



Medical Technology
Association of Australia



*Review of the Stoma Appliance
Scheme
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Medical Technology Association of Australia Limited
Level 12, 54 Miller Street
North Sydney NSW 2066 Australia
P: (02) 9900 0650
E: reception@mtaa.org.au
www.mtaa.org.au

MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. Executive summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to respond to the long-awaited review of the Stoma Appliance Scheme (SAS). MTAA supports the rationale behind the proposed reforms to listing and pricing of products on the Stoma Appliance Scheme, specifically the use of improved evidence to support an application for listing and an application for a premium price.

However MTAA has several concerns about aspects of the report. These include the limited nature of the material made available for comment, the underlying assumptions on growth in demand for stoma products and the modeling used to direct the restructure of the Stoma Appliance Scheme, and the proposed governance of the arrangements. At the very least the full consultant's report and underpinning modeling should be made publicly available.

MTAA is also concerned at the limited time given to suppliers to provide additional evidence in support of applications for listing with a premium price. After a delay of three years in the listing of products with a premium, the very short time made available is unreasonable.

2. About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, diagnostic imaging equipment, and products which use biological materials.

Medical technologies also include the range of ostomy products used in the management of both short-term and long-term medical conditions which have resulted in a stoma.

The medical technology industry had sales in Australia of more than \$7 billion in 2008/2009 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately two-thirds of all medical products on the Australian market.

3. Response to the review paper – general comments

MTAA notes that the review paper addresses a small number of issues covered under the consultant's brief. This is unfortunate as there are several areas which were examined by the consultant that are not addressed in the paper such as the establishment of preferred principles, policies and objectives associated with a robust framework for the operation of the SAS. It also means that the evidence required to support some of the assumptions has not been produced, despite one of the outcomes purporting to be an improved evidence base.

MTAA notes the graph at Table 1 of the report setting out the increased expenditure on stoma appliances. What is not clear from the graph is the extent to which utilization has changed over the 10 year period. MTAA has analysed data for a different set of medical devices, namely prostheses on the Prostheses List, and it is evident from this data that the growth in expenditure is attributable to increased utilization, and not price increase. A similar set of data would be helpful to understand what lies behind the growth. It would also be useful to understand the differences in utilization of stoma products between short-term and long-term stomas. This analysis would assist in understanding the likely direction of future demand.

The report is silent on other aspects of the costs of the SAS. For example it does not analyse the current distribution arrangements which deliver a handling fee to Australian Council of Stoma Associations (ACSA). There are multiple distribution options that could be considered (and which are used in other countries). It may be that the current model is the most cost-effective but there is no evidence in the report to this effect.

MTAA notes that the consultant has “considered the vision, goals, objectives and principles” articulated in the final report of the Review of Health Technology Assessment (HTA Review) in considering how the sustainability of the SAS could be improved.

MTAA made a significant contribution to the HTA Review and many of the objectives which MTAA sought for improved health technology assessment of medical devices in Australia are reflected in the report from the HTA Review. The outcomes of the HTA Review, accepted in large part by the Commonwealth Government, could be better reflected in some of the proposed arrangements for the restructured SAS.

MTAA supports an assessment approach which is informed by robust and relevant evidence. However the process must also be fit for purpose and reflective of the nature of the medical technologies which are being assessed. There is no ‘one size fits all’ for health technology assessment. This goes to the level of evidence available to support a claim for inclusion in the SAS and the quantum of reimbursement.

Good health technology assessment must also be consultative, and transparent, accountable and independent. The proposed arrangements for the new SPAP do not appear to comply with this principle. For example, the report makes no provision for independent review of decisions, or the opportunity for resubmission with additional evidence where listing is denied, or an inadequate reimbursement is offered.

The report makes reference to the need to avoid conflicts of interest on the Stoma Product Assessment Panel (SPAP) but has responded to a perceived conflict in a way which is inconsistent with other HTA bodies assessing medical technologies. This issue is discussed further at section 4.

4. Stoma Product Assessment Panel

The report proposes the re-establishment of the SPAP with a revised membership. MTAA supports the inclusion of experts with knowledge of the clinical and economic evidence. However the proposal to not include stakeholders on an equal basis is

inconsistent with other recent Commonwealth HTA reforms. It also confuses the nature of conflicts of interest where stakeholder representatives are drawn from, or nominated by, an industry body (but with no personal pecuniary interest) with direct conflicts of interest where a representative is drawn from a stakeholder with a direct pecuniary interest – whether a distributor association or a supplier.

The recently-established Protheses List Advisory Committee (PLAC), which also considers a wide range of medical devices, draws representation both from experts and from stakeholders. Industry is represented by two individuals nominated by MTAA. MTAA represents most of the major suppliers and manufacturers of stoma products (some of which might distribute through a third party distributor). However it does not itself have a vested interest in the outcome of SPAP's deliberations. It may be that an MTAA employee might not be appointed to represent the industry but as MTAA is the only industry body which has broad coverage of the medical technology manufacturers and suppliers it is reasonable that MTAA be asked to provide an industry nomination.

It is inappropriate to differentiate between the voting and non-voting members of SPAP. All members of the SPAP should have equal standing with equal consideration given to their input. The members of PLAC, in comparison, have an equal vote whether they be stakeholder representatives or experts.

It is more appropriate to approach an independent health consumer body, such as the Consumers' Health Forum, for the nomination of a consumer representative. It would not be appropriate for a consumer representative to be a member of ACSA as there would be a direct conflict of interest while ACSA benefits financially from the current distribution arrangements.

MTAA supports the increased transparency of SPAP's activities through publication of agendas, and summary outcomes from meetings.

5. Listing products on the SAS

MTAA supports the use of available evidence to substantiate an application for listing, or an application for a premium where a product can be shown to be superior to other products in the category. However as the HTA Review report recognizes, the assessment processes must be 'fit for purpose' and recognize that medical devices such as stoma products do not have the same level of evidence that is available for pharmaceuticals.

MTAA acknowledges that the Government's response takes account of the difficulty in generating adequate evidence in all cases. The evidence is more likely to be available for comparative clinical outcomes. It is more difficult to generate evidence of cost effectiveness, given the limited health economics expertise available in the medical device sector as it matures. It would be helpful to have a better understanding of the type of cost effectiveness evidence that would be most effective and therefore likely to have more influence.

MTAA asks for clarification of the final paragraph in the Government response to this section (on page 7 of the report). Does the Department propose that outstanding applications proceed under the new arrangements for listing with a premium, or does it require fresh applications of products that have been denied listing for the past three years?

6. Pricing of products listed on the SAS

MTAA supports the review of current groupings and sub-groupings to ensure consistency of grouping and use of a benchmark to set the price for a standard or benchmark product. A similar process is being undertaken to confirm groupings of products on the Prostheses List, with the application of a benchmark benefit once the groupings are confirmed. It is appropriate that suppliers are asked to confirm that each product is correctly grouped. However the features groupings which have been provided to suppliers are neither exhaustive nor mutually exclusive. Further, many features are proprietary, branded product claims.

MTAA questions the use of health outcome as a differentiator between subgroups as part of the product description. Again, using the Prostheses List grouping as an example, it is the physical characteristics of the device which are used to differentiate between groups, not the health outcomes. An improved health outcome might be used as evidence to argue for a premium but not for grouping purposes.

The process for setting a benchmark is not disclosed, nor is the basis for differentiation between a benchmark product and a product which might attract a premium. Examples are given of possible relevant evidence, but no explanation is provided as to how the claims will be assessed, or whether there might be tiers of reimbursement based on a scaled, evidence-based differentiation.

The report refers to anomalies in maximum monthly allowances. However the Government has not addressed this critical issue in its response. The usage of products inherently will impact on the cost of the scheme but no solution has been outlined to address current anomalies.
