the opportunity to respond to this consultation on recommendations made by PwC in its May 2023 report to the Department of Health and Aged Care (the Department) on reforms to the Prostheses List ('PL') Part B.

The AMA also acknowledges the efforts made by the Department to respond to the AMA's calls for more detailed consultation on PL Part B reforms, which it achieved through its engagement of PwC to conduct additional consultations with stakeholders.

Overall, the AMA supports the PwC recommendations and notes that the Department has already indicated its support for them subject to feedback received in response to this consultation.[1]

For ease of reference, this submission responds to the substantive questions included in the Department's consultation response survey instrument (questions 4-15)[2] using the same question numbering as the survey.

4. As per (PwC) Recommendation 1 - Do you agree with the proposed definition for Part B products?

Yes. The AMA notes that this definition is the same as the definition that is already administratively applied as the listing criterion for inclusion on Part B of the PL.

5. Do you support Recommendation 2 - that the Department consider whether the exemption from fees associated with Part B of the PL be restricted to Sponsors of Class 2 biologicals or Sponsors who are registered as a not-for-profit entity with the Australian Taxation Office?

Yes. It is essential that sponsors who are registered not-for-profits are exempted from fees associated with listing on Part B of the PL. Providing an exemption to this group of sponsors is preferable to offering an exemption for sponsors of Class 2 biologicals only, because as

noted in the PwC report, in rare instances, some non-profits may need to use the Tier 3 Full HTA (MSAC) pathway.[3]

6. As per Recommendation 3 – do you agree with the updated structure for Part B products?

The AMA supports the updated broad structure for Part B products, given that it was substantially reworked following feedback from clinicians during PwC stakeholder consultation processes.

However, it is critical that any further clinical feedback submitted in response to this consultation is incorporated into the final updated Part B product structure. The updated structure should then be subject to regular review as noted in response to Question 7 below.

7. Do you support Recommendation 4 – that the Department establish a regular review process of the Part B groups?

Yes. Regular review of Part B groups informed by the knowledge and experience of all key stakeholders — clinicians, hospitals, sponsors, and insurers — will be essential to ensure that

- the new structure does not result in unintended or adverse impacts on patient outcomes, clinical choice by medical practitioners, or services offered by private hospitals
- Part B groups remain fit for purpose as technology and clinical practice evolve.

8. Do you support Recommendation 5 – that the Department proceed with implementing the three assessment pathways which mirror the pathways for Parts A and C of the PL?

Yes. In particular, the AMA supports the introduction of the proposed Tier 1 Abbreviated pathway (for low-to-medium risk products already included on the ARTG and representing well-established biological technology substantially like other devices already on the PL) which will apply to most Part B listing applications.

This should be a more efficient process that will see effective products making their way into clinicians' hands more quickly.

The listing process needs to have an appropriate balance that provides for an adequately strong assessment without discouraging companies from developing or importing products. This is especially the case for

- niche and novel products with smaller profit margins
- products labelled high risk where there are already similar products on the PL and no new clinical evidence is required.

Given the additional information provided by PwC on the pathways proposed for Tier 2 and 3 Part B products following stakeholder consultation, the AMA is of the view that these pathways do strike an appropriate balance. They do not appear to impose a greater administrative or evidentiary burden on sponsors than current assessment processes and are likely to speed up the process of applications reaching the right area of the Department, or the right body (e.g., MSAC) for assessment.

Incorporating novel and innovative products into the PL list in an appropriate timeframe will be especially important in the future as sponsors of new biologicals with the potential to significantly improve patient outcomes seek to make them available for clinical practice.

The use of the online HPP portal for all applications and related communications should considerably speed up the assessment and listing process, which will also make it easier for both funds and private hospitals to prepare for 'list effective' dates.

However, given that the new listing process does require sponsors to essentially self-select the pathway through which their application will be assessed in the first instance, the efficiencies of the new listing process will only be realised if the updated Prostheses Guide provides crystal clear guidance to prospective Part B sponsors.

Government provision of adequate funding for the PL listing and review process will also be critical to reap the intended efficiencies of the new listing pathways, and to ensure that new products and amendments are listed on the PL within appropriate timeframes.

Provision of adequate funding to the Department will be particularly important given the key role the Department is proposing to take to facilitate the assessment of most Part B listing applications through the new and abbreviated Tier 1 pathway.

9. Do you support Recommendation 6 – that the Department provide additional support and guidance for Sponsors of Class 2 biologicals to navigate HTA pathways?

Yes. This is important given that such sponsors are mostly non-profit organisations, many of whom noted their resource and capability constraints relative to commercial sponsors during the PwC stakeholder consultation process.[4]

10. Do you support Recommendation 7 – that the Department undertake further work on the methodology for pricing including the development of costing standards?

Yes. The AMA notes comments made during the PwC consultation process to the effect that costings provided by sponsors vary widely and that stakeholders currently have very limited guidance in seeking reimbursements due to the lack of costing standards across the industry.

The AMA also notes that in its interim response to PwC's recommendations, the Department has advised that is investigating the development of a costing methodology through the Jurisdictional Organ and Tissue Steering Committee (JOTSC) and will seek further feedback from stakeholders on the outcome of its discussions with JOTSC.

11. Do you support Recommendation 8 – that 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?

Yes. Although most states and territories appear to allow for cost-recovery associated with donation or supply of human tissue products for therapeutic or medical purposes,[5] there needs to be absolute clarity on this point before any further consideration of benchmarking is undertaken.

12. Do you support Recommendation 9 – that the Department retain the PL items for autologous skull flaps and femoral heads?

Yes. The AMA notes the strong stakeholder support for this course of action detailed by PwC.[6]

13. Do you support Recommendation 10 – that the Department does not pursue restricting the use of Part B items to specific MBS items at this time?

Yes. The AMA notes that the Department has advised that any such restriction would be inconsistent with Prostheses List Parts A and C requirements.

It is important to add that while there are typical pathways in medical care, there are also many exceptions where it is important not to limit clinician choice.

However, the AMA supports measures to track use of prostheses, collect data about prostheses performance, and discourage inappropriate use of donated tissue in some settings. We understand that when prostheses and implants are used in the private system it is difficult for government to obtain downstream data on their use and performance, except where those prostheses are covered by a register.

The AMA supports the use of registry mechanisms as mandatory, for this reason. Inclusion on appropriate clinical registers will increase the availability of data and thus improve the evidence base on the clinical safety and comparative cost-effectiveness of prostheses when used for specific clinical indications.

14. Do you support the proposed restructure of Part B (as shown on the Excel worksheet issued as part of the Consultation Papers)

The AMA can see that changes to the detail of the proposed restructure recommended by clinicians during the PwC consultation process have been incorporated into the structure shown on the Excel worksheet issued as part of the Consultation Papers.

The AMA defers to the various Colleges, Associations and Societies that represent all relevant specialties on this question. These groups have the specific and technical knowledge required to fully assess the detailed structure provided in the worksheet.

Contact

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[1] CONSULTATION - Table 1 - Part B Recommendations table.DOCX

[2] Questions 1-3 ask the name, email and organisation of the survey respondent.

[3] PwC (2023). Reforms to the Prostheses List Part B. Report to the Department of Health and Aged Care. Retrieved on 23/8/23 from CONSULTATION - Attachment A - PwC Final Report - Part B Reform of the PL (Redacted).PDF, p.14.

[4] PwC. (2023). Reforms to the Prostheses List Part B, p.12.

[5] PwC. (2023). Reforms to the Prostheses List Part B, pp. 22-24.

[6] PwC. (2023). Reforms to the Prostheses List Part B, p.16.