Medical Technology
Association of Australia

Productivity Commission

# Annual Review of Regulatory Burdens on Business
*Manufacturing & Distributive Trades*

Submission by
Medical Technology Association of Australia

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## 1. 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 and pacemakers.

The medical technology industry in Australia has an annual turnover of $4.75 billion and earns an export income of $1.75 billion (in 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.

## 2. Previous submissions

MTAA confirms the positions which it put to the Productivity Commission in previous submissions, in particular those contained in:

- *Impacts of Advances in Medical Technology in Australia*, Research Report 2005

- *Rethinking Regulation, Report of the Taskforce on Reducing Regulatory Burdens on Business,* 2006.

If anything the position has worsened since the previous submissions in several aspects:

- Regulatory burdens identified in previous submissions have not been addressed and with the demise (or at least indefinite suspension) of the proposed ANZTPA regulatory reforms, there is no clear timeframe within which much needed regulatory reform will be introduced. MTAA specifically restates the need for reform of conformity assessment processes to address timeliness, cost and sustainability implications for Australian manufacturers

- Timeframes have extended for the processing of applications for registration of higher risk devices as a result of the backlog arising from the surge of products transitioning to meet the cut-off date under the regulatory changes introduced in 2002 which required the transition of product registrations to be

completed by 4 October 2007. As a result there is a significant backlog in products awaiting conformity assessment (both new products caught up in the backlog) and transitioning products (which require conformity assessment because of the change in regulatory requirements)

- Reimbursement processes have not improved despite the recommendations from the statutory review delivered by Robert Doyle in October 2007. MTAA has provided its detailed submission to the Doyle Review to the Productivity Commission by way of elaboration

- Assessment of new medical procedures, involving medical devices, by the Medical Services Advisory Committee (MSAC) continues to lack transparency and a sense of urgency. Improvements that might have resulted from MSAC's review of itself have not eventuated

- There continues to be a lengthy, sequential pathway to bring medical technology to the patient through mandatory regulatory requirements, procedural review by MSAC, and reimbursement examination for the Prostheses List. A well-defined, coordinated, transparent, consistent process understood by industry, regulators and other decision-makers at State and Federal level would streamline the introduction of medical technology without compromising patient safety. This would overcome the burden of providing similar confirmatory clinical trial and investigation information, for example, to different government agencies due to a lack of coordination and understanding.

The Medical Device Industry Action Agenda provided a focus on the industry's issues, including the need to implement the reforms previously identified by the Productivity Commission (such as the need for a review of Health Technology Assessment). The current government has cancelled the Action Agenda in favour of a review of the innovation process in Australia, and establishment of innovation centres. It is not yet known where the biomedical and medical technology industries fit within this revised agenda.

A tangible loss arising from the cancellation of the MDIAA is the outcome of surveys and assessments of skills and resource audits vital to the development of the industry.

# 3. New directions for reform

## 3.1 Introduction

Absent the opportunity to argue for a new paradigm for review and funding of technologies through a review of health technology assessment, MTAA proposes some options which might address some of the impediments to more rapid adoption and equitable reimbursement of medical technologies for the benefit of Australia's healthcare system.

## 3.2 Policy framework

A sustainable Australian industry will be best supported by the establishment of an underpinning framework that recognises not only the need for safe and effectively regulated medical technology products but also the need for a viable and sustainable industry.

MTAA supports the development of a national framework along the lines of the National Medicines Policy which 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.

MTAA supports a system that enables:

- a streamlined process for the registration, assessment and reimbursement of new technologies
- a 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
- an accountable process that is open to review in the event that an element of the process has been applied incorrectly
- cost-effective adoption of new medical technologies within the healthcare system.

### 3.3 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 3.4.

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

Without compromising the safety to 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.

### 3.4 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. 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.

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. Conclusions

Notwithstanding the positive recommendations in earlier work by the Productivity Commission and more recent reviews such as the Doyle Review, the medical technology industry has seen little progress in structural reform of the processes to which the industry is subject and which act as barriers to the development of a strong

and effective industry in Australia supporting the needs of Australia's healthcare system and Australian patients.

If anything MTAA has seen additional impositions on industry to the disadvantage of both industry and the healthcare system as a result of failures to restructure and address the inconsistencies and inequities in access to medical technologies.

MTAA strongly supports a review of health technology assessment as an opportunity to review the multiple and overlapping processes to which medical technology products are subject. MTAA reiterates its support for a system that puts patient safety first but also calls for a national framework that will provide context to the policy decisions impacting the industry.