



Medical Technology
Association of Australia



*MTAA response to draft NSW
Manufacturing Industry Action Plan
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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. Introduction

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to contribute to the development of the NSW Government's Manufacturing Industry Action Plan.

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, pacemakers and diagnostic imaging equipment.

Medical technology saves and improves lives by detecting diseases earlier and by providing more effective treatment options for patients and the healthcare system. MTAA is encouraged that the NSW Government recognises the potential of the medical technology sector as a high performing growth industry and prioritises the sub sector of medical devices as a key focus of this plan.

The medical technology industry is one of the few manufacturing industries with the potential to deliver economic growth in NSW. Medical technology can make a significant contribution to the NSW economy by generating employment and creating new export markets. It also has the potential to provide innovative solutions to the NSW Government's escalating health budget over time.

Australia has a good public healthcare system with strong clinical research capabilities and a highly educated workforce as well as an internationally respected and stable finance system. Australia's proximity to emerging markets in Asia with a desire for sophisticated medical products also presents significant export opportunities. Nevertheless, there is currently a policy vacuum at the federal and state government level in terms of fostering this potential. MTAA believes the NSW Government can provide a framework to support industry development by establishing clear goals and priorities to form part of a growth strategy for the industry. The development of a Manufacturing Industry Action Plan is a crucial opportunity to contribute to such a strategy.

This paper provides an overview of the medical technology industry in NSW and Australia and an analysis of the types of medical technology companies and products that characterise the industry. The paper then recommends short and long term goals for consideration by the Industry Taskforce including the following priority areas:

- Formation of a life science industry cluster
- Establish a Medical Device Fund to support emerging companies
- Develop strategies to improve the synergies of growth industries and their access to finance
- Re-train workers in declining industries for medical technology
- Develop a High Value Manufacturing Technology and Innovation Centre

2. The Medical Technology Industry

Globally the medical technology market is valued at over \$300 billion per annum with Australia's share set at 2.61% in 2010¹². The United States is the traditional epicentre of medical technology innovation with 32 companies having an annual turnover greater than US\$1 billion. While the US remains the biggest market, Asia holds the greatest promise with the Asia-Pacific market for medical devices expected to account for 25% of global market share by 2012³. The growth rate is projected to be double that of worldwide growth figures by 2015⁴⁵.

The medical technology industry had sales in Australia of more than \$7.5 billion in 2009-10 and employs more than 17,500 people⁶. It is strongly research-based with clinical input from healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately 70% of all non-pharmaceutical medical products on the Australian market. About 54% of medical technology companies in Australia are located in NSW with approximately 79% of all employees in the industry.

Australia has a trade deficit in medical technology. Nearly all medical technology products manufactured in Australia are exported, while the majority of medical technology products used in Australia are imported⁷. In 2010, the value of medical technology imports was \$3.3 billion and the value of medical technology exports was \$1.2 billion⁸. The comparative values for medicinals and pharmaceuticals were \$9.5 and \$3.9 billion respectively⁹.

There are around 500 companies in Australia with medical technologies registered on the Australian Register of Therapeutic Goods (ARTG). This number does not include *in vitro* diagnostic (IVD) companies (of which there are approximately 60) or dental (of which there are over 50). There are 53 medical technology companies listed on the Australian stock exchange (ASX) with a combined market capitalisation of \$2.4 billion. The majority (>75%) of companies in Australia are independent distributors or Australian affiliates of international companies. The remaining 27% of the industry are Australian manufacturers.

Medical technology companies invest a considerable portion of their revenue in research and development (R&D). It has been estimated that high technology

¹ Hack, Griffith. (2010, June) *Mind the gap: medical technology innovation in Australia*. Retrieved from http://www.griffithhack.com.au/Assets/1675/1/GH_Medical_Technologies_June2010.PDF

² Clinica (2010) *Review and Analysis of the Medical Technology Industry*

³ Glowing Prospects in Medical Technology: Singapore MedTech Directory 2011/2012. Retrieved from <http://www.singaporemedtech.com/Indprof/MED/ED01.pdf>

⁴ Frost & Sullivan: APAC's Medical Devices Market ready to skyrocket (2010, 17 June). Retrieved from <http://www.frost.com/prod/servlet/press-release.pag?docid=204528598>

⁵ Ministry of Trade and Industry Singapore (2010, 3 March). *Mr Lim Hng Kiang at the Medtronic Singapore Operations Opening Ceremony*. Retrieved from http://app.mti.gov.sg/default.asp?id=148&articleID=24401#_ftn1

⁶ There are no official statistics on the size of the industry. The MTAA calculates the size of the industry based on extrapolation of data provided by its 20 member companies and estimates of non member companies.

⁷ NSW Department of Health (Population Health Division) (2011). *NSW Health and Medical Research Strategic Review: Issues Paper*. Retrieved from http://www.health.nsw.gov.au/resources/omr/review/pdf/nswhealth_msr.pdf

⁸ ABS - 5368.0 International Trade in Goods and Services, Australia, November, 2010.

⁹ ABS - 5368.0 International Trade in Goods and Services, Australia, November, 2010.

medical technology companies in the United States devote upwards of 20% of their revenue on R&D¹⁰. Australian government expenditure on health and medical research as a percentage of GDP is within the 0.11%-0.12% band¹¹. The annual spend on R&D for the medical technology sector in Australia was \$388 million in 2008-2009. This includes expenditure on R&D for medical biotechnology, nanotechnology and biomedical engineering¹². There were 18,000 medical technology patents filed in Australia between 2003 and 2009. Only 7% of these patents were filed by Australian companies. The most popular international patent classifications were 'diagnosis, surgery and identification', followed by 'blood vessel filters and prostheses' and 'devices for introducing media into and onto the body'¹³.

Medical technology can deliver significant savings to the health system over time. Unfortunately, the benefits of medical technology are often poorly understood, insufficiently articulated and developed and may be perceived as being a burden on the healthcare system. In Australia for example, medical technology has been seen as a contributor to the rising cost of health expenditure when in fact it is a function of increased uptake rather than the rising cost of devices¹⁴. However the National Health Workforce Innovation and Reform Strategic Framework for Action 2011–2015 suggests that 'achieving efficiency gains, for example in improved uptake of advances in technology, will help to ensure that increased resources are available for future reform initiatives'¹⁵.

The recent changes by the Australian Government to R&D tax incentives have provided encouragement for companies to invest in product development in Australia. The number of clinical trials of medical technologies in Australia has also increased exponentially from around 10 in 2001 to around 340 in 2010 according to the ANZ Clinical Trials Registry. However all these gains will be lost if we continue to have a policy vacuum in support of industry development or face increased barriers to market entry.

Development of a Manufacturing Industry Action Plan: two year goals

3. Establish a Life Science Industry Cluster in NSW

From the MTAA's perspective, one of the barriers to growth in the medical technology industry is the lack of a clear mechanism to facilitate translational research capabilities. There are many examples of world class research at various institutions in NSW but the absence of co-ordinated strategies to ensure that a product can be developed, manufactured, taken up in the Australian hospital system and exported overseas means successful commercialisation of product is often not realised.

¹⁰ USITC, "Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets," March, 2007.

¹¹ Research Australia. Trends in Health and Medical Research Funding, April 2009.

¹² ABS. Research and Development. Businesses. 8104.9, 2008-09.

¹³ Griffith Hack, Mind the gap: Medical technology innovation in Australia, June 2010.

¹⁴ In North America the rising cost of technology is cited as one of the reasons for the high number of uninsured and under insured people when in reality the current healthcare system is not prepared to provide the necessary care required for low income earners.

¹⁵ Health Workforce Australia (2011) National Health Workforce Innovation and Reform Strategic Framework for Action 2011–2015. Retrieved from <https://www.hwa.gov.au/sites/uploads/hwa-wir-strategic-framework-for-action-201110.pdf>

International examples in Denmark, Ireland and Canada and Singapore indicate the most successful way of improving translational research is through commercial engagement between industry, research institutions, universities, and hospitals. These examples suggest the most effective way of achieving this formal engagement is through establishing industry clusters.

While there are many examples of successful life science hubs or clusters around the world, there is not one simple formula for success. However, it is a combination of supporting infrastructure, physical, social and commercial, that makes up a cluster. Global trends indicate clusters create a competitive advantage by signalling to innovative companies and world class researchers that the appropriate linkages are in place for successful commercialisation pathways.

Although there is limited evidence of successful clustering to date in Australia, the NSW Government is presented with a significant opportunity to improve our competitive advantage through a natural concentration of medical technology companies, as well as pharmaceutical and biotechnology companies, in North-western Sydney, primarily in North Ryde and Macquarie Park. Not only are Macquarie University and the new Macquarie University Hospital located in this area, the Australian Hearing Hub is already under development in the area. It is planned as a world-class facility purpose-designed to facilitate collaborative research into hearing and related speech and language disorders. It brings together relevant Macquarie University's research teams (Language Sciences and Cognitive Sciences, Audiology and Speech Language Pathology) with a major government research organisation, Australian Hearing and the National Acoustic Laboratories, as well as not-for-profit organisations offering clinical and related social services for hearing disorders, like The Shepherd Centre. Importantly it also includes the global headquarters for the market leader in implantable hearing devices, Cochlear Limited, which is establishing its manufacturing facility in the hub.

MTAA suggests that government can facilitate the social infrastructure of a technology hub in a similar way to Medicon Valley in Denmark, one of Europe's largest life sciences clusters. Covering eastern Denmark and south-western Sweden it consists of 12 universities, 32 hospitals, and more than 300 life science companies together with the cluster organisation Medicon Valley Alliance. The formal role of Medicon Valley Alliance is to facilitate the diffusion of knowledge by building networks between all the parties within the cluster as well as with potential investors, service providers and government.

Industry clusters come in different forms and varying sizes but the common theme in all examples is the formal information sharing amongst partners. Another example of a regional neighbor prioritising growth in medical technology is New Zealand where a Health Innovation Hub is currently under development. The plan is to bring together the district health boards with industry as core stakeholders to focus on early stage development and commercialisation of medical device technologies.

Clusters provide incentives for companies to establish operations in the location as they know they will have access to highly skilled researchers within universities, hospitals to improve clinical investigation opportunities and opportunities for uptake of their product in the hospital system. As a clean manufacturing industry, companies could also be encouraged to establish manufacturing sites within or adjacent to a hub.

4. Establish a Medical Device Fund to support Small and Medium Enterprise

In recent times it has become apparent that Australia faces significant competition from regional neighbours such as Singapore attracting many large medical technology companies to set up commercial operations, research and development centres and manufacturing operations. There are many incentives for companies to operate in Singapore including access to a highly skilled workforce and a competitive tax rate with a current headline corporate tax rate of 18%. Overlaying all efforts by the medical technology industry to ensure that Australia remains aligned with major competitor economies and remains a place to undertake research and development, conduct clinical trials, and bring products to market, must be a supporting industry framework that encourages investment in manufacturing.

One component of a growth strategy must be a mechanism to support emerging companies in the medical technology industry. There are many challenges faced by small and medium enterprise, one of which is covering essential costs and accessing the right skills to cover all the steps in the process from turning an excellent research idea into a commercialised product. The commercial potential of publicly funded research is often not realised because the skill sets required to create innovation are not the same as those to commercialise innovation.

The challenge for government is to increase commercialisation capability while building policy frameworks that encourage and facilitate the conversion of innovation into product that is manufactured in Australia and exported overseas.

Action 4.6.1 in the NSW Health and Medical Research strategic review discussion paper recently released by the NSW Government proposes the establishment of a medical device incentive program in partnership with venture capital companies, to assist with clinical assessments and trials of innovative medical devices to assist greater uptake of these products by the health system.

Although MTAA is very encouraged by this recommendation, we argue its focus needs to be much broader to have an impact on successful medical technology product development and its uptake in the Australian hospital system. A fund of this nature could provide sufficient support for all of the costs involved in bringing a product to market such as intellectual property, regulatory approvals, clinical investigations, and marketing as well as facilitating access to local manufacturing to ensure maximum benefit is returned to the state through job creation and exports.

MTAA in its submission to the NSW Health and Medical Research Review (26 September 2011) recommended the government establish a mechanism to ensure research ideas that have potential for rapid health benefits are captured at the critical early commercialisation stage when a prototype is being developed. MTAA envisions a Medical Device Fund tasked with formalising linkages between universities, hospitals, research institutions and emerging companies to improve the likelihood that a product is investment ready at the early stages of the commercialisation process. In addition, the Fund could be established to work with government to ensure that technology development is linked in with priority health areas to meet an identified need.

The Medical Device Fund would work closely with government by leveraging existing government programmes as appropriate such as those currently offered by Commercialisation Australia.

5. Access to finance

One of the major hurdles for many small and emerging companies in the medical technology industry is access to affordable finance. There needs to be a clear strategy as part of the action plan for increasing access to affordable finance. Countries such as the United States, Canada, Japan, Korea and Singapore all have established government entities tasked with providing assistance to small business. MTAA recommends the NSW Government consider adopting a similar strategy in the aftermath of the global financial crisis which has resulted in stricter lending conditions which affect small business growth.

By way of example, the United States provides support through a government agency, the Small Business Administration. Its purpose is to ensure small businesses receive a 'fair proportion' of government contracts. Part of its role is to facilitate a loan program to assist companies acquire loans through a bank or financial institution, and then act as a guarantor for the loan.

MTAA suggests the NSW Government engage the finance industry in the development of this industry action plan so they are acutely aware of emerging productive sectors in the NSW economy ensuring their lending policies and practices are aligned with them. In addition MTAA suggests the NSW Government give consideration to establishing a SME unit either within the Department of Trade and Investment or as part of the one stop shop administered by the Small Business Commissioner to provide assistance to emerging companies in growth sectors with loan applications and for government to act as guarantor for a portion of the loan. In addition the role of the SME unit would be to ensure ongoing collaboration with the finance sector to ensure support is being given to growth sectors at an affordable rate.

6. Re-train workers to work in medical technology

MTAA believes that government should shift its focus from declining industries like the automotive industry and work more strategically with growth industries such as medical technology which have demonstrated potential for new job creation. A common challenge for emerging companies which manufacture in NSW is access to a skilled workforce. MTAA suggests government invest in a re-training program targeted at employees in the automotive industry (even if located in other States) for manufacturing roles in medical technology.

The skills involved in the manufacturing of products in medical technology are similar to skills required in the automotive industry such as high skilled engineering, materials science, bioengineering, nanotechnology and informatics. As an example, a community college in Detroit, Michigan in the United States has developed a program to re-train displaced workers in the automotive industry for new careers in growth industries to further support their potential, one of which is medical technology.

The Australian Government administers a variety of government funded programs targeted at providing assistance to the automotive industry, one of which is a

Structural Adjustment Support Program. One component of this program, the Labour Market Adjustment Support Initiative, is administered by the Department of Education, Employment and Workplace Relations¹⁶ with the aim of offering intensive employment services to workers who have been made redundant from the automotive industry. Workers are provided with access to intensive employment and training assistance such as job search and career advice, skills assessment and development.

MTAA recommends the NSW Government partner with the Federal Government as part of this action plan to re-train workers in this program and link them with medical technology companies.

The strategy has the dual purpose of attracting skilled workers to the medical technology industry and ensuring displaced workers the opportunity to build on existing skills.

7. Regulatory Barriers

The Therapeutic Goods Administration (TGA) regulates the supply of medical technology in Australia according to criteria prescribed by the *Therapeutic Goods Act 1989* and related regulations. Since October 2002 the fundamental principles of the testing and assessment of medical technology in Australia have been based on similar principles developed for the European Union which are part of a global harmonisation approach steered through the Global Harmonization Task Force. However the control of supply in Australia is unique in that an approval process resulting in an entry in the ARTG has to be granted.

Under the *Therapeutic Goods Act*, the TGA is required to examine and certify the conformity assessment procedures undertaken by Australian manufacturers supplying medical devices in Australia as well as manufacturers producing medical devices containing particular designated materials, irrespective of where the manufacture occurs. One of the areas of additional burden for Australian manufacturers supplying their products in Australia is that while the TGA accepts CE certification for medical technology manufactured overseas, inspections by the TGA are required for Australian manufacturers of equivalent technology.

An additional burden has been created because restricting the choice of conformity assessment certification options for the Australian manufacturers, coupled with longer timeframes and costs in obtaining the TGA certification, the manufacturers have felt compelled to also obtain CE certification from EU Notified Bodies in order to supply their products in the EU earlier than if the TGA issued CE certification available through the mutual recognition agreement between Australia and the EU. This inconsistency is currently under review by TGA which is examining options for third party conformity assessment which would enable Australian manufacturers to also use certification granted by bodies other than the TGA.

For medical technology companies to grow in NSW they need to be able to export product to overseas markets. The challenges are not just presented in navigating export markets but in getting recognition of Australian approvals outside Australia.

¹⁶ Australian Government Industry Structural Adjustment Program (ASIAP)
www.innovation.gov.au/Industry/Automotive/NewCarPlan/Pages/AISAP.aspx Accessed 25 October 2011

The NSW Government needs to be aware of this regulatory barrier in the context of supporting growth in the medical technology industry.

8. NSW Government Procurement Policy – Local Jobs First Plan

MTAA is aware the Local Jobs First Policy is currently being reviewed by a NSW Government interdepartmental committee. It is MTAA's understanding the policy was announced in the 2009/10 budget as a major component of the NSW Government's Procurement Policy and includes 20% price preference schemes for tenders with products manufactured in Australia and New Zealand. This policy was revised in February 2010 with a view to prioritising industry development for small and medium enterprise, categorised as companies with up to 500 full time equivalent employees. This change was also required as the original policy was in breach of the Australia US Free Trade Agreement which prevents price preference arrangements in government procurement for Australian manufacturers in exchange for entry to the US market.

MTAA is supportive of any government assistance targeted at growth for small and medium enterprise. However, MTAA argues the NSW government should ensure procurement policies are developed with the aim of establishing an even playing field for companies to fairly compete for government contracts. It is important for the government to be aware that there are some larger medical technology companies which manufacture in NSW and employ more than 500 staff and which are currently disadvantaged by this policy as the SME definition prevents them from being considered a 'local employer'. In the context of the high Australian dollar and the industry facing significant competition from regional neighbours prioritising growth in the industry, MTAA argues this review should be considered in the context of developing an action plan to provide incentives for companies of all sizes to expand their operations in NSW.

5 year goals

9. Establish a High Value Manufacturing Technology and Innovation Centre:

As a long term platform for growth, MTAA recommends the NSW government consider establishing a High Value Manufacturing Technology and Innovation centre offering access to state-of-the-art equipment to support product development. A facility of this nature will strengthen innovation in manufacturing and provide an incentive for industry to maintain or establish manufacturing premises in the state. It will assist in establishing NSW internationally as a destination with access to the latest technologies and improve local capabilities to conduct more complex manufacturing activities.

Innovation centres also improve collaboration between emerging and larger companies in the industry improving the skills and knowledge in small companies giving them the best opportunity for growth. They also have the ability to improve co-ordination between industry, researchers and government creating the opportunity to maximise business innovation leading to jobs and export opportunities.

In March 2011, the UK Government released A Plan For Growth to improve economic activity in the UK and create a more competitive business environment. The Life Science sector has a specific set of actions in the plan including simplified regulation, measures for more public involvement in clinical trials, translational research partnerships and expansion of geographical clusters. In addition to this the UK Government has focused on development and adoption of new technologies as a key to economic growth. It has announced the delivery of a High Value Manufacturing Technology and Innovation Centre (TIC) as the first of an elite network of centres by allowing businesses to access state-of-the-art equipment and technical skills which individual companies and universities could not afford to invest in on their own.¹⁷

Recognising innovation as a key economic driver, Victorian Premier Ted Baillieu also announced a new multi-million dollar state of the art innovation centre in May this year to be opened at the Victorian Centre for Advanced Materials Manufacturing facility in Knoxfield Victoria. The innovation centre will accommodate 50 staff from a combination of emerging and larger companies to work on advanced engineering projects.¹⁸

A technology centre of this nature also has the potential to bridge the gap between research and technology commercialisation ensuring much needed product is investment ready earlier in the commercialisation phase to get product to market faster.

10. Payroll tax

MTAA proposes that the government consider payroll tax as a barrier for industry growth as part of the action plan. Although the NSW Government faces budgetary challenges it is pertinent to acknowledge that the current NSW payroll tax rate is 5.45% (1 January 2011) compared with 4.9% in Victoria and 4.75% in Queensland.¹⁹ For the state to increase its competitive edge and attract more businesses it must be able to compete with other jurisdictions.

MTAA proposes that the NSW government lower payroll tax rates to the lowest rate of all states and territories to the current rate applicable in Queensland, as part of an industry action plan to offer a key incentive for companies to operate and expand in NSW.

11. Conclusion

The state of NSW is home to 54% of Australian medical technology companies and 79% of employees. Internationally renowned companies are among those in NSW including Cochlear which develops implantable medical devices to provide hearing to the hearing-impaired, and ResMed which manufactures products for the diagnosis and treatment of sleep disordered breathing. Both companies are major Australian success stories and are leaders on the world stage, choosing to manufacture in NSW. Baxter Healthcare manufactures and delivers critical life saving therapies to the people of Australia and New Zealand in the areas of cancer, kidney disease, haemophilia, immune disorders, infectious diseases and trauma.

¹⁷ The Plan For Growth, HM Treasury, Department for Business, Innovation and Skills

¹⁸ www.premier.vic.gov.au Accessed on 21 November 2011

¹⁹ Tax Resources Australia www.taxresources.com.au Accessed on 21 November 2011

Emerging companies in the industry include Applied Physiology, Simavita, Mac Surgical, Nanosonics, Gel Works and Sirtex all of which manufacture medical technology products in NSW. The products are as diverse as devices to generate clinical decision support, solutions to urinary incontinence, repair of instruments for use in hospitals, solutions for infection control in the healthcare industry, personal lubricant products and small technologies to treat patients with liver cancer.

MTAA is encouraged by the development of the 10 year action plan and proposes that the NSW government work more closely and strategically with the industry to shape it. MTAA believes that medical technology companies would respond to policy leadership which values the contribution of a highly skilled industry which can draw on linkages with health and medical research capability.

MTAA recommends government consider establishing initiatives to support emerging companies in the industry with access to finance and the right skills to improve the rate of commercialised medical technology product as well as addressing the availability of skilled employees for the industry. MTAA also recommends the government consider establishing a High Value Manufacturing and Innovation Centre to ensure medical technology companies in NSW have access to state of the art technology.

Fostering growth in the medical technology industry has the potential to deliver economic and social benefits to NSW through employment and export opportunities as well as establishing a knowledge economy to be more internationally competitive.