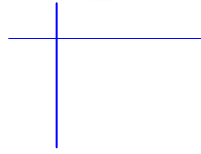




Medical Technology  
Association of Australia



NHHRC Terms of Reference  
NHHRC Draft Principles for Australia's Health System

Submission by  
Medical Technology Association of Australia

May 2008

Medical Technology for a Healthier Australia

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## 1. Summary of the submission

The Medical Technology Association of Australia (MTAA, formerly Medical Industry Association of Australia) 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.

The development of medical technology is often iterative and rapid. The average life cycle of a medical technology product is 18 months (although many complex technologies may take much longer). As a result systems which support speed to market are as critical to the survival and success of the industry as they are to the capacity to make new technologies available to patients who need them.

MTAA has addressed two areas only in its submission:

- The Term of Reference looking at a long-term health reform plan to reduce inefficiencies generated by cost-shifting, blame-shifting and buck-passing; and
- The Draft Principles for Australia's Health System that deal with design principles and governance principles.

The submission is directed to the need to undertake a fundamental review of the role of medical technology in the healthcare system, in particular the need to ensure equity of access to medical technology by patients. The system that currently regulates and funds medical technology (to the extent that there is any funding) is out of date, poorly-designed and not sufficiently flexible to keep pace with the rapid development in medical technologies.

The system needs to better value the benefits and potential cost-savings to the healthcare system which are provided by medical technologies. At present there is an ill-equipped mechanism to identify and value these benefits. Medical technology is very much subject to the cost-shifting and silo-ed structure of the healthcare system. Medical technologies frequently are not readily accessible, or accessible without subsidy and at a cost to the patient, or available only after considerable, lengthy and linear processes for regulation, evaluation and assessment for reimbursement. These processes are unnecessarily time-consuming and often lacking in transparency. There is no clear framework and very little evidence base to funding decisions.

MTAA proposes a revision of the current system for evaluation and funding of medical technologies. MTAA outlines a structure which establishes a High Technology List for complex medical technologies and an Essential Care List for less complex but nonetheless essential technologies that many patients need to access for their ongoing care. While both concepts require further development and discussion, they offer a transparent process, supported by an evidence base, that is sufficiently flexible to meet the evolving nature of medical technology and patient needs.

MTAA asserts that the healthcare system as presently structured results in healthcare decisions being made on the basis of cost-shifting to another entity, for example, a hospital in the case of illness arising from failure to invest in early

diagnosis, or the Pharmaceutical Benefit Scheme where a reimbursed and publicly-funded drug may be available as an expensive alternative to the application of a medical technology which is unfunded and therefore at cost to a patient.

For the medical technology sector of the health system reform is long overdue and desperately needed. We need to take a fresh look at the interface between medical technologies and the healthcare system and the assessment of, access to, and funding for, medical technologies.

Medical technologies are evolving rapidly. We need a system that is robust, flexible, speedy but conscious of safety and efficacy issues, and above all, able to provide positive patient outcomes cost-effectively.

MTAA seeks the opportunity to expand on the submission and invites further investigation by the NHHRC on the issues raised in the submission.

## **2. About the Medical Technology Association of Australia and the Medical Technology Industry**

The Medical Technology Association of Australia (MTAA, formerly Medical Industry Association of Australia) 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 items such as bandages and syringes, to high technology items such as orthopaedic implants and cardiac defibrillators, pacemakers and diagnostic tools.

The medical technology industry in Australia has an annual turnover of \$4.75 billion (2006/2007) and earns an export income of \$1.75 billion (2006/2007). It is characterised by a small number of global multinational companies (approximately 20% of the industry) and a large number of small and medium sized enterprises (80% of the industry). The Australian market is small - less than 2% of the global market for medical technologies.

Medical technology development has been characterised as a continuous, iterative process. This iterative and ongoing development process, characterised by constant product changes made in response to user needs and preferences distinguishes medical technology innovation from other therapeutic products. The life cycle of an average medical device is about 18 months, after which the device is replaced by newer technology. Medical devices are also less likely to benefit from extended patent protection. For these reasons, systems which support speed to market are as critical to the survival and success of the industry as they are to the capacity to make new technologies available to patients who need them.

## **3. NHHRC Terms of Reference - A long-term health reform plan to reduce inefficiencies generated by cost-shifting, blame-shifting and buck-passing**

### **3.1 Overview**

Of all the Terms of Reference, the first is the one which most impacts medical technology. Medical technology is assessed and funded through a multiplicity of sources, and in many critical areas not funded at all, to the detriment of patients. Some of the reasons for this haphazard arrangement may be attributable to the fact

that medical technology is a more recent participant in the healthcare system, and less clearly identified within the healthcare framework. For many years medical technologies were regulated in Australia as pharmaceuticals (and in fact still are in many emerging economies). With no overarching framework for policy development, decisions on medical technology often appear random and without an evidence-based foundation.

The result is that the treatment of medical technology in our healthcare system is somewhat akin to the first home built by a new family. There is the core house, built with meagre funds, to which various additions have been made over the years, sometimes well-furbished when economic circumstances permitted, and at other times a tacked-on lean-to has had to suffice when funds were scarce. As a result the house is somewhat unstable, certainly outgrown and in need of an extensive overhaul.

The NHHRC's review of Australia's healthcare system provides the first substantive opportunity to address the inequities of access and cost-shifting that are inherent in the funding of medical technologies. MTAA had anticipated the long-awaited review of Health Technology Assessment but with no announcement of timing, welcomes the opportunity to contribute some initial thoughts on a framework for more equitable access to medical technology.

As a starting point, MTAA supports the development of a national Medical Technology Policy along the lines of the National Medicines Policy. The National Medicines Policy has four supporting pillars:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford
- medicines meeting appropriate standards of quality, safety and efficacy
- quality use of medicines
- maintaining a responsible and viable medicines industry.

Each of these supporting pillars is equally relevant for the medical technology sector of the healthcare system and provides a framework for the development of relevant policies. The framework can be used to measure policy development against one or more of the pillars as relevant.

MTAA also advocates the adoption of a system that supports the Medical Technology Policy by providing:

- a streamlined process for the registration, assessment and reimbursement of new medical technologies
- a regulatory process that is aligned or at least harmonised globally so that Australian companies are not disadvantaged by the imposition of additional burdens
- a transparent process so that requirements are clearly understood and articulated and applied in a uniform manner across all areas of registration, assessment and reimbursement
- an accountable funding process that is open to review; and
- evidence-based decision-making for funding arrangements for medical technologies.

### 3.2 High Technology List

The current processes for registration, assessment and reimbursement do not take account uniformly of the differences in complexities of medical technologies. MTAA suggests that there be a dual process to enable more effective use of time and resources. Low risk items should be registered, relying on prior registrations overseas where the product is not Australian, and if Australian, with no additional barriers to registration.

In general the low risk products are not reimbursable, with the exception of the products that fall within the scope of the Essential Care List discussed at paragraph 3.3.

Higher risk products should be reviewed once for multiple purposes - regulatory and reimbursement. MTAA proposes the establishment of a High Technology List to redefine the Prostheses List and to include all high cost items of medical technology. The Prostheses List has not kept pace with innovation in medical technology. At present items are reimbursable if they are a 'prosthesis' and listed on the Prostheses List. However there are some technologies on the List that many would not consider to be prostheses, and many other technologies that should be considered for reimbursement that are not reimbursed because they are not prostheses.

As a result treatment decisions are being driven by whether or not a particular therapy is reimbursed, rather than by a decision based on the most appropriate procedure. An example of this is radio frequency ablation which is not reimbursed because it is not a prosthesis. Alternative treatment is a pharmaceutical treatment which is expensive but which is reimbursed under the Pharmaceutical Benefits Scheme.

An option is to list all high technology items on the High Technology List, using the safety and efficacy assessments undertaken by the Therapeutic Goods Administration in the regulatory process as the basis for determining appropriateness for listing. The only additional procedure that needs to be undertaken is the cost-effectiveness assessment for setting an appropriate reimbursement level. MTAA proposes that once the product is approved, and the reimbursement determined, no further assessment is required<sup>1</sup>. Once the product is listed there is an automatic MBS number allocated with a fee to the doctor for the associated procedure.

Publicly-funded reimbursement of items on the High Technology List might be off-set by a re-examination of the level of private health insurance rebate. It is MTAA's view that there should be no barriers to access critical medical technologies on the basis of affordability. The test should be cost-effectiveness of the product within the framework of the healthcare system, with equity of access, regardless of public or private status, a fundamental principle.

In the diagnostics sector there is a greater disincentive to the take up of newer technologies because of the way in which reimbursement operates. Perversely, in a sector where the application of cutting edge technologies can deliver wide-ranging benefits to the healthcare system through earlier diagnosis of disease, there is a

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<sup>1</sup> This proposal is consistent with recommendations 10b and 10c of the Doyle Report. Doyle, Robert *Report of the Review of the Prostheses Listing Arrangements*, October 2007

disincentive for pathologists to adopt newer technologies because the additional cost reduces the profit available to the pathologist.

Without compromising the safety of the Australian public benefiting from the use of medical technology, Australia is in an excellent position to take greater advantage of regulatory approval processes undertaken by its international regulatory partners so that the emphasis of the regulatory resources in Australia can be changed to one of a structured post-market review process.

### **3.3 Essential Care List**

There is a wide range of medical technology items that come within the definition of 'essential care items', necessary for the care, well-being or, in some cases, survival, of patients. Many of these items can provide cost saving treatments for chronic conditions but their purchase is generally beyond the capacity of many Australians to afford over long periods of time. Some of these items receive reimbursement or subsidy from the Federal Government, some from the State Governments, and some receive no reimbursement at all. In some cases the level of reimbursement or subsidy depends on the State in which the patient is living.

MTAA proposes the establishment of an Essential Care List that would operate in a similar manner to the PBS scheme for pharmaceuticals for a range of products that come within acceptable parameters of essential care. A qualifying criterion is that there be a form of healthcare professional intervention to determine the patient need before a prescription is issued. In other words items listed on the Essential Care List are not provided to consumers without appropriate validation of their clinical needs. Examples include modern wound care devices, insulin pumps, continence products and stoma products.

The structure of an appropriate scheme requires further consideration and consultation. However the underlying aim is to address current inconsistencies in access to and availability of funding arrangements for a range of medical technology items essential to the well-being of patients with a wide range of conditions.

## **4. Draft Principles for Australia's Health System**

### **4.1 Overview**

MTAA supports the proposed design principles and governance principles outlined in the Draft Principles for Australia's Health System. In particular we support the principles that the health system be **comprehensive** and **value for money**. The health system has to be sufficiently flexible to admit new technologies that provide support to particular patients.

Companies in the medical technology sector of the healthcare system have had significant experience working in a system that has often lacked appropriate governance (and indeed continues to fail to meet the governance principles outlined in the Draft Principles for Australia's Health System).

### **4.2 Design Principles**

MTAA recognises that the health system has to be sustainable in the long term and therefore the adoption of medical technologies has to provide value for money. Value for money can be measured in many ways. MTAA argues that there is a

tendency in the current system to take a short term solution to treatment, or a solution driven by the most available subsidy, rather than to look at the long-term cost of a patient or a disease state to the health system. An example is where a diagnostic product is considered expensive because it will be used too frequently by a doctor as an aid to identifying relevant treatment. The alternative is undiagnosed disease or disability which may preclude or delay a patient from returning to productive working life or include long term hospitalisation.

False economies might also be presented by the deferral or refusal to provide a subsidised medical technology which similarly would have the outcome that a patient is unable to return quickly to a productive working life, is kept in hospital longer than necessary because alternative treatment was not provided early enough, or worse, the overall health of a patient deteriorates because the patient does not have subsidised access to a medical technology.

Recent material published by the Advanced Medical Technology Association (AdvaMed) in the United States<sup>2</sup> provides compelling evidence for the cost-savings that can be attributable to medical technology. These include:

- A recent study which found that testing all hospitalised patients in 2005 for drug-resistant infections would have saved US\$8.3 billion
- Medical imaging to diagnose and treat stroke leads to better outcomes, shorter hospital stays, and nearly US\$800 million per year in savings
- Total knee replacements save an average of US\$77,000 per patient in lifetime healthcare costs.

In Australia, the Productivity Commission<sup>3</sup> in its major research paper on the impacts of advances in medical technology, noted that:

- “Hypothetical assumptions using reasonable assumptions about the value of additional life expectancy and improved quality of life, and the contributions in medical technology to these observed improvements, suggest that the benefits of technological advances to the Australian community have outweighed the costs”<sup>4</sup>
- “Advances in prostheses enabling minimally invasive surgery and the use of computer assisted surgery may also reduce the length of hospital stay. These advances may also deliver benefits in the form of reduced care requirements and a lower need for revision surgery”<sup>5</sup>.

The timely provision of medical treatments to patients in need should also be considered for inclusion in the design principles. Access to new medical technology can be delayed by sequential processes of regulatory approval, procedure reimbursement, and in some cases, device reimbursement. Patients in need of life-saving procedures can have access delayed to new treatments by the regulatory approval process through the Therapeutic Goods Administration; a procedure reimbursement process through the Medical Services Advisory Committee (which the

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<sup>2</sup> Ubl, Stephen, *Industry View: Medtech myths must be dispelled*, Clinica Issue 1305 May 9 2008, page 9

<sup>3</sup> Research Report, *Impacts of Advances in Medical Technology in Australia*, 31 August 2005

<sup>4</sup> Ibid page XLIV

<sup>5</sup> Ibid page 401

Productivity Commission noted takes on average 13 months); and a six month period through the Prostheses List process. Whether for a public patient seeking elective surgery or a private patient waiting for reimbursement approvals, timely access to medical treatment and technology should be considered an integral principle.

### **4.3 Governance principles**

MTAA strongly supports the Governance Principles and as an organisation is committed to working within a comparable governance framework. MTAA has developed a self-regulatory industry Code of Practice that requires industry to work with integrity with healthcare providers in the healthcare system.

However industry members have experienced many failures of governance in the health system in the assessment and funding processes for medical technologies and at times have had their confidence tested that the system can be reformed to ensure integrity of behaviour, transparency of dealings, and accountability for decisions. In many areas of decision-making involving medical technologies, companies are left uninformed about the process, or the reason for decision.

In the Doyle Report, Robert Doyle noted in his covering letter that "...it is already clear that some elements of the current arrangements are unsustainable or inefficient." Mr Doyle reflects variously on the need to remove any real or apparent disadvantage private patients may have in access to the latest technology<sup>6</sup>; mentions his concern at a listing process that "...is being used to second guess the TGA process..."<sup>7</sup>; observes the Australian propensity to require trial data which may not be required in other jurisdictions and notes there is a difference between "world's best practice" and "world's first practice"<sup>8</sup>.

There are many examples that MTAA can provide where the lack of transparency has not only disadvantaged the industry sponsor for a medical technology product but also the intended beneficiary, the patient.

## **5. Conclusion**

MTAA welcomes the work being undertaken by the NHHRC. For the medical technology sector of the health system reform is long overdue and desperately needed. We need to take a fresh look at the interface between medical technologies and the healthcare system and the assessment of, access to, and funding for, medical technologies.

Medical technologies are evolving rapidly. We need a system that is robust, flexible, speedy but conscious of safety and efficacy issues, and above all, able to provide positive patient outcomes cost-effectively. MTAA looks forward to working further with the NHHRC as it develops its policies and strongly urges the Commission to include structural and systemic review of medical technology and its role within the healthcare system as part of its policy work.

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<sup>6</sup> Doyle Report, supra, page 15

<sup>7</sup> Ibid page 16

<sup>8</sup> Ibid page 23