



**Medical Technology**  
Association of Australia



*Proposed changes to MSAC  
processes for applications for  
public funding  
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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 discussion paper released by the Australian Government to elicit comments on proposed changes to processes used to assess applications for public funding by the Medical Services Advisory Committee (MSAC). In its submission to the Review of Health Technology Assessment<sup>1</sup> (HTA Review), MTAA offered several proposals for reform of the assessment system as it then applied. Many of these recommendations have been incorporated into the reforms to Australia's health technology assessment (HTA) processes over the past year.

MTAA welcomes the reforms to MSAC processes contained in the discussion paper but would have preferred that the proposed changes were not already in train before consultation was undertaken with potential applicants. Nevertheless MTAA welcomes ongoing dialogue beyond finalisation of the current consultation process to ensure that continual improvement is assured.

Proposals in this submission primarily focus on requirements to improve transparency, balanced with the protection of commercially sensitive information. MTAA reiterates the concerns it expressed in its submission to the HTA Review that HTA processes must be fit for purpose and transparent, while affording due process.

One significant area of concern is the prospect that budgetary considerations may act as a block to further assessment of a technology at an early stage in the MSAC process, to the detriment of a proper HTA assessment. MTAA argues that there must be a separation of the assessment of the technology from the decision to fund. Consideration of the capacity to fund before a full analysis of the clinical and cost effectiveness of a product may preclude uptake of an otherwise beneficial technology.

MTAA repeats its call for the establishment of a review process to ensure accountability. MTAA urges ongoing consultation with stakeholders as the changes are fully implemented to ensure that the objectives of the HTA Review are achieved.

## 2. About the medical technology industry

MTAA represents the manufacturers, exporters and suppliers 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.

The medical technology industry had sales in Australia of more than \$7.5 billion in 2009-10 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for

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<http://www.mtaa.org.au/pages/images/Health%20Technology%20Assessment%20Review%20MTAA%20Submission%20May%202009%20final.pdf>

improved patient benefit. MTAA represents companies supplying approximately two-thirds of all medical products on the Australian market.

### **3. Response to the discussion paper – general comments**

In its submission to the HTA Review, MTAA commented that in lieu of any overarching HTA for medical technology, the recommendations of MSAC, and establishment of an Medicare Benefit Schedule (MBS) item number, act as a proxy HTA assessment for all Australian patients. Without an MBS item number and funding, private patients are not able to access treatment options.

Despite the original expectation that the majority of MSAC applications would originate from professional medical organisations, the source of applications quickly moved to the medical technology industry as being the main and almost exclusive source of applications. Over recent years a large percentage of MSAC applications have come from the medical technology industry - a curious situation in respect to a process primarily designed to facilitate fees for medical practitioners. The reason lies with the nature of the new procedures. A close examination reveals that without exception all new MSAC applications cover procedures that include the use of new technology, that is, capital equipment, consumables, disposables, prostheses or medical devices.

MTAA identified several areas of generic application in HTA processes, and specifically in MSAC processes, where improvements could be made. These included:

- Establishment of a timetable for processing applications
- More efficient appointment of advisory panels by MSAC to avoid extensive built-in delay
- Improved guidance on the data which an applicant would be required to collect under conditional funding approval
- Improved governance through clearly articulated procedural mechanisms, collaborative communication, increased transparency, and accountability
- International harmonization through the acceptance of overseas data, facilitation of Australian researchers into global research programs, and the use of overseas assessments, as a result of which Australia will become networked into global HTA processes. Not only would this enhance the HTA processes in Australia, but it would also mean that there are no unique rules in Australia.

MSAC is charged with considering, amongst other things:

- The strength of evidence in relation to comparative safety, effectiveness, cost-effectiveness and total cost of the medical service
- Whether public funding should be supported and, if so, under what circumstances
- The circumstances under which interim funding could be supported for a period during which defined data collection under agreed clinical protocols would be collected, where there is uncertainty in relation to the clinical or cost-effectiveness of a service.

In its submission MTAA considered possible approaches to development of clinical evidence and to assessment of cost effectiveness. In discussing the development of

clinical evidence, MTAA made the point that there are significant differences between pharmaceuticals and medical technologies. One of the key differences is the scope and degree of clinical evidence available to the assessment body.

While MTAA proposes that clinical evidence from clinical trials conducted in other countries should be used by the Australian assessment body, there remains a significant cost in developing the range of clinical evidence required to satisfy a full health technology assessment. MTAA encourages the use of observational studies and patient experience, to add to the clinical information available to assessors.

MTAA argues that the evaluation system needs to be flexible and to take into account a broad range of factors including stakeholder involvement, evaluation of the totality of the evidence, and focus on evidence that is relevant to the research question at hand. The level of evidence is a function of the risk/benefit of the technology or procedure. MSAC could consider utilising a sliding scale of evidence requirements as a function of risk assessment.

MTAA also commented extensively on the cost effectiveness assessments undertaken by MSAC. Its submission to the HTA Review contained an analysis by Access Economics<sup>2</sup> of the key requirements for an effective economic evaluation process for HTA. The proposed framework acknowledged the need for flexibility but at the same time underscored the need for a consistent methodological approach.

Access Economics took a broad perspective in considering the scope of an economic evaluation. MTAA supports this position and the argument put by Drummond et al<sup>3</sup> that a full societal perspective should be used. It is not sufficient to assess only the direct cost to the health care system. The Access Economics evaluation framework proposes a methodology for identifying costs and benefits that are both direct health care system costs and benefits, and broader.

Access Economics also discuss the problem of Type I and Type II errors which have resulted in the current HTA processes for medical technologies within MSAC denying a positive assessment to many beneficial technologies as first identified by O'Malley in her paper<sup>4</sup>. The outcome of a Type II error is that a new health technology is assessed as not cost-effective when the opposite should have been the outcome, based on all observed and unobserved information. This means that society misses out on a social welfare improvement. Avoiding Type I errors at the expense of Type II errors trades-off social welfare improvements that could have been achieved with the avoidance of a reduction in social welfare. Because the traditional strategy has been to err on the side of caution, there is an implicit bias in the economic evaluation<sup>5</sup>.

The proposed economic evaluation framework addresses this bias. The economic evaluation framework proposes that a range of economic evaluation tools be available and outlines the circumstances in which a particular tool would be selected.

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<sup>2</sup> Access Economics, An improved HTA economic evaluation framework for Australia, May 2009 [http://www.mtaa.org.au/pages/images/Final\\_220509.pdf](http://www.mtaa.org.au/pages/images/Final_220509.pdf)

<sup>3</sup> Drummond MF, Stanford Schwartz J, Jonsson B, Luce BR, Neumann PJ, Siebert U, Sullivan SD, Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Technology Assessment in Health Care*, 24:3 (2008), 244 at page 252

<sup>4</sup> O'Malley, SP (2006), The Australian experiment: the use of evidence based medicine for the reimbursement of surgical and diagnostic procedures (1998-2004). *Australia and New Zealand Health Policy*, Vol 3

<sup>5</sup> Access Economics at page 46

The analysis also points out that an important point of differentiation between the evaluation of pharmaceuticals and medical technologies is in identification and measurement of benefits<sup>6</sup>. Whereas the primary benefits of pharmaceuticals tend to be improved health outcomes, non-pharmaceutical health technologies can deliver more than just changes to health status. They can be grouped into improved health and other health care system benefits. Procedures and medical technologies deliver other economic and social benefits that should be incorporated within an economic evaluation.

## **4. Discussion paper – specific comments on proposed changes**

### **4.1 Pre-lodgment**

MTAA supports the proposal that there be a mandatory pre-lodgment meeting between the applicant and the MSAC secretariat. However the meeting must do more than pay lip service to the process by fully canvassing the issues which an applicant will need to address in developing a protocol, or otherwise in meeting the requirements of an application.

### **4.2 Eligibility**

MTAA argues that there needs to be transparency around the decision on eligibility of an application. If there is to be broad engagement within the health portfolio on policy implications of an application then these considerations must be transparent to an applicant. Considerations might include the likely level of the clinician fee and the budgetary impact of a commitment to the new technology and procedure. In these circumstances MTAA argues that while policy considerations are relevant, they should not act as a stop to an application at this preliminary stage. The decision to fund or otherwise should be a separate decision from an assessment of the suitability of the technology and the procedure.

If the applicant is made aware of the basis of policy concerns, with a breakdown of the likely impact, then additional material may be provided to address these concerns. For example, if the policy response is modeled on assumptions about likely patient groups, there may be scope to refine the data on which the application has been modeled. The Department of Health and Ageing (Department) can assist this process by providing the disaggregated data on which it has relied.

Transparency is also needed in the response to the applicant after eligibility is assessed. For example, if the application is assessed as eligible based on certain assumptions about patient groups, then the basis of this determination needs to be made known to the applicant.

A further factor in determining eligibility is the application of a 'rule of rescue'. The application process needs to allow for items that might benefit only small numbers of patients.

### **4.3 Protocol development**

MTAA proposes that in a submission-based application it should be the applicant that prepares the first draft of the protocol as the starting point for review. Not only will this assist with the demands on the resources of the MSAC secretariat but it is also

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<sup>6</sup> Ibid page 48

likely to result in fewer amendments as the company has the best understanding of the product and supporting evidence. The protocol review will identify where the evidence needs to be supplemented.

Contracted assessment is most likely to be used by applicants that do not have the resources or competency to develop a protocol. After completing the MSAC information request form as an initial step, the applicant should then be consulted during development of the protocol by MSAC and/or the third party contractor retained by MSAC.

MTAA proposes that a commitment to fixed timeframes be given to applications based on company-developed submissions as an incentive for companies to take on this responsibility. There is a benefit to the Commonwealth in having the company bear the cost – this could be recognised in assisting the company with speed to market. Proposed timelines can be abridged where it would not compromise assessment. MTAA proposes that the Department commit to a maximum of 12 months from application to Cabinet submission. An optimal target might be six months. The HTA Review anticipates measurable benchmarks for HTA processes, of which time to process and approve an application would be one.

For applicant generated submissions, MTAA proposes that the applicant be provided with relevant economic modeling data held by the Department to assist in building the quality and relevance of the application. The information used by the Department, or its contracted advisers, to develop a protocol is equally relevant to a company-developed application.

By whichever path the protocol is developed, MTAA proposes that the draft protocol be returned to the applicant for review before it is exposed for public comment. If the content of the protocol cannot be agreed between the applicant and the Department, the company should have the right to withdraw the application at that time. There is significant commercial risk to an applicant to have publicly exposed an inaccurate or incomplete protocol without the opportunity to address these deficiencies. There is also a waste of resource within the Department to proceed with development of a protocol which is not supported by the applicant.

Where there is disagreement on the content of the protocol MTAA proposes that there be an opportunity for a face-to-face meeting to address the issues. Where an applicant has negotiated with the Department on changes to the draft protocol, there needs to be a record made of the discussion to ensure that the changes are minuted.

The discussion paper does not address the issue of exposure of commercially confidential information through publication of the protocol. Will the Department make an assessment on a case-by-case application as to which parts of a protocol should be removed before publication, based on claims of potential commercial harm? Release of the full suite of information available in a protocol may give rise to conflicts between competing commercial and clinical interests which are voiced only when the detail of the protocol becomes known. There would also be significant demands made on secretariat staff in assessing competing and potentially conflicting responses.

MTAA strongly proposes that confidentiality concerns be dealt with as part of the process changes. These concerns might be accommodated in one of two ways. The first is to release a public summary document rather than the full protocol. Where a protocol uses company-developed economic modeling, the model should not be freely available for manipulation.

The alternative to a public summary document is to obtain comment from informed, relevant stakeholders through a more selective exposure to the relevant clinical craft group and health consumers. If further input is felt to be essential, a notice could be posted on the MSAC website advising that the draft protocol is available for review and then giving access to the protocol to those parties prepared to sign a confidentiality agreement.

Once a draft protocol is released for public exposure, it is not clear how public comments will be reviewed and consolidated. Responses may reflect a variety of competing interests – between therapies, craft groups, commercial competitors. This issue is not addressed in the discussion paper. One solution would be for the Department to develop guidelines for comments on draft protocols/public summary documents.

MTAA suggests that the outcome of the public exposure should be communicated to the applicant, again in the interests of transparency of process. Further, there should be an opportunity for a face-to-face dialogue at this point in the process if the consultation raises issues which may be detrimental to an assessment of the submission which follows.

#### **4.4 Assessment**

MTAA proposes that all available evidence be considered in assessing an application. It will depend on the type of technology as to what evidence is available. Where clinical practice is the same in Australia as in other countries, then clinical evidence generated in those countries should be accepted without the need for Australian-specific evidence. As MTAA argued in its submission to the HTA Review, there is benefit in international harmonization of clinical evaluation requirements and outcomes. In contrast, the economic modeling is contextualised for Australia.

The evidence required must be fit for purpose so that the range of evidence reflects the level of risk, both safety and clinical.

#### **4.5 Evaluation**

MTAA acknowledges that an application may trigger a review of an existing comparator. However the focus should be on any negative evidence that results from an application. Any decision on disinvestment should be based on an assessment of evidence equivalent to that provided in the submission for the new procedure.

If the existing comparator is a direct comparator then it is not a straightforward matter of removal of the existing item number or procedure. There are implications which may not be immediately apparent, such as the need to educate clinicians on the replacement technology, identification of the locations where the procedure is performed (which may lend themselves to continued use of the comparator procedure). In other words, an item number should not be automatically removed from funding unless it has been shown to be unsafe as a result of the evidence supporting the application.

From time to time there may be circumstances where new evidence is expected to emerge during the evaluation phase. While this is not likely to be a regular event, an applicant needs to flag the possibility in its application and there should be recognition of the opportunity to do so as part of the assessment procedures. It is

more likely that additional data may be needed to fill in gaps identified during assessment, for example, identification of a patient population.

MTAA proposes that an applicant have the right to withdraw its submission at this point in the process. For example, there may be circumstances where additional evidence is sought but which the company is unable to provide. If the submission is made public without the company addressing a deficiency in the evidence, and the application is subsequently rejected, there is a commercial risk to the applicant which can be avoided through withdrawal.

#### **4.6 MSAC appraisal**

As discussed in paragraph 4.2, MTAA is concerned that the proposed MSAC processes might not adequately differentiate between policy impacts (including budgetary implications) and appraisal of the technology and procedure. If policy barriers are applied too early in the process it may mean that a beneficial technology is rejected before it has been assessed.

This approach is consistent with the views expressed by MTAA in its submission to the HTA Review. Assessment looks at the value of the technology, including its cost effectiveness and clinical effectiveness. Appraisal goes to the decision as to whether there is capacity within the healthcare budget to fund the procedure. These are separate and distinct issues. To illustrate the point, if bariatric surgery did not have a procedure item number, an application for listing may be rejected because of the potential budgetary impact based on potential population demand. This is a separate consideration from an assessment of the benefits of the procedure for specified population groups. Both the Pharmaceutical Benefits Advisory Committee (PBAC) and National Institute for Health and Clinical Excellence in the United Kingdom make a clear distinction between assessment of a potentially cost-effective technology and the capacity to fund it.

In a similar vein to the concerns about commercial-in-confidence material discussed in paragraph 4.3, MTAA has concerns about the scope of the information which is to be made public following appraisal by MSAC. It is not clear from the discussion paper whether commercial-in-confidence material would be extracted or whether the applicant has an opportunity to review the information proposed to be made public.

#### **4.7 MSAC advice to Minister**

As previously argued in this response to the discussion paper, MTAA supports the differentiation of a decision made on the grounds that a procedure is not supported by health technology assessment of clinical and cost effectiveness, from a decision based on the capacity of the Commonwealth to fund a new procedure. MTAA strongly supports a process which facilitates this differentiation, making it clear that the decision is based on affordability, not evidence.

#### **4.8 Changes to MSAC subcommittees**

MTAA has previously advocated the need for an industry representative on MSAC and repeats this call. Concerns about conflicts of interest are understood but these can be addressed as they have been in the establishment of the Prostheses List Advisory Committee.

## **5. Areas for further development**

### **5.1 'Fit for purpose' submissions**

The discussion paper does not distinguish between the evidence requirements for a minor submission, which may be no more than a slight variation to coverage of an existing item number, and a major submission for a new procedure using a novel technology. MTAA suggests that the process be fit for purpose as identified in the report of the HTA Review, with acceptance of a reduced submission where this will suffice. It should be sufficient for an applicant to establish that the subsequent application is equivalent to an earlier submission without the need to produce additional evidence.

### **5.2 Coverage with evidence development**

In the case of a procedure that involves new technology, there is often a timing problem created by the on-going development and refinement of the technology. Unlike a pharmaceutical that enters the market as a finished product, technology continues to evolve once in the market based on feedback from the medical practitioners and patients, resulting in newer and incrementally better versions. A clinical trial based on the first version will often generate less than optimal results. However, a delay in carrying out the clinical trial and the resulting delay in funding reduces the financial viability of the product.

Clinical trials with statistically significant outcomes in many instances are simply not feasible, especially where the change to predicate technology is incremental. Unlike pharmaceuticals, where the potential market is often measured in tens of millions of dollars per annum, the market for technology is far smaller. This limits the affordability of clinical trials covering procedures.

There needs to be a clear process and facility for negotiating coverage with evidence development (CED) within the framework of MSAC processes. CED can act as a bridge between available and desired evidence to allow earlier market access. It should be structured to enable a range of types of data generation strategies and designs beyond randomised controlled trials (RCTs) as RCTs are often impractical or unsuitable for post market introduction research. The end point for the evidence development must be well understood by MSAC and the applicant and agreed upfront.

The discussion paper touches on interim funding arrangements but further guidelines are required.

### **5.3 Review mechanisms for adverse decisions**

As with other health technology assessment processes reviewed as a result of the HTA Review, the Department has yet to publish its approach to review of adverse decisions. MTAA supports recommendation 5 of the report of the HTA Review, to improve procedural fairness and consistency of Commonwealth HTA processes by establishing independent review mechanisms and opportunities for re-submissions in a consistent manner. This gap in HTA processes must be addressed as a priority.

#### **5.4 Review of existing MBS codes**

MTAA supports the Quality Framework Review currently underway with its bottom up review of item numbers and coverage. However, as with the use of new evidence as a tool to drive disinvestment in a comparator procedure and technology discussed in paragraph 4.5, the review needs to ensure that there are no unintended consequences. MTAA acknowledges the complexity of the review process and is willing to work with the Department to ensure that the Government's objectives are achieved.

#### **5.5 Co-dependent and hybrid technologies**

The discussion paper makes no specific allowance for the expanded processes required for assessment of co-dependent and hybrid technologies. While the Government has accepted the recommendation of the HTA Review to establish a single entry point, the process for assessment of these technologies needs to be established and publicised so that an applicant can ensure that it understands and prepares for the assessment pathway.

#### **5.6 Capacity building in secretariat staff**

MTAA is supportive of efforts to build capacity and capability within the MSAC secretariat. This is not a reflection on current staff but is mindful of the significant technological challenges which are likely to be presented by medical technology products in the future. Medical technologies are highly innovative with increasing complexity and variety.

Ideally, over time, the capability within the MSAC secretariat will develop to the point where there is less reliance on external contractors. MTAA looks to the PBAC model as a good example of in-house specialist capability.

It is evident that the considerable increase in the work of the MSAC secretariat through the increase in the number of submissions and responsibility for the quality framework review, will impact on the capacity of the secretariat to undertake all that is required to ensure that timelines are met. MTAA supports funding of MSAC activities on an activity-based model, supported by an expansion of available resources to meet changing needs.