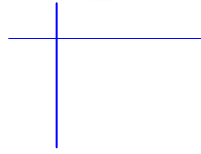




Medical Technology
Association of Australia



Review of the National Innovation System

Submission by
Medical Technology Association of Australia

April 2008

Medical Technology for a Healthier Australia

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, 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.

2. Overview of the submission

There are two primary elements in this submission in considering innovation in the medical technology sector - current impediments to innovation and opportunities for a fresh approach to innovation. MTAA does not address tax incentives or other financial incentives to innovation. These will no doubt be addressed by many other submissions. MTAA is strongly of the view that the removal of unnecessary structural impediments will enable industry to function more efficiently. This action will address many of the financial issues faced by companies in the medical technology sector where the systemic impediments act as the greatest disincentive to the development of an indigenous innovative industry.

3. Impediments to innovation in the medical technology industry

3.1 Overview

The structure of the medical technology industry is unusual. Most of the medical technology used in Australia is imported. Almost 100% of the medical technology manufactured in Australia is exported. There are obvious challenges for the indigenous industry - to enable import replacement, to enhance export opportunities (critical to success given the small size of the Australian market globally at 2%), and to achieve sustainability.

As presently structured there are multiple barriers to achieving these aims. The Productivity Commission produced a Research Report in 2005, *Impacts of Advances in Medical Technology in Australia*, which highlighted many of the structural barriers faced by the medical technology industry. Despite the subsequent Report by the Productivity Commission on *Rethinking Regulation, Report of the Taskforce on Reducing Regulatory Burdens on Business*, 2006, these barriers have not been removed. Indeed, if anything the barriers have grown since the publication of these reports.

3.2 Policy framework

A sustainable and innovative 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 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.

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 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 Regulatory barriers to innovation

Australian manufacturers are doubly-disadvantaged by the current system of therapeutic product regulation. Other than for the lowest risk class of medical devices, a medical device manufactured in Australia must have conformity assessment certification issued by the Therapeutic Goods Administration (TGA) if the product is supplied in Australia. The commercial realities of overseas medical technology markets also necessitate those Australian manufacturers to seek similar, yet more widely accepted, certification from European Notified Bodies or by the Food and Drug Administration (FDA) in the United States. A European CE mark is recognised beyond the borders of the EU, including Australia for imported goods. However, a reciprocal recognition for Australian manufactured devices having TGA conformity assessment certification has not been achieved.

A more open acceptance by the TGA of third party conformity assessment would be of immediate assistance to product development, commercialisation and export of Australian-manufactured medical technologies. Further, as a TGA approval has no recognition within many Asia Pacific regulated countries, the recognition of a TGA approval by these countries should be pursued as a matter of urgency. This will then be seen as tangible support for the manufacturing base of Australian medical technology industry. Countries such as Japan, India, Korea and China do not recognise Australian certification.

Countries such as Taiwan have agreements with the EU and US regulators that allow recognition of their approvals and provide their goods with rapid market entry. Australian policy does not allow the TGA to have a similar agreement if EU CE certification has not been issued, so once again TGA conformity assessment certification is required to supply those products within Australia. This also applies to products approved by the US FDA that do not have CE certification.

Case study - Sirtex Medical Limited

Sirtex Medical Limited (SRX) was established in 1997. The company focuses on innovative, targeted, tailored oncology treatments. Research on its core product, selective internal radiation treatment (SIRT) with SIR-Spheres¹® microspheres for the treatment of inoperable liver cancer, has its origins in the 1980s and the product commenced use in the early 1990s under the Authorised User Access Scheme. It was listed on the Australian Register of Therapeutic Goods (ARTG) in 1998. SIR-Spheres microspheres were approved by the FDA in March 2002 and received a CE Mark in October 2002.

SRX exports SIR-Spheres microspheres into Asia, Europe, the Middle East and North America. The existing MRA with the EU excludes radioactive products, so there is no pathway to reduce the auditing and regulatory burden by allowing the TGA to allocate a CE Mark.

MTAA supports the revision of the Medical Devices Sectoral Annex of the EU-Australian MRA by including radioactive medical devices which would overcome this regulatory anomaly.

The additional time taken to obtain conformity assessment certification means that companies bringing a medical technology to market in Australia are significantly disadvantaged by the extended time and cost involved in the double-handling by the foreign regulator and the additional review by the Australian regulator. The medical technology industry accepts that while the TGA might question the certification procedures of some third party conformity assessment bodies, the MTAA argues that there must be sufficient assessment bodies globally that TGA could approve and certify as equivalent in standard, to permit assessments undertaken by those bodies without further review prior to supply in Australia. This argument can be made out even more strongly when looking at a unique complex medical technology where there may not be the requisite experience within the Australian regulator to undertake the review.

¹ ® SIR-Spheres is a registered trademark of Sirtex SIR-Spheres Pty Ltd

Case study - Ventracor Limited

Ventracor is a global medical device company, founded in Australia, which manufactures an implantable blood pump, the VentrAssist[®] left ventricular assist device (LVAD). The VentrAssist is a new third generation implantable blood pump primarily designed for people with heart failure and for whom heart transplantation is not an option. It may also be used for patients waiting for heart transplant as a bridge to transplant or as a bridge to recovery.

VentrAssist has a CE Mark, FDA approval for Destination Therapy Trial and for Bridge to Transplant Trial. In Australia the product is included on the ARTG. Ventracor was required to obtain conformity assessment certification in both Europe and Australia which required additional time and effort, resulting in significantly greater financial outlays in meeting the duplicated regulatory requirements.

The acceptance of third party conformity assessment certification by the TGA and/or the recognition of TGA regulatory approval by Australia's GHTF partners would overcome this regulatory inadequacy.

In circumstances where a medical technology is custom-made to meet the needs and specifications of an individual patient, the product is not listed on the ARTG but approved on a case-by-case basis under the TGA's Special Access Scheme.

Case study- Cook Australia

Cook Australia is a part of the global private US company Cook Medical. Cook Medical was established in the US in 1963, commenced operations in Melbourne in 1974 before moving to Brisbane in 1989. Cook's product range covers: women's health (assisted reproduction, IVF); diagnostic and interventional radiology; aortic intervention (endovascular stent grafting); endoscopy; urology; critical care and general surgery. Cook has over 15,000 product lines globally. Cook Australia also has a research facility in Perth which develops devices to fill unmet endovascular aortic repair (EOR) needs.

Cook Australia has a multi-function facility at Brisbane Technology Park which includes the manufacturing of endovascular stent grafts. The Brisbane manufacturing site is one of five of Cook Medical's global capability.

As part of Cook Medical's global manufacturing capability, Cook Australia is obliged to gain ARTG listing before exporting to over 50 countries world-wide. Cook must then obtain local regulatory approval in most international jurisdictions where ARTG listing is unable to deliver accreditation. Cook Australia would benefit from an Australian regime which was more effectively recognised and which permitted third party conformity assessment.

Case study - Global Manufacturing Technology Pty Ltd

GMT is the manufacturing arm of the Global Group of Companies (Global). Global is a wholly Australian owned and operated medical device manufacturer and distributor specialising in orthopaedic and spinal products. GMT has a TGA Certified facility located in Wollongong, NSW which was commissioned in March 2004 and

manufactures the Global range of knee products as well as its primary hip prosthesis. Global claims to be the largest orthopaedic device manufacturer in Australia.

Global has exported several knee products to the USA, New Zealand, Russia, Turkey, Italy, Azerbaijan and Columbia. Conformity assessment certification issued by the TGA in Australia has not obviated the need for further conformity assessment certification in other jurisdictions. In contrast a CE mark obtained through the EU is recognised beyond its borders by a number of countries, including Australia, but not in respect to Australian manufactured devices which must require TGA conformity assessment certification before local use.

3.4 Reimbursement barriers to innovation

There are multiple components to the reimbursement process within Australia's healthcare system. In summary these are:

- the approval process for new medical technologies involved in a medical procedure which requires the allocation of a Medicare Benefits Schedule (MBS) number through processes involving the Medical Services Advisory Committee (MSAC)
- the application process for reimbursement of high technology implantable prostheses by private health insurance funds managed by the Prostheses and Devices Committee (PDC)
- the allocation of funding by MBS for pathology testing under the 5 year pathology agreements which cap payments to pathologists providing diagnostic services
- the provision of medical technologies by public hospitals through the State-funded public health system
- the 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.

The complexity, lack of transparency, and dysfunctional structure of reimbursement of medical technologies means that 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 for the best patient outcome.

Case study - Sirtex Medical Limited

SRX has manufactured SIR-Spheres microspheres locally since the early 1990s. The delay from ARTG listing in 1998 to allocation of an MBS procedure number and Prostheses List reimbursement in 2005 has adversely affected full commercialisation of SIR-Spheres microspheres.

Application was first made in 2000 to MSAC for MBS reimbursement of the procedure but this was rejected in early 2003. A subsequent application submitted in

early 2004 was given provisional approval in 2005 with the requirement to demonstrate clinical effectiveness by 2011. Allocation of a MBS procedure number cleared the way for listing on the Prostheses List in 2005, however SIR-Spheres microspheres plus delivery apparatus was listed with a minimum benefit of \$7,650 and a maximum benefit of \$8,014, meaning that a co-payment of \$364 per patient treatment has been and is currently required.

SRX as an emerging medical technology business has been unable to forego collection of the patient co-payment since its first listing – public and private pricing is the same. Although the publicly-stated intention is that the Prostheses List contain at least one no-gap item per MBS number, this has not been the case for MBS procedure numbers 35404 and 35406 using SIR-Spheres microspheres.

A product that is created to the custom requirements of a patient is unable to receive reimbursement, even if it is an implantable prosthesis, through the Prostheses List process because the item is not included on the ARTG, a pre-requisite to reimbursement.

Case study - Cook Australia

Although endovascular stent grafts are surgically implanted prostheses, they cannot be reimbursed through the Prostheses List because the items are not included on the ARTG, a pre-requisite. Cook liaises on occurrence with health funds for reimbursement through ex-gratia payments but such payments are not guaranteed from all funds and the process is time intensive and not reliable. Cook Australia believes that procedures to allow the inclusion of custom made devices on the ARTG would significantly underpin their local manufacturing capability.

The unpredictability and subjectivity of price negotiations by the negotiators within the Prostheses List reimbursement process has resulted in many companies facing financial uncertainty and reluctant to make long-term investments in further innovation in Australia.

As the majority of orthopaedic surgery in Australia is performed in private hospitals,² inclusion on the Prostheses List at an acceptable reimbursement level is fundamental to effective commercialisation of newly developed medical technology. Furthermore, differing clinical requirements for listing on the Prostheses List compared with that required by the TGA for ARTG listing can lead to a situation where a device may be eligible for use in the public sector but not reimbursed in the private sector.

Case study - Global Medical Manufacturing Technology Pty Ltd

Global's primary focus has been on import replacement within the Australian market and it has manufactured a number of strongly selling and competitive products. A new product line, the Global Apex Modular Hip System, was released on the market in 2005 and performed well with year to year growth in sales in excess of 45%.

Before December 2006, Global had been in various stages of development of an acetabular cup system, a minimally invasive fixed bearing primary knee, a revision

² APHA 2007 Data show that 77% of knee surgery, 64% of spinal and 55% of hip surgery are performed in private hospitals – see http://www.apha.org.au/media_files/2375386209.html

hip system, a minimally invasive primary hip system, a temporary hip spacer for infected hips and a dynamic stabilization device for spinal surgery. The company also had a number of research projects underway looking at implant coating systems and ceramic material technologies.

In November 2006 Global received price offers from negotiators representing the PDC for their locally manufactured hip system which reflected reductions in price of 32.1% in one case, 55.4% in another and 27.7% in another. In aggregate, the price reduction offered for the system as a whole was in the order of 40.1%. As a result of the business uncertainty generated by these reductions, Global finalised development of several products close to completion, but cancelled all other projects. It has not commenced any new projects since December 2006.

The outcome of 2006 negotiated benefits was that while no benefits increased and reductions were moderated, benefits offered to Global in subsequent rounds have continued to fall and as a result, a significant number of their products are now listed with gaps. This outcome places Global at a significant disadvantage in the marketplace.

Following further reductions in negotiations in October 2007 the company's Board of Directors took the view that attempts to maintain manufacturing capability in Australia were misplaced and the risks were too great. As a result of a Board decision in January 2008, all manufacturing functions will be subcontracted to suppliers in the US and Europe and the manufacturing facility in Wollongong will be closed with a significant number of redundancies.

MTAA has submitted to the Productivity Commission³ that one option is to list all high technology items on a High Technology List, using the safety and efficacy assessments undertaken by the TGA 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 proposed 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.

In the in-vitro 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 more effective diagnosis of disease, there is a disincentive for pathologists to adopt newer technologies because the additional cost reduces the profit available to the pathologist.

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.

³ MTAA Submission to Productivity Commission Annual Review of Regulatory Burdens on Business *Manufacturing & Distributive Trades* March 2008

3.5 Access to publicly-funded infrastructure

Typically, universities, which are well equipped in both expertise and equipment, require all IP developed during any collaboration with an industry partner to be assigned to them. This is despite the fact that, in some cases, all work performed is paid for by the industry partner. Normally a royalty bearing licence is then given to the industry partner, after negotiating mutually agreeable terms, allowing them to commercially exploit the IP in a restricted field of use. Government grants to industry are usually inadequate to enable the purchase of expensive capital equipment (eg electron microscopes).

Smaller companies needing access to equipment as part of their R&D program must do so via universities or other large research organisations where such facilities are available. Universities argue that their costs are publicly funded, so IP involved in use of their resources belongs to them, despite the fact that companies have paid for the use of those resources and, in many cases, are also expected to pay for all the costs of having any new patents filed. The lack of ownership of the IP under these conditions can be a disincentive for a company to seek to collaborate with a university at all or at least in areas too closely related to their core intellectual property.

Case study - Sirtex Medical Limited

SRX and its predecessor organisation have experienced ambiguities in the product development phase in relation to intellectual property agreements with partnering universities. SRX has its own R&D group in-house, but finds that research work requires partnering to progress because of the scale and cost of capital equipment.

4. Future directions for innovation in the medical technology industry

4.1 Health sector demand-lead innovation

One of the challenges of investment in research and development through publicly-funded institutions is to maximise commercial returns on the investment. R&D in medical technology has generally followed the traditional linear model where results flow from basic research through applied research, product development, manufacturing and marketing to launch.

A supply-oriented model assumes sufficient public funding for research followed by technology transfer with incentives to get the research from a science base into the hands of entrepreneurs.

The alternative is the 'market-pull' approach which may be more appropriate given the rapid innovation cycles for a significant amount of medical technology. In such a model:

- there is a business-centric innovation process
- businesses are supported to create concepts for new products and services that can deliver growth for the business
- business can be differentiated through development of new, enabling technology

Lessons can be learned from the approach taken in the United Kingdom in recent years. The Wanless Report⁴ in 2002 described the UK's 'slow adoption' problem and called for investment in modern healthcare technologies. Subsequently the cross-sector Healthcare Industries Task Force (HITF), which reported in 2004⁵, established the National Health Service (NHS) on a course of encouraging and fostering innovative medical technology initiatives.

The HITF Report identified the need for the NHS, the medical technology industry, universities and the healthcare sector generally to work in partnership to deliver 'translational medicine'.

One of the proposals from the HITF was for a National Innovation Centre (NIC) to be established under the authority of the National Health Services Institute for Innovation and Improvement. The NIC is seen as a cross-governmental initiative sought by the Department of Trade and Industry (DTI) and the Department of Health (DoH) because they saw a gap with early-stage technology. The departments saw the NIC as an 'enabling service' that stimulates hybrid relationships at an early stage.

In 2006 the NIC oversaw the establishment of four spin-outs and 40 licensing deals from regional hubs. In September 2007 the NHS National Technology Adoption Hub was launched in Manchester to promote the increased uptake of innovative technology in the NHS. The National Technology Adoption Hub (NTAH) has the following aims⁶:

- to work with partners to source excellent technologies for the benefit of patients
- to increase the uptake of new technology across the NHS
- to improve understanding of how new technologies are taken up by the NHS.

A key output from the HITF review was the release early in 2008 of the first Healthcare Technology Co-operative (HTC) pilots⁷. The pilots are being undertaken in two hospitals which have been funded to 'catalyse the process of developing new technologies' in areas of research that have traditionally been under-funded. The program is backed by both the health (DoH) and science and innovation (DIUS) ministries. The HTCs bring together clinicians, scientists, engineers and business people to focus on unmet patient needs.

4.2 Medical technology industry interface with other industries

One of the features of the medical technology industry is its reliance on the skills of many other industries. It is heavily dependent on developments in areas such as:

- high skilled manufacturing
- materials science
- bioengineering
- nanotechnology

⁴ Wanless, Derek, *Securing our Future Health: Taking a Long Term View*, April 2002 http://www.hm-treasury.gov.uk/consultations_and_legislation/wanless/consult_wanless03_index.cfm

⁵ Healthcare Industry Task Force, *Better health through partnership: A programme for action*, 17 November 2004

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072655

⁶ <http://www.nic.nhs.uk/About/Pages/Introduction.aspx>

⁷ *UK embarks on key HITF output with programmes to develop 'neglected' high-potential technologies*, Clinica 1294 February 15 2008 page 2

- informatics.

To the extent that some traditional industries which are in decline and use these skills, in particular high skilled manufacturing expertise, there is merit in investigating the migration of these skills into newer industries such as medical technology. The lack of supporting industries will mean that an indigenous industry will not be able to prosper and grow to the same extent. One of the issues identified by the Medical Device Industry Action Agenda was the lack of awareness of the means to access other industry sectors.

The network of industries that sits around the medical technology industry needs to be identified and developed as part of a broader innovation strategy for the industry. Some of the emerging developments in the medtech area provide an indication of the skills needs and the potential benefits to the healthcare system:

- miniaturisation of medical devices – will allow more minimally invasive and non-invasive procedures which move care from hospitals to outpatient setting
- replacement organs and tissue engineering advances - will provide new options for addressing serious conditions eg. diabetic patient with an artificial pancreas, combining skin-based sensors to measure blood glucose levels, a hand held monitor to analyse the information, and an implantable fusion pump that adjusts glucose levels as needed
- molecular and gene-based diagnostics - detect diseases earlier in their progression, improving patient outcomes and lowering treatment costs eg. molecular imaging diagnostic tests will be able to detect cancers and other diseases at the molecular level
- health information technology innovations - allow critical medical data to be processed and transmitted rapidly, speeding up delivery of treatment; information will be monitored remotely via wireless connections eg. pacemakers, defibrillators and blood glucose tests.

4.3 Adopting a collaborative framework

In addition to the cross-sectoral industry collaborations referred to in paragraph 4.2, there are many other collaborative opportunities that would support innovation within the industry. These include collaborations between:

- multi-national companies and indigenous companies
- universities and industry
- industry associations providing mentoring services to companies
- Federal government departments with an industry focused portfolio.

Collaborations will also address the skills shortages that have been identified in the skills audit⁸ undertaken by the Medical Device Industry Action Agenda and the Training Needs Analysis undertaken by MTAA in late 2007.

MTAA strongly supports the development of a framework that would strengthen these collaborations. Adopting a holistic approach to this issue, by harnessing the

⁸ Deloitte Insight Economics for Department of Industry, Tourism and Resources, *Skills Audit for the Medical Device Industry*, not yet published

complementary expertise of these key drivers of the medical technology sector, should deliver efficiencies for the health care sector from more focused short to long term planning, monitoring, delivery and evaluation.

4.4 Regional partnerships

Australia has limited resources to undertake all of the initiatives needed to develop and sustain a viable medical technology industry. Even if all the suggestions outlined in this submission were to be implemented there is value in exploring potential partnerships in the Asia-Pacific region. In particular MTAA observes the considerable investment in medical technology that has been committed by the Government of Singapore.

The Singapore Government has invested heavily in education, spending more than 3% of its GDP on public education. With the manufacturing sector contributing to 28% of Singapore's GDP, the country produces over 15,000 engineers and engineering science graduates per year, approximately 40% of the total number of graduates. Since the 1980s Singapore has strengthened its expertise in electronics, precision engineering and materials sciences. The combined manufacturing output of these industries is about S\$100bn, equivalent to 50% of Singapore's total manufacturing output⁹.

This is critical for medical technology companies which engage in both product development and manufacturing. A number of smaller industries also support the diverse medical technology sector, including electronic manufacturing services (EMS), plastic components, metal forming and casting, ceramics, surface treatment and cleansing, packaging and sterilisation.¹⁰

The competitive tax environment in Singapore also plays an important role in attracting companies to start manufacturing high-value products in Singapore. The current headline corporate tax rate in Singapore is 18%, far lower than in the US, many European countries and Australia.

Another initiative to enhance the operating environment within the medtech sector was the establishment of the Medical Technology Advisory Committee (MTAC) in 2006 in response to requests from industry to enhance manpower, regulation, policies and infrastructure.

Australian companies have been attracted by the offers that have been made by the Government of Singapore. This poses the question of why the investment in medical technology might not be undertaken as a partnership to create an Asia-Pacific hub to produce innovative and competitive products that can compete more effectively with the market domination of the US and European companies.

⁹ Yeoh Keat Chuan, Executive Director, Singapore Economic Development Board *Island Thrives on Industry*, <http://www.medicaldevice-network.com/features/feature1332/>

¹⁰ *ibid*

5. Conclusion

Australia has the skeleton of a medical technology industry which with vision and removal of impediments to further development, has the capacity to evolve further a significant innovative industry. This submission outlines some of the steps that can be taken to ensure sustainability in the future and to expand the industry through collaborative partnerships, within Australia and regionally. MTAA urges the Innovation Review committee to make recommendations to address the systemic issues that impede further development and sustainability.