

Senate Economics References Committee
Inquiry into Australia's innovation system

1 August 2014





Medical Technology
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Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to make this submission on Australia's innovation system to the Senate Economics References Committee. MTAA supports reform to make innovative healthcare solutions accessible to all Australians. The medical technology industry is highly innovative and utilises high skilled manufacturing with significant investment in research and development (R&D). Australia has many of the right attributes to grow a strong domestic industry – a significant health and medical research capability, quality health system, highly skilled manufacturing workforce, stable financial system and access to the growing middle class markets of Asia. A robust Australian medical technology industry fosters economic and social growth, creates jobs in an innovative manufacturing sector and contributes to healthcare solutions which support improved quality of life.

MTAA has provided a number of recommendations for each of the terms of reference. In summary these are:

Recommendation 1

- a) Introduce an Advanced Manufacturing and Innovation tax incentive scheme that supports development and maintaining IP in Australia
- b) Alignment of industry development with the health system needs to support the commercialisation and market entry of valuable technologies

Recommendation 2

- a) Continue to support the R&D Tax Incentive
- b) Government investment to better support in-house R&D undertaken by the Australian medical technology industry.
- c) Develop national Blue Print for Medical Technology sector which sets the right environment for the medtech sector to contribute economically and socially

Recommendation 3

- a) Implement the recommendations of the Strategic Review of Health and Medical Research
- b) Introduce industry hubs to mitigate the issues which prevent commercialisation of Medical Technology in Australia
- c) Foster industry innovation and growth by putting into place mechanisms to support and accelerate commercial outcomes from public investment in research
- d) Provide assistance to entrepreneurs to translate an idea into a product that can be developed and commercialised

Recommendation 4

Provide the right financial and business environment for Medical Technology manufacturers to maintain their business or bring their operations into Australia

Recommendation 5

- a) Establish or dedicate a division of the health system to develop a work plan on identifying, understanding and overcoming the barriers that are preventing medical technology adoption.
- b) Identify entrepreneurial clinicians, universities and engineers and provide the resources to develop and implement technology solutions for immediate healthcare problems.

Recommendation 6

Develop infrastructure to support research collaboration between academia, research institutes and industry at each stage of the medical life cycle

Recommendation 7

- a) Target students with information about the employment opportunities in the medtech sector and high value manufacturing.
- b) Support research in the health system, building health professionals' research capacity and maintaining the research excellence through training
- c) Build enabling infrastructure through such things as patient databases, registries and biobank hubs

Recommendation 8

- a) Explore retraining of skilled workers
- b) Encourage school aged students to continue with mathematics and science in years 11 and 12
- c) Develop a long term MedTech workforce planning strategy depicting where the career opportunities are, where the gaps lie and what the future gaps are likely to be in the context of global trends

Recommendation 9

- a) Link Australian companies to international research agencies for collaboration of ideas, which will assist them in becoming part of the global solution
- b) Mentoring support companies and researchers to identify pathways through the available 'jungle of opportunities'

Recommendation 10

- a) The MedTech sector works across and adds value to various government portfolios and the Department of Industry should provide leadership to ensure collaboration between and understanding of the health, education, employment, small business, treasury/finance, innovation, manufacturing and trade portfolios
- b) Provide market intelligence on trends, both overseas and nationally, to enable Australian SMEs, entrepreneurs and researchers to respond to identified opportunities

We welcome the opportunity to discuss this further with the Senate Standing Committee on Economics.

Susi Tegen
Chief Executive

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Introduction

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small and medium sized Australian innovator companies.

Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, to diagnostic imaging and operating theatre equipment, to products which incorporate biological materials or nanomaterials. The industry is characterised by a high level of innovation, resulting in short life cycles for many products. Medical technology innovation is characteristically incremental in nature. Many medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical technology.

The Australian medical technology industry¹:

- had turnover of approximately \$10.2 billion in 2012-13 (revenue is ~\$11.8 billion if *in vitro* diagnostic (IVD) and dental products are included)
- included over 500 medical technology companies with products listed in the ARTG
- was responsible for ~44,000 medical devices listed on the 2014 ARTG, estimated to represent 500,000 to one million different devices²
- employed more than 19,000 people
- was mainly located in NSW (55%) followed by Victoria (24%) and Queensland (12%)
- imported goods to the value of \$4.4 billion and exported goods to the value of \$1.9 billion in 2013.

The medical technology industry compares favourably in turnover and size with other major Australian industries. The automotive manufacturing industry had revenue of \$11 billion in the period 2011-12 with employment at around 16,289 while the wine industry had revenue of \$7 billion and employment of 13,208 in the same period³. In 2011–12, health spending in Australia was estimated to be \$140.2 billion. Australian demand for medical technology is growing due to the ageing population and increased prevalence of chronic diseases.

Senate Economics References Committee Inquiry into Australia's Innovation System

The Australian Senate review into innovation aims to address the challenges to Australian industries and jobs posed by increasing global competition in innovation, science, engineering, research and education. Ten reference points are provided:

¹ *Medical Technology in Australia: Key facts and figures 2013*, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2013)

² Data obtained from the TGA. ARTG as at 13 June 2014

³ IBIS_World. Motor Vehicle Manufacturing in Australia. 2012; Available from: <http://www.ibisworld.com.au/industry/default.aspx?indid=250>

(a) The need to attract new investment in innovation to secure high skill, high wage jobs and industries in Australia, as well as the role of public policy in nurturing a culture of innovation and a healthy innovation ecosystem;

Recommendation 1

- a) Introduce an Advanced Manufacturing and Innovation tax incentive scheme that supports development and maintaining IP in Australia
- b) Alignment of industry development with the health system needs to support the commercialisation and market entry of valuable technologies

The Australian Government has not traditionally played a large role in attracting new investment in innovation and the role of Government is not well understood in this process. There is limited support for innovative medical technology companies in Australia (see Appendix 1 for Government Assistance Programs). In contrast to countries where public policy supports innovation (e.g., Israel and Ireland), access to finance is one of the greatest challenges for emerging companies in the Australian medical technology sector. Each stage in the development of a medical device can be lengthy (albeit significantly shorter than pharmaceutical development) and it is commonly accepted that the time to market can take between 5-10 years. The sector is considered high risk compared to other industry sectors and the return on investment is typically long term.

While there are many benefits for innovative companies in Australia (e.g., quality research institutions and a highly skilled workforce), there are a large number of medical technology, biotechnology and research companies looking for investment and few local venture funds that have the capital to invest. Commitment to venture capital (VC) is falling in Australia and there are few incentives to attract international investment. On the international scene VC investment in medical technology has shown a steady decrease⁴. In the last five years VCs have become wary of the difficulties medical technologies face in the lengthy commercialisation lifecycle which includes gaining regulatory approval, the requirements for reimbursement, the need for comparative effectiveness studies and the need to prove cost effectiveness of a medical technology. For this reason investment in later stage companies is more favourable.

The 2013 *Strategic Review of Health and Medical Research (HMR)* highlighted the need to attract large global philanthropy and to leverage philanthropy with Government matching⁵. The review suggested identifying new funding sources for health and medical research such as:

- alternative debt financing: for example, performance-based social bonds to fund initiatives that generate specific social outcomes and long-term cost savings. Government bonds could fund health and medical translational research that aims to reduce the cost and health burden associated with chronic disease
- continued support of R&D tax incentives
- additional schemes such as research prizes to stimulate interest and investment in innovation.

Access to finance is one of the greatest challenges for emerging companies. In other countries (e.g., Canada) government acts as a guarantor for funds provided to small companies which would otherwise have limited access to finance. There are few incentives

⁴ *Medical Technologies What's hot and key trends in medtech in 2013*. Results Healthcare, 2013

⁵ *Strategic Review of Health and Medical Research in Australia – Better Health Through Research*. Commonwealth of Australia, 2013

to attract international investment in the medical technology industry in Australia. It has been suggested that Government implement a 'patent box'-style tax incentive, known as the Australian Innovation and Manufacturing (AIM) Incentive, where businesses receive a reduced tax rate on qualifying profit from intellectual property (IP) attracting international investment^{6,7}. Once an innovative idea reaches the commercialisation phase, companies would be incentivised to keep Australian IP and manufacturing in Australia (the scheme would reward companies who succeeding in exporting products).

Public policy is needed to nurture a culture of innovation and a healthy innovation ecosystem. The Pennsylvania Life Sciences Greenhouse (PLSG)⁸ is a good example of where Government and industry have worked together to attract capital investment and establish VC funds dedicated to funding medical technology innovation. The PLSG is based in Pittsburgh and was founded as a public/private partnership in 2001 by the Commonwealth of Pennsylvania, University of Pittsburgh, Carnegie Mellon University, University of Pittsburgh Medical Center and Pittsburgh's regional foundation community. Its mission is to foster the development of a research and economic community that will put Pittsburgh at the forefront of the life sciences industry and accelerate the introduction of biomedical innovations to market. In 2012, PLSG announced that it had completed a further capital-raising of more than US\$8 million to invest in local medical device and diagnostic companies.

The reduction in angel investment following the global financial crisis prompted the province of Ontario, Canada, to start a C\$40 million government-backed VC funding initiative. The government has recognised that R&D tax credits assist going concern companies but less so start-up companies. The government in Ontario has changed its focus from R&D to translation, commercialisation and direct investment funding. The Ontario Centres of Excellence program draws funding from provincial and federal governments, matched with industry funds⁹.

In Australia Brandon Capital Partners¹⁰ works collaboratively with entrepreneurs and makes seed and VC investments available to demonstrate the benefits of innovative technology and invest in early stage development and commercialisation opportunities. The company aims to turn innovative science into improved outcomes and manages the \$51 million Medical Research Commercialisation Fund. The fund is supported by AustralianSuper, StatewideSuper and the Australian Government, with support from the state governments.

Public policy that aligns industry development with health system needs can support the commercialisation and market entry of valuable technologies. The Cochlear story is an example where sustained government policy focus and public investment in hearing health underpinned technology development and resulted in the creation of Cochlear Limited.

(b) The Australian Government's approach to innovation, especially with respect to the funding of education and research, the allocation of investment in industries, and the maintenance of capabilities across the economy;

Recommendation 2

- a) Continue to support the R&D Tax Incentive
- b) Government investment to better support in-house R&D undertaken by the Australian

⁶ http://www.ausbiotech.org/userfiles/file/AIM_AusBiotech_April%202014.pdf

⁷ <http://www.australianmanufacturing.com.au/8690/advanced-manufacturer-proposes-incentive-for-companies-that-succeed-in-exporting>

⁸ <http://www.plsg.com/>

⁹ <http://www.oce-ontario.org/>

¹⁰ <http://www.brandoncapital.com.au/>

medical technology industry.

- c) Develop national Blue Print for Medical Technology sector which sets the right environment for the medtech sector to contribute economically and socially

Australia has a strong education system and renowned research capabilities. Governments have a strong track record of investment in education and research. The World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) collaborate to respond to increasing demand and to ensure access to innovative medical technologies¹¹. Medical technology patent applications made up 7.7% of the total number of applications between 1998-2012 (comparable to pharmaceuticals 6.5%)¹². Patent applications by medical technology companies provide a good indicator of innovation and the number of Australian medical technology patent grants has shown a steady increase since 2009. These data are favourable and suggest that there is a strong culture of innovation in Australia.

The Australian Government needs to ensure that an effective innovation eco system is supported and that Australia is prepared for the opportunities available in emerging markets. In 2011 PricewaterhouseCoopers (PwC) released an innovation scorecard for the medical technology industry¹³, assessing the capacity of nine countries with strong medical technology market potential to adapt to the changing nature of innovation. The countries examined were Brazil, China, France, Germany, India, Israel, Japan, United Kingdom and United States. In analysing the current position in each of the nine markets, the scorecard looks forward to 2020 with the conclusion that the traditional pillars which have underpinned the growth of the sector in the US are becoming less relevant. The report highlights the changing nature of healthcare innovation and demonstrates that the gap between innovation leaders such as the US, Germany, Japan and France and emerging economies such as China, India and Brazil is narrowing.

The dominance of the medical technology industry in the US stemmed from its strength in five areas; powerful financial incentives, leading resources for innovation, a supportive regulatory system, demanding and price insensitive patients and a supportive investment community. PwC concludes that five new pillars of innovation will be required for the medical technology ecosystem in 2020:

- system-oriented and value-based incentives (with a focus on the development of whole-care, patient-centred solutions)
- global networks of academic medical centres (noting the increasing investment by emerging nations in research and development)
- competing regulatory systems (companies will move into markets where they can obtain approvals more quickly, generate returns faster and engage patients and providers in the cycle of innovation)
- individualized solutions and price-sensitive customers (providers will look to companies worldwide for technology solutions that offer more integrated, holistic, cost-effective devices combined with wellness and disease management services)

¹¹ World Health Organization, World Intellectual Property Organization and World Trade Organization (2012). *Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade*

¹² http://www.wipo.int/ipstats/en/statistics/country_profile/countries/au.html

¹³ PricewaterhouseCoopers. *Medical Technology Innovation Scorecard. The race for global leadership*, January 2011

- global financial networks (funding will follow the shift of investment opportunities to new markets).

In this context, emerging countries such as China, India and Brazil are starting to take the lead in developing lean and frugal innovations which simplify devices and processes that are less costly and better customised to patients' needs. These countries do not have entrenched and bureaucratic healthcare systems that seek to maintain the status quo and lack the impetus to deliver services differently.

The Australian R&D spend in 2011-12 for medical and surgical equipment manufacturing was \$237 million¹⁴. The medical technology industry is a sector that invests heavily in R&D. It has been estimated that high technology medical technology companies in the US devote upwards of 20% of their revenue to R&D. The current R&D benchmark level in Australia is around 2% of gross domestic product (GDP). This is below other leading OECD countries which have R&D targets of at least 3% of GDP. The 2013 *Strategic Review of Health and Medical Research* review panel recommended a minimum 3-4% of total expenditure on health and medical research be dedicated to R&D¹⁵.

Australian businesses spent approximately \$29 billion on innovation between 2010-11 across all industry sectors. However, the most common expenditure categories were acquisition of machinery, equipment, or technology and training, rather than in-house R&D¹⁶. Government investment is needed to better support in-house R&D undertaken by the Australian medical technology industry.

In Australia research has traditionally been conducted in the university sector. Approximately 60% of all Australian researchers are employed in higher education, with another 10% employed in research agencies. Only 30% of Australian researchers are in the business sector, in contrast with 80% in the US, 64% in Switzerland and 70% in Japan¹⁷.

Tax incentives are vital for innovation. The R&D Tax Incentive was introduced in 2011, replacing the R&D Tax Concession, R&D Tax Offset, and the associated Incremental Premium and International Premium Concession systems. It provides a tax offset to encourage companies to engage in R&D and product development. The R&D Tax Incentive provides a 43.5% refundable tax offset to eligible entities with an aggregated turnover of less than \$20 million per annum and a non-refundable 38.5% tax offset to all other eligible entities. The incentive helps businesses offset some of the R&D costs. It is a broad-based entitlement program open to companies of all sizes in all sectors that are conducting eligible R&D. It is important that the Australian Government continues to support the R&D Tax Incentive.

At 2% of the global market Australia must remain competitive with other nations to achieve industry growth. The current Australian regulatory system involves significant red tape for businesses, particularly in relation to the time and cost of bringing medical devices to market. Regulatory hurdles can significantly disrupt the innovation pipeline. The Australian regulatory system (adopted in 2002) is based on the Global Harmonization Taskforce (GHTF) regulatory model and is therefore also closely aligned with the European Union (EU) regulatory system for medical devices.

¹⁴ 81040DO009_201112 Research and Experimental Development, Businesses, Australia, 2011-12

¹⁵ *Strategic Review of Health and Medical Research in Australia – Better Health Through Research*. Commonwealth of Australia, 2013

¹⁶ Australian Bureau of Statistics (ABS) (2012) Innovation in Australian Business, 2010–11, data cube: Types of Expenditure for Innovation, cat. no. 8158.0, [Accessed 20 June 2013].

¹⁷ Science, Technology, Engineering and Mathematics in the National Interest: A Strategic Approach, Office of the Chief Scientist, July 2013

Adoption of this system in Australia provided more opportunities in the global market for Australian manufacturers. Although closely aligned with the regulatory requirements in Europe, there remain a number of aspects of the current Australian regulatory system, which result in Australian medical technology companies experiencing unnecessary and burdensome costs to their business, and ultimately affect the ability of Australian patients to access the latest medical technology.

Standards play a crucial role in determining market success. In the medical technology sector, innovation can not gain wide spread market acceptance and success unless there is demonstrated conformance to Standards such as ISO 13485. In a recent research paper from Standards Australia, they suggest that the role of standards are four fold and are directly related to productivity. Specifically standards protect the safety of the community; facilitate international trade; enhance the interoperability of technologies and processes; and facilitate technological change and economic development by reducing information asymmetry¹⁸.

Sustainability of the Medical Technology Industry

In early 2012 MTAA called for the development of policies to support a sustainable national med-tech sector and issued a white paper on *Building a Sustainable Medical Technology Industry*¹⁹ calling for government and industry to work together more strategically to establish a supportive business environment for the industry. The MTAA white paper proposes a number of strategies to foster growth in the industry and maintain capabilities across the economy. Commitment to these strategies would ensure maintenance of capabilities across the economy.

In reviewing the drivers for success in other countries, the MTAA white paper suggests that there are a number of common attributes:

- national strategy and national leadership
- dedicated national institutions or networks
- tax and other critical incentives
- market access and integration with the health system
- commitment to advanced sector training
- sustained long-term focus.

The MTAA would like to work in partnership with the Australian government to establish a Medical Technology Blueprint – a vision and a framework to create an optimal business environment for an innovative industry. Decisions and policies made in a number of government portfolios impact on the development of a sustainable medical technology industry.

- education decisions impact on whether current and future workers have the skills necessary to innovate, create and manufacture the technology of the future or have to be retrained
- decisions on how health services are delivered to indigenous, rural and remote communities
- the role of volunteers in Australia and their economic impact

¹⁸ Research paper: The Economic Benefits of Standardisation, Standards Australia

¹⁹ <http://www.mtaa.org.au/docs/position-papers/building-a-sustainable-australian-medical-technology-industry-white-paper-final-march-2012.pdf?sfvrsn=0>

- how health services are delivered to the people of Australia sustainably
- planning and infrastructure and whether there are alternatives to building hospitals, and how the benefits of remote monitoring and health at home impact on planning
- creating high technology business parks similar to Tonsley Park, South Australia, and those in Singapore, Denmark and Sweden for an environment that fosters innovation
- reducing the unnecessary and duplicative regulatory burden on small business
- government assistance to individual companies through advisory services as well as financial partnership programs
- support for research and translation of research in industry into commercialised technologies

See Appendix 2 for a more detailed explanation of this.

A critical path for this plan is changing the way the healthcare system and industry interact. A sustainable health care system and a sustainable medical technology industry are commensurate goals. We deliver the technologies that keep people out of the health system, contributing to the economy. We need to be partners in innovation – finding new ways to deliver services with finite resources.

The health aspect of the MedTech Blueprint will prepare Australia for the increasing demand on health care services by the population living and needing to work longer and the burden of chronic illnesses.

(c) The importance of translating research output into social and economic benefits for Australians, and mechanisms by which it can be promoted;

Recommendation 3

- a) Implement the recommendations of the Strategic Review of Health and Medical Research
- b) Introduce industry hubs to mitigate the issues which prevent commercialisation of Medical Technology in Australia
- c) Foster industry innovation and growth by putting into place mechanisms to support and accelerate commercial outcomes from public investment in research
- d) Provide assistance to entrepreneurs to translate an idea into a product that can be developed and commercialised

The medical technology industry presents significant economic opportunities for Australia through the creation of new high skilled jobs and increases to export revenue. It also has the potential to provide solutions for major challenges, such as addressing escalating health budget; through development of innovative medical technologies that will keep people out of hospitals. In addition to its economic value, the medical technology industry, through its products, also contributes to improving quality of life for patients.

When compared to non-innovative businesses, businesses that innovate in Australia are 78% more likely to report increases in productivity²⁰. The Australian Government has a poor record in supporting the translation of research projects from publicly funded research institutions into successful commercial ventures.

²⁰ Australian Government, Department of Industry, *Australian Innovation System Report 2013*.

The 2014 Global Innovation Index (GII) (analysis of 125 countries) shows that Australia ranks an impressive 17th place on innovation input but a lower 22nd place on innovation output (translation)²¹. Innovation leaders were Switzerland, UK, Sweden, Finland, Netherlands, US, Singapore and Denmark. The GI “innovation efficiency ratio” shows how much output a country is getting for its inputs (ratio of the output sub-index over the input sub-index). Australia’s overall innovation efficiency ratio is among the lowest of countries surveyed (81st). Australia performs well on the input side of innovation (featuring in the top 10 for research, tertiary enrolments, market sophistication, ease of starting a business, infrastructure and deployment of information), but poorly in innovation output. For example, Australia has a low proportion of science and engineering graduates in the population (73rd) and attracts minimal R&D investment from abroad (76th)²².

Strategic Review of Health and Medical Research

The Commonwealth Government recently conducted a *Strategic Review of Health and Medical Research (HMR)*²³. The review found that there was not a strong connection between HMR and delivery of healthcare services (translation). The review provided a number of relevant recommendations including the need to:

- drive research activity in the health system
- establish sector leadership and governance
- establish integrated health research centres
- build health professional research capacity
- accelerate clinical trial reforms
- train, support and retain the workforce
- streamline competitive grant processes
- rationalise indirect cost funding for competitive grants
- build enabling infrastructure and capabilities.

The review covered enhancing both non-commercial and commercial pathways to impacts. It addressed the need to accelerate research translation and health system innovation by incentivising clinically relevant research. The report suggests that commercialisation can be enhanced by the provision of funding to address the twin ‘valleys of death’ in commercialisation, which occur at the preclinical/discovery and the early clinical trials phases. The report also covers the need to attract philanthropy and new funding sources such as R&D tax incentives and levies, research prize schemes and alternative debt finance.

Australian researchers have a strong reputation internationally and citation rates for Australian medical research are high²⁴.

However, Australia lags behind in the translation of research into social and economic benefits. For the medical technology industry this equates to commercialisation of innovative ideas, i.e., bringing a new medical technology to market. The review of health and medical research notes that Australia does not reap the full benefits of medical research output due to lack of support for early clinical projects and an ‘immature commercialisation

²¹ <http://www.globalinnovationindex.org/content.aspx?page=data-analysis>

²² <http://theconversation.com/australia-ranks-on-innovation-but-indolence-could-cost-us-29329>

²³ *Strategic Review of Health and Medical Research in Australia – Better Health Through Research.*

Commonwealth of Australia, 2013

²⁴ Source: Thomson Reuters

environment'²⁵. The review panel proposed a Translational Biotech Fund, with half of the funds provided by Government and half by institutional investors.

Government spends around \$8 billion a year on research, however only ~1.5% of this figure is spent on commercialisation²⁶. The abolition of the Innovation Investment Fund and Commercialisation Australia will hit SMEs in the medical technology space hard. Of the 503 companies assisted by Commercialisation Australia, 79 were in the medical device sector (15.7%).

Collaboration

The Australian medical technology industry lags significantly behind its global counterparts in the successful commercialisation of research into profitable products and services. When compared to countries such as Singapore, Ireland or Israel, a key feature missing in the Australian medical technology industry landscape is collaboration. Extensive networks and communities that enable productive relationships are crucial to driving success in industries where knowledge and expertise is not easily accessible.

International evidence indicates positioning the right people and the right process in the form of industry hubs can largely mitigate the issues which prevent commercialisation of medical technology in Australia. The main reason for this is that all aspects of commercialisation overlap and a company is most efficient when it can define early in the process what the end user wants and how to get the product to that stage. Because Australia doesn't have these structures commercialisation rates are low and most medical technology is imported and distributed by companies that are sales and marketing experts.

International Examples of Research Translation

Policy is needed to foster industry innovation and growth by putting into place mechanisms to support and accelerate commercial outcomes from public investment in research. There are several countries with significantly smaller economies than Australia where government policy support has enabled the medical technology industry to flourish. Among these is Ireland where the government prioritised funding with €646 million invested in Science Foundation Ireland as well as the establishment of the National Centre for Biomedical Engineering Science to increase medical technology research and education. Denmark and Israel are other countries which have provided significant policy support to invigorate the sector.

The translation of innovative ideas into medical devices that reach market has wide-spread social and economic implications. Examples of countries which have been successful in the translation of innovative research in the medical technology sector are shown in Table 1.

²⁵ *Strategic Review of Health and Medical Research in Australia – Better Health Through Research.* Commonwealth of Australia, 2013

²⁶ Australian Government 2011-12. Science, Research and Innovation Budget Table

Table 1: Countries and mechanisms promoting the translation of research into social and economic benefits

Country	Mechanisms promoting research translation
Canada	<ul style="list-style-type: none"> • Federal and Provincial Government tax credits, incentive schemes • Federal subsidy programs, repayable loans and facilitation of financing • Small business financing program, Government guarantees 85% of eligible small business loans for a small fee • Investment programs, equity capital to companies, often partnering with private equity or venture capital firms • Support for projects that support industry growth/export capabilities • Financing of projects that develop innovative technologies and create jobs²⁷ • Collaboration among key stakeholders to drive the development of leading edge innovative medical devices²⁸ • Assistance for SMEs to expand growth in foreign markets²⁹
Ireland	<ul style="list-style-type: none"> • Medical technology generates 8% of Ireland's total exports • 25,000 employees, the highest number of people working in the industry in Europe, per head of the population³⁰ • Proven location for high value manufacturing and R&D • Funding for Centres of Excellence in science and technology³¹ • Intensive collaboration between research institutions, clinicians, manufacturing companies and government agencies³² • Range of investment incentives to foreign businesses • Enterprise Ireland offers specific programs to convert the outputs of Government funded research into innovative products and companies³³ • Investment in export strategies, trade missions and trade fairs • MedTech Accelerator Fund - focused on export oriented high potential start-up Life Sciences companies³⁴
Israel	<ul style="list-style-type: none"> • Sector dominated by young startup and early stage companies³⁵ • Focus is on unique opportunities of major diseases for which existing therapies are largely ineffective or non-existent³⁶ • Highest number of scientists and engineers per capita in the world³⁷ • Generous incentives provided to companies interested in developing R&D or manufacturing facilities in Israel³⁸ • Generous funds for R&D expenditure³⁹ • Programs at all stages of the R&D to commercialisation cycle

²⁷ <https://www.htx.ca/FundingList.aspx>

²⁸ <http://www.research.uottawa.ca/mdi2/index.html>

²⁹ Healthcare Technology Exchange, www.htx.ca

³⁰ Irish Medical and Surgical Trade Association (2010). Retrieved from http://www.careersportal.ie/sectors/sector_org_answer.php?client_id=61&group_name=Questions+about+the+sector

³¹ Galway Medical Technologies Centre, www.gmedtech.ie

³² http://www.imda.ie/Sectors/IMDA/IMDA.nsf/vPages/About_us~sector-profile?OpenDocument

³³ <http://www.enterprise-ireland.com/en/funding-supports/Researcher/Funding-to-Commercialise-Research>

³⁴ <http://businessbanking.bankofireland.com/loans/medtech-accelerator-fund/>

³⁵ Israel Medical Devices Industry – Market Overview August 2012, p4

³⁶ http://www.ilsa.org.il/industry_profile.asp

³⁷ <http://newmedicalideas.weebly.com/medical-devices-from-israel.html>

³⁸ <http://www.investinisrael.gov.il/LifeSciencesBrochure2012.pdf>

³⁹ R&D Incentive Programs – Ministry of Industry, Trade & Labor brochure

	<ul style="list-style-type: none"> • Multinationals encouraged to forge alliances with local start-ups • Close proximity of university and industry clusters • Israel's 12 Technology Transfer Organisations (TTOs) showcase the fusion between universities, hospital systems industry and the military⁴⁰ • Technological Incubators Program: funding for two years. Government funds 85% of the total budget and incubator funds 15%. Grant paid back from royalties (3%). Nearly all incubators have been privatised⁴¹ • Of the 200 current incubated companies, 40% are medical device companies⁴²
Singapore	<ul style="list-style-type: none"> • Proven location for high value manufacturing and R&D • 30 medical technology companies have set up commercial scale plants to produce devices for the regional and global markets⁴³ • Established electronics and precision engineering industry • Biomedical Sciences Accelerator (BSA) Program encourages the formation of medical technology start-ups in Singapore • A variety of funding schemes are available to help fuel biomedical start-ups and transform technology ideas into viable businesses⁴⁴ • Substantial new funding to support translational research and foster public-private partnerships in the biomedical sciences sector⁴⁵ • The Biomedical Sciences Industry Partnerships Office (IPO) assists the translation of science into healthcare solutions through public-private partnerships and matches companies R&D needs to expertise in research hospitals and institutions⁴⁶ • Export strategy focus on attracting multinationals to establish R&D facilities as well as regional headquarters • Singapore has the vision to become the Biopolis of Asia – an international biomedical sciences cluster advancing human health • Heavy investment in talent development programs, e.g., collaboration with Stanford University to enable Singaporeans to be trained in the medical device innovation process under the guidance of industry experts in Silicon Valley⁴⁷ • Large focus on support of research, innovation and enterprise activities, US\$3 billion is dedicated to enhancing existing biomedical R&D infrastructure and translating science into tangible outcomes⁴⁸ • Dedicated infrastructure, Singapore has begun construction of a seven hectare science park which will nurture medical technology companies. The MedTech Hub will host 'an integrated ecosystem' of medical device manufacturers, suppliers, and service providers⁴⁹

⁴⁰ <http://www.investinisrael.gov.il/LifeSciencesBrochure2012.pdf>

⁴¹ <http://www.investinisrael.gov.il/LifeSciencesBrochure2012.pdf>

⁴² <http://www.incubators.org.il/category.aspx?id=606>

⁴³ <http://www.edb.gov.sg/content/edb/en/industries/industries/medtech.html>

⁴⁴ <http://www.edb.gov.sg/content/edb/en/why-singapore/ready-to-invest/incentives-for-businesses.html>

⁴⁵ <http://www.clinica.co.uk/marketsector/Singapore-earmarks-major-new-funding-for-biomedical-partnerships-and-research-323725?autnID=/contentstore/clinica/codex/fd12ef4e-0fb1-11e1-bbe6-4d8e6a53eb99.xml>

⁴⁶ Biomedical Sciences Fact Sheet 2012, EDB Singapore

⁴⁷ <http://www.mdtmag.com/blogs/2012/12/singapore-pumps-innovation-heart-asia%E2%80%99s-growing-cardio-device-industry>

⁴⁸ Biomedical Sciences Fact Sheet 2012, EDB Singapore

⁴⁹ <http://www.clinica.co.uk/regions/world/Singapore-to-develop-dedicated-medtech-hub-329382?autnID=/contentstore/clinica/codex/6c04994a-87d5-11e1-9497-ad152d0bfb07.xml>

Assistance for SMEs

Over 70% of the Australian medical technology industry can be categorised as a SME with fewer than 100 employees⁵⁰. SMEs may struggle to plan and execute a commercialisation strategy because they may not have the expertise required or access to the necessary skills at each stage of the product development lifecycle. Managers of SMEs may have technical expertise but are less likely to have the skills required to commercialise a product.

In order to translate health and medical research into viable products there is a need to support the development of prototype products at the critical early commercialisation stage. This means providing appropriate assistance to entrepreneurs to translate an idea into a product that can be developed for use across the health system. A well-documented issue in Australia is the lack of entrepreneurial skills in (amongst others) researchers and innovators.

Feedback from smaller MTAA members suggests that the main issues are the lack of understanding of:

- the process from idea to sale/trade
- awareness of capabilities and skills lacking
- how to access funding programmes, information, legal, legislative, compliance
- access to market data and how to use it.

The Entrepreneurs' Infrastructure Programme⁵¹ will benefit innovative companies which are presented with significant challenges navigating multiple entry points to access available programs. The program will supply \$484.2 million over five years and offers support through three streams:

- business management: plans for improvement focused on business needs
- research connections: access to advisers who can assess research needs and direct them to an appropriate research institution (may provide matched funding of up to \$50,000)
- commercialising ideas: tailored commercialisation services designed to provide entrepreneurs and innovative businesses access to advice, connections and support, to enhance their prospects of commercial success.

Government should consider programs such as those offered by the US National Science Foundation in collaboration with the National Health Institute (NIH). The initiative equips scientists with business training to help them transition from skills required in academia to skills required in the business world. The goal is to accelerate the development and commercialisation of drugs, devices and services. The Innovation Corps accepts applications from recipients of specific grants and a nine week boot camp educates biomedical entrepreneurs on business matters such as how their companies can protect intellectual property and develop regulatory and reimbursement strategies⁵².

⁵⁰ *Medical Technology in Australia: Key facts and figures 2013*, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2013)

⁵¹ <http://www.business.gov.au/advice-and-support/EIP/Pages/default.aspx>

⁵² http://nsf.gov/news/news_summ.jsp?cntn_id=131760

(d) The relationship between advanced manufacturing and a dynamic innovation culture;

Recommendation 4

Provide the right financial and business environment for Medical Technology manufacturers to maintain their business or bring their operations into Australia

Innovation drives productivity and growth and knowledge-based manufacturing and related services still make up 70% of world trade. Advanced manufacturing and a dynamic innovation culture are closely related and local innovation is often lost when manufacturing is taken offshore. Australian manufacturing has declined in the last decade with its share of GDP falling from 14% to 8%. Only 10% of medical technology companies operating in Australia were established prior to 1970. Through the 1950s and 60s the industry experienced sustained growth but it was not until post 1970 that more rapid expansion occurred and a number of companies began manufacturing medical devices in Australia⁵³. Manufacturing in Australia is largely dominated by small companies who may not have the resource or expertise to dedicate to innovation programs. For the most part Australian manufacturers produce high-volume, low-value items. Professor Göran Roos, a world expert in innovation management, has stated that: *"There is a manufacturing sweet spot for Australia, which is low-volume, high-variability, medium-high complexity, and high-value-added. That is what we are very good at. You can't go to China and find those ... companies because they are about scale."*⁵⁴

Of the medical technology companies operating in Australia, approximately 23% are manufacturers, 21% are subsidiaries of multinational companies, and the remainder are independent distributors. Australia has excelled in the manufacturing of niche products to supply the global market. Examples include Resmed's devices to treat sleep disorders, Cochlear's electronic hearing implants, and Sirtex's Sirspheres' cancer treatment device. Of those employed in the medical technology industry, a large number are employed in the manufacturing sector. The Australian Bureau of Statistics (ABS) estimates that in 2009-10 there were 12,545 people employed in the medical technology manufacturing sector (this includes those in the medical and surgical equipment manufacturing sector, $n=11,199$ and those in the photographic, optical and ophthalmic equipment manufacturing sector $n=1,346$)⁵⁵.

Innovative businesses have a competitive advantage if they are able to commercialise new products faster than their competitors. In comparison to businesses that do not innovate, Australian businesses that innovate are twice as likely to report increased productivity and 40% more likely to report increased profitability⁵⁶.

A discussion paper released by the Future Manufacturing Industry Innovation Council identifies several factors that will support the robustness of Australian manufacturing. These include the capability to identify, design, develop, make and sell products that are in demand; maximise leverage from strong and sustainable partnerships through local and global supply chains; and seek markets in emerging growth economies⁵⁷.

⁵³ *Medical Technology in Australia: Key facts and figures 2013*, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2013)

⁵⁴ <http://www.theaustralian.com.au/national-affairs/innovation-key-to-keeping-manufacturing-onshore/story-fn59niix-1226761314445?nk=e7dc5ce1880a1f1a03dfb2a5538f9ab2>

⁵⁵ Sources ABS, Cat. No. 8159.0. Experimental Estimates for the Manufacturing Industry. 2009

⁵⁶ ABS (Australian Bureau of Statistics) 2011, *Selected characteristics of Australian business, 2009–10*, cat. no. 8167.0, ABS, Canberra

⁵⁷ *Future Manufacturing Council. Trends in manufacturing to 2020*. Canberra September 2011

Manufacturing Exports

Australia imports significantly more medical devices than it exports. Even smaller countries such as the Netherlands achieve a positive balance of trade. Some reasons for the net deficit in trade are:

- limited linkage between industry development and health purchasing meaning there is no effort by the health system to purchase clinically effective products which are the result of publicly funded research
- a lack of a broad mechanism that brings together all the partners in the industry including academics, venture capitalist, clinicians, regulator and the health system
- medical technology commercialisation is difficult and risky
- a lack of access to expertise and the necessary skills resulting in many small companies struggling to plan and execute a commercialisation strategy
- a lack of access to funding for emerging companies to progress research projects with commercial potential.

If Government does not make a sustained effort to provide incentives for medical technology manufacturers to maintain their business operations in Australia, as well as improving the business environment for medical technology commercialisation, it faces a very real risk that advanced manufacturing companies will move offshore to destinations where governments make a clear and strategic effort to establish supporting infrastructure around innovative companies. For example Singapore has established a medtech hub which offers:

- research partnerships with public sector researchers and clinicians
- Global Instrument Centre of Excellence in Singapore, which will design and manufacture next-generation instruments
- Medical Technology Manufacturing Consortium, a publicly-funded research agency to establish medical technology R&D platforms for knowledge transfer by exploiting the results of R&D collaboration with the research institutes, value chain partners and multinational corporations
- Singapore aims to build an industry-ready workforce to meet the needs of companies that require globally-oriented talent including engineering, regulatory science and clinical
- to encourage the formation of medical technology start-ups in Singapore, SPRING Singapore launched a S\$40 million Biomedical Sciences Accelerator Programme to support and nurture innovative companies and help bring their innovative ideas and technologies to the market
- Bio*One Capital is a dedicated fund manager which invests in innovative healthcare IT and device companies helping them grow and target market opportunities
- to accelerate the commercialisation process, locally based companies have opportunities to test-bed their ideas in collaboration with local hospitals.

Singapore makes it easy to do business. For medical technology companies seeking entry to regional markets, Singapore's pro-business stance makes it easy to commence operations within a short time frame. It takes 15 minutes to register a business online, three to six weeks to receive approval for clinical trials, and 24 to 36 months for a manufacturing facility to be operational.

There are few such incentives that encourage Australian companies to maintain their manufacturing operations in Australia. We need to shift our focus to growth sectors such

as the medical technology industry by providing incentives for companies to invest in additional research and development and local manufacturing much in the way that John Button's plans for the pharmaceutical industry were structured in the 1980s when he was the Minister for Industry. Not only would this have the potential to grow an industry that can develop solutions to complex health policy challenges but would also signal that Australia is an innovative country that values medical technology manufacturing as a key economic and social driver.

The UK Government has similarly focused on the need to transition its economy to high skilled manufacturing. The white paper *New Industry, New Jobs (NINJ)*⁵⁸, published in April 2009, set out a number of specific technological opportunities for economic growth and renewal. Advanced manufacturing is one of the six priority areas identified in the white paper where there is a global growth potential.

The value of innovation and advanced manufacturing needs to be recognised. A report⁵⁹ for the Advanced Medical Technology Association (AdvaMed) in the US, by The Lewin Group, Inc showed that each additional medical technology industry job created in the US generates an additional 4.5 jobs across the country. Each additional \$1 of payroll spent in the medical technology industry induces a further \$2.30 in added payroll across the country.

(e) Current policies, funding and procedures of Australia's publicly-funded research agencies, universities, and other actors in the innovation system;

Recommendation 5

- a) Establish or dedicate a division of the health system to develop a work plan on identifying, understanding and overcoming the barriers that are preventing medical technology adoption
- b) Identify entrepreneurial clinicians, universities and engineers and provide the resources to develop and implement technology solutions for immediate healthcare problems.

Lack of collaboration between industry and the healthcare system means Australia is missing out on economic and social opportunities in the form of new jobs, new export markets and access to state of the art medical technologies. Publicly funded research institutions in Australia need to be involved in the process of health technology adoption. International evidence indicates one way of doing this is to establish or dedicate a division of the health system to develop a work plan on identifying, understanding and overcoming the barriers that are preventing technology adoption.

The National Institute for Health Care Excellence in the UK has recently been tasked with taking on the responsibilities of the NHS Technology Adoption Centre. The Centre's role is to help the National Health Service (NHS) adopt innovative technologies such as surgical implants, diagnostic and remote monitoring services which have already demonstrated clear benefits to patients. It works directly with industry and NHS in order to improve technology uptake and develops 'adoption guidelines' that detail how the health system can sustainably introduce technologies for clinical use by outlining what the barrier is (e.g., staff training). Its role is also to provide advice to manufacturers of innovative medical technologies to navigate the complexities of the NHS to improve market access.

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http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/gb/policydocument/policydoc_mig0001

⁵⁹ The Lewin Group, Inc, *State Impacts of the Medical Technology Industry*, 2007

NHS has also funded the Health Technologies Adoption Programme to provide a system approach to the adoption of new technologies in three ways:

- engaging with front line health staff and services to understand and assess the factors that will promote access to, and increase the sustainable uptake of evidence based health care technologies
- establishing partnerships with academics to better engage, support and work alongside them to improve the identification, adoption and spread of innovation in the NHS
- supporting the expansion of the medical technologies industry in the UK by working in partnership with industry and providing advice to them to support the introduction of new technologies to improve outcomes for patients.

This scheme works with a small number of clinical staff to take a technology and sustainably bring it into routine use in clinical care. The team will produce a guide, detailing the activities and research that took place during each project including data collection, procurement of kit, pathway redesign, staff training and business case development. This information is then used as a case study for how to adopt new technologies.

Another example of how to prioritise technology adoption is the Center for Medicine and Innovative Technology (CIMIT) in Boston which is focused on finding ways of moving ideas from 'bench to bedside'. It does this through collaboration projects with world class experts in translational research, medicine, science and engineering with industry and government with the aim of improving patient services. CIMIT identifies entrepreneurial clinicians and engineers and provides the resources to develop and implement technology solutions for immediate healthcare problems. One of its priority projects is the development of medical technology to help military and civilian patients.

To achieve similar objectives, the NSW Medical Device Fund⁶⁰, announced in 2013, was developed to encourage development of new and innovative medical devices and to increase the uptake of NSW medical devices by the health system. The fund is a \$5 million per annum, competitive technology development and commercialisation program funded by the NSW Government, through the NSW Ministry of Health. In its inaugural year, \$10.3 million in funding was delivered to five projects. The fund provides key financial and expert technical assistance to companies when a working prototype is being developed.

More recently the Office for Health and Medical Research has announced funding for a medical device commercialisation training program to build commercialisation capabilities in NSW available to post-doctoral and other researchers with an interest in the development of medical devices. The program will be delivered by ATP Innovations who will deliver training in entrepreneurship, medical device design, development and commercialisation.

⁶⁰ <http://www.health.nsw.gov.au/ohmr/mdf/pages/default.aspx>

(f) Potential governance and funding models for Australia's research infrastructure and agencies, and policy options to diversify science and research financing;

Recommendation 6

Develop infrastructure to support research collaboration between academia, research institutes and industry at each stage of the medical life cycle.

Social infrastructure is a critical component of diffusion of knowledge amongst relevant parties. There is a lack of research collaboration between academia, research institutes and industry companies and many researchers work in 'silos'. Infrastructure is needed to support collaboration at each stage of the medical life cycle. There are significant gaps in how Australian companies access new knowledge and collaborate with the research sector. The 2011 *Innovations Systems Report* found that less than 5% of businesses had obtained information about new technologies from universities or research organisations⁶¹. A study undertaken in Sydney in 2010 led by Professor Roy Green examined the potential for industry clusters to deliver significant competitive advantage for regions with a concentration of innovative and entrepreneurial activity. The report found that while businesses in the biomedical sector are co-located in the Global Technology Corridor, there is a low level of collaboration and knowledge diffusion among the companies⁶².

There are several examples of successful medical technology industry clustering in other countries around the world. A reason for the success of Medicon Valley, which spans eastern Denmark and south-western Sweden, is because medical technology companies, research companies, universities and hospitals are co-located along with service providers to improve the innovation skills of members.

In Canada, MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE) is an innovation incubator which brings together a health system (the Ontario Health Technology Advisory Committee) and hospitals, academic institutions and industry. It seeks to harmonise health technology evaluation into a single pre-market evidence-based evaluation for technologies with disruptive potential and specific relevance to health system priorities.

The NSW Medical Technology Hub will provide an unprecedented opportunity to establish a collaborative network of expert industry partners including representatives from academia, venture capital, innovators and policy experts to focus on improvements in the business environment for the medical technology industry. The Hub's focus is on:

- developing policy and program ideas that establish a supportive business environment for all facets of the industry – manufacturers, distributors and importers of medical devices
- accelerating the translation of Australia's research investments into commercial products to be adopted in our health system and overseas by addressing the local challenges that prevent commercialisation opportunities.
- setting up the hub as the vehicle to coordinate all industry partners to work together more strategically to realise the industry's potential.

⁶¹ Australian Government, Department of Innovation, Industry, Science and Research. *Australian Innovation System Report, 2011*

⁶² Macquarie Graduate School of Management, University of Technology Sydney and Bugseye Pty Ltd in conjunction with Industry and Investment NSW and the Australian Business Foundation "Northern Sydney's Global Technology Corridor: A Scoping Study of Clustering Development" Sydney 2010

(g) The effectiveness of mechanisms within Australian universities and industry for developing research pathways, particularly in regards to early and mid-career researchers;

Recommendation 7

- a) Target students with information about the employment opportunities in the medtech sector and high value manufacturing.
- b) Support research in the health system, building health professionals' research capacity and maintaining the research excellence through training,
- c) Build enabling infrastructure through such things as patient databases, registries and biobank hubs

The industry's ability to grow depends on its capacity to recruit and the quality of candidates available. Increasing the number of technology based tertiary graduates is a priority. Effort must also be put into targeting school level students with information about the benefits of jobs in high value manufacturing. There are excellent tertiary programs available in centres of specialisation such as the new Institute of Biomedical Engineering and Technology at the University of Sydney. There are also strong biomedical engineering programs at Monash University, Flinders University, the University of NSW and the Queensland University of Technology. Biomedical engineering is the fastest growing area of engineering education but we need to do better in capturing the talent amongst our students and directing them into the industry. There is little formal collaboration between the universities and industry, an area that needs improvement. Collaboration will help to focus research into areas that support product development to meet identified need.

The Strategic Review of Health and Medical Research made a number of recommendations regarding the fostering of research. The recommendations included embedding research in the health system, building health professionals' research capacity and maintaining research excellence through training. The Review also recommended building enabling infrastructure through such things as patient databases, registries and biobank hubs.⁶³

The NSW Medical Device Commercialisation Training program is designed to provide researchers with commercialisation skills. It is available to post-doctoral and other researchers who have an interest in the development of medical devices. The three month intensive training program fulfils a commitment to build medical device commercialisation capacity in NSW. It contributes to the discovery and application of new treatments and diagnostic techniques to improve patient outcomes.⁶⁴

(h) Policy actions to attract, train and retain a healthy research and innovation workforce;

Recommendation 8

- a) Explore retraining of skilled workers
- b) Encourage school aged students to continue with mathematics and science in years 11 and 12
- c) Develop a long term MedTech workforce planning strategy depicting where the career opportunities are, where the gaps lie and what the future gaps are likely to be

⁶³ *Strategic Review of Health and Medical Research in Australia – Better Health Through Research.* Commonwealth of Australia, 2013

⁶⁴ <http://www.health.nsw.gov.au/ohmr/Pages/nsw-medical-device-tp.aspx>

in the context of global trends

The medical technology industry in Australia employs over 19,000 people. Employees are highly qualified with 50% having a tertiary qualification and 21% having a postgraduate qualification⁶⁵. During 2007 Deloitte was commissioned by the Department of Industry, Tourism and Resources to conduct a skills audit for the medical technology industry in Australia. This resulted in a comprehensive report called the *Skills Audit of the Medical Devices Industry 2007*. As identified in the report, the Australian medical technology industry is a knowledge-based industry that is expected to face significant challenges in the future to meet its increasing skills needs.

In order to advance the medical technology sector in Australia it is critical to have access to a sufficient number of appropriately skilled workers. The lack of a skilled workforce is identified by manufacturers in particular as a significant challenge. The skills required for manufacturing of medical devices are similar to those used in the automotive industry. They include high skilled engineering, componentry, miniaturisation, computerisation, and materials science. The Federal Government administers a variety of programs targeted at the automotive industry including the Structural Adjustment Program⁶⁶, aimed at offering employment and training assistance to automotive workers. Consideration should be given to using these programs to benefit medical device companies and re-train available skilled workers into a growing industry sector.

MTAA is seeking to conduct an external review of workforce needs specific to the medical technology industry. MTAA aims to develop a long term workforce planning strategy depicting where the jobs are, where the gaps lie and what the future gaps are likely to be. We hope to better understand what the skill gaps are for current employees, as well as the 'job readiness' of new entrants by fostering linkages between universities and companies.

Using data from the review MTAA will develop a strategy to work with government, companies and the university sector to:

- increase the number of qualified workers for careers as regulatory affairs specialists, reimbursement specialists, product R&D engineers, health economists, business development, operational personnel (HR, T&D, finance, IT, senior management), sales and marketing professionals, in particular for export
- develop a strategy to retrain workers in traditional manufacturing roles for advanced manufacturing
- develop a strategy to promote the medical technology industry and its employment opportunities to high school students, university students and the broader community
- establish better networks with universities to ensure a pipeline of qualified graduates continue to meet the changing needs of the industry's workforce.

The review will enable MTAA to better understand who is working in our industry, now and in the future. Consideration needs to be given to changing the perception that manufacturing jobs are blue collar, low skilled and low paid. In fact, the medical technology industry is highly skilled with 50% being tertiary qualified. School aged students need to be encouraged to continue with mathematics and science in years 11 and 12. This would place them well to study engineering and gain employment in companies such as Cochlear, ResMed and innovative SMEs.

⁶⁵ Estimate from MTAA database and MTAA industry wide survey 2012

⁶⁶ <http://www.industry.gov.au/industry/automotive/InitiativesandAssistance/Pages/AISAP.aspx>

(i) Policy actions to ensure strategic international engagement in science, research and innovation; and

Recommendation 9

- a) Link Australian companies to international research agencies for collaboration of ideas, which will assist them in becoming part of the global solution
- b) Mentoring support companies and researchers to identify pathways through the available 'jungle of opportunities'

The value of the worldwide medical technology market is expected to reach \$440 billion by 2018⁶⁷. The largest drivers of growth are an aging population and an increase in the ability of emerging markets to pay for medical technology. Innovation is a vehicle to international markets and businesses engaged in these markets tend to be innovative⁶⁸. The 2012 *Australian Innovation System Report* found that innovative Australian businesses are three times more likely to export than those that do not innovate⁶⁹.

The US is the traditional epicentre of medical technology innovation. While the US remains the biggest market, Asia holds the biggest promise with the Asia-Pacific market for medical technologies expected to account for 25% of global market share by 2012⁷⁰. The growth rate alone is projected to be double that of worldwide growth figures by 2015⁷¹. Asia is fast becoming a major market for medical technologies due to rapid growth of a middle class with a desire for improved healthcare products. The major theme of the 2013 *Australian Innovation System Report*⁷² is engagement with Asia. The report notes that two key factors are fundamental to successful business engagement with Asia – innovation capacity and knowledge of Asian markets (also termed 'Asian literacy').

Increasing health costs is an issue facing most countries. Medical technology companies are part of the healthcare solution. Linking Australian companies to international research agencies allows for collaboration of ideas, which will assist them in becoming part of the global solution. Mentoring support to identify pathways through the available 'jungle of opportunities' will be invaluable.

(j) Policy options to create a seamless innovation pipeline, including support for emerging industries, with a view to identifying key areas of future competitive advantage.

Recommendation 10

- a) The MedTech sector works across and adds value to various government portfolios and the Department of Industry should provide leadership to ensure collaboration between and understanding of the health, education, employment, small business, treasury/finance, innovation, manufacturing and trade portfolios
- b) Provide market intelligence on trends, both overseas and nationally, to enable Australian SMEs, entrepreneurs and researchers to respond to identified

⁶⁷ *Medical Technologies What's hot and key trends in medtech in 2013*. Results Healthcare, 2013

⁶⁸ Elko, J. Et al., (1988). The Performance Impact of an International Orientation on Product Innovation, *European Journal of Marketing*, 22(10), 56–71.

⁶⁹ Australian Government (2012) *Australian Innovation System Report—2012*, DIISRTE, Canberra, p.6

⁷⁰ *Glowing Prospects in Medical Technology: Singapore MedTech Directory 2011/2012*.

<http://www.singaporemedtech.com/Indprof/MED/ED01.pdf>

⁷¹ Frost & Sullivan: *APAC's Medical Devices Market ready to skyrocket (2010, 17 June)*.

<http://www.frost.com/prod/servlet/press-release.pag?docid=204528598>

⁷² Australian Government, Department of Industry, *Australian Innovation System Report 2013*.

opportunities

Creating a Seamless Innovation Pipeline

Medical technology contributes to and works across many government portfolios. To deliver a strong programme, we would recommend the Department of Industry provides leadership to ensure collaboration between the health, education, employment, small business, treasury/finance and trade portfolios.

The environment to foster innovation cannot be 'right in just one area'. One of the most critical interconnection points is changing the way the healthcare system and industry interact.

1. The lifecycle of medical technology is a seven stage process.
2. Research
3. Product requirements, assessment
4. Engineering, design, technical clinical/advice
5. Manufacturing
6. Regulatory approvals
7. Sales and marketing
8. Product support and improvement

Overlaying all this is the need for business planning skills and access to funding. There are existing government programs at state and federal level to help individual companies at all of these stages including business and financial planning advice.

Areas of Future Competitive Advantage

Australia has a good public health system with strong clinical research capabilities and a highly educated workforce. Backing all of these attributes is an internationally respected and stable finance system. Australia is in close proximity to Asia which is becoming a major market for medical technologies with rapid growth in a middle class with a desire for improved healthcare. Medical technology solutions need not be limited to high end niche products. There is an opportunity for innovative Australian companies to respond to the need of many Asian countries for more frugal technology which is suitable for low resource settings. This need has been identified by the WHO which has put out a call for innovative technology in each of the past two years. Australian innovators have identified and responded to this need. For example, the hand-held personal ultrasound device developed by Signostics Ltd in Adelaide is completely portable and can be used in low resource settings. The company was established as a start-up in 2005 and is now a world leader in the manufacture of the world's smallest portable ultrasound systems. The company's most recent product, Signos RT, has recently been unveiled.

Medical technologies are often 'disruptive technologies', for example mobile health and telehealth. A disruptive innovation helps create a new market and value network and often displaces an earlier technology. Mobile health and telehealth are examples of key areas of future competitive advantage with the medical technology industry.

Mobile health is based on the delivery of healthcare services using smart phones and tablets. The use of a smart phone to deliver health information or measure vital signs provides a viable alternative to a patient having to attend a costly healthcare facility. The

mobile health market is still in its infancy. However the 2011 market was estimated at \$720 million and is rapidly increasing⁷³.

Telehealth is the delivery of medical services through information technology and telecommunications. It is an overarching definition that includes remote monitoring or the exchange of medical data between a patient who is at home and a healthcare professional based (usually) in a medical centre or call centre. A number of surgically implanted devices can be monitored remotely for clinical or device assessment (e.g., pacemakers). Remote monitoring is particularly well-suited to Australia which has approximately one-third of the population living in rural and remote areas.

The medical technology industry in Australia has all the prerequisites to become a successful, globally relevant and competitive industry employing highly skilled engineers, improving our advanced manufacturing capabilities and drawing on the research expertise of Australia's clinical, university, research organisations and innovative companies.

Conclusion

The Medical Technology sector adds value to many aspects of the economy and society. Above all medical devices change and give active life to those who need it most. We deliver the technologies that diagnose, prevent, treat and manage disease and disability. We are partners in innovation – finding new ways to deliver services with finite resources – but the environment is not conducive for the Australian originated idea or company to commercialise and grow.

The establishment of a Medical Technology Blueprint will give a vision and a framework to create an optimal business environment for an innovative industry. The health, research and development, education, business, trade, employment and economic development aspect of the MedTech Blueprint will prepare Australia for the increasing demand on health care services by the population living and needing to work longer and the burden of chronic illnesses. A sustainable health care system and a sustainable medical technology industry are commensurate goals.

⁷³ *Medical Technologies What's hot and key trends in medtech in 2013*. Results Healthcare, 2013

Appendix 1. Government Assistance Programs for Medical Technology Innovators

Research and Development	
Federal Government Programs	R & D Tax Incentives Research Service Providers Australian National Fabrication Facility Co-operative Research Centres (CRCs)
State Government	
QLD	Science and Research Project based funding, support for commercialisation. Additional assistance from the Queensland Office of Health and Medical Research
NSW	TechVouchers Opportunities for SMEs to create research collaborations, seed funding of up to \$15,000
VIC	Technology Voucher Program Vouchers are valued between \$50,000 and \$250,000 Innovation Voucher Program Includes two vouchers: the Business Research and Development Voucher (value up to \$25,000) and the Innovation Skills Voucher (value up to \$10,000)
SA	Innovation Voucher Program Between \$10,000 and \$20,000 is awarded on a competitive basis to eligible research and development projects that partner SMEs with an annual turnover of less than \$20 million
WA	Innovation Promotion Program Maximum funding of 25,000
Commercialisation	
Federal Government Programs	Entrepreneurs' Infrastructure Programme Venture Capital Programs Ausindustry
State Government	
Joint State Initiative	Medical Research Commercialisation Fund (MRCF) Investors gain access to promising technologies
NSW	Medical Devices Fund Promotion of new and innovative medical devices/technologies within NSW that may have a global benefit. Funding in the range of \$50,000 to \$5 million Innovate NSW Three components. 1. Minimum Viable Product (MVP) (matched funding of 50% of project costs). 2. TechVouchers 3. Collaborative Solutions
VIC	Smart SMEs Innovation Commercialisation Program Aims to increase the rate of technology commercialisation by assisting the development and growth of technology businesses, products and services Health Market Validation Program \$15million competitive grants program that encourages innovation in healthcare

SA	Medical Technologies Program (MTP) Supports the early stage development of new commercially viable medical and assistive devices. Delivered as part of the Medical Device Partnering Program (MDPP) based at the Flinders University Medical Device Partnering Program Supports the development of medical devices through collaborations between researchers, industry, end-users and government
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Business Improvement/Growth	
Federal Government Programs	Medical and Scientific Technologies Suppliers Advocate Manufacturing Precinct (META) Austrade Austrade offers the Export Market Development Grant (EMDG)
VIC	Technology Trade and International Partnering Program (TRIP) Grant assistance for companies to attend recognised overseas conferences, trade events and meetings
SA	Gateway Business Program Assists SMEs prepare for export, reimbursement of eligible export-related expenditure

Appendix 2: The attributes needed for the perfect environment

The MedTech sector works across and adds value to portfolios.

	The attributes needed for the perfect industry environment				
Government portfolios	Skills/Employment	Access	Business environment	Innovation	Exports/Trade
Communication		<ul style="list-style-type: none"> communication infrastructure to effectively deliver remote monitoring capability 			
Education	<ul style="list-style-type: none"> secondary school curriculum university understanding of industry mentoring internships 			<ul style="list-style-type: none"> foster research in health related areas 	<ul style="list-style-type: none"> support international collaboration
Employment	<ul style="list-style-type: none"> skilled workforce opening of new industries 		<ul style="list-style-type: none"> employment regulatory environment 		
Defence	<ul style="list-style-type: none"> growth diversification skills 		<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> foster research in health related areas 	<ul style="list-style-type: none"> support international collaboration
Veterans Affairs		<ul style="list-style-type: none"> continue support for remote monitoring 			
Social Services	<ul style="list-style-type: none"> 	disabled <ul style="list-style-type: none"> quality of life contribution to society health at home ageing <ul style="list-style-type: none"> quality of life contribution to society/ volunteer contribution health at home 	<ul style="list-style-type: none"> aged care regulations 	<ul style="list-style-type: none"> foster innovation in aged care delivery foster cultural change to accept innovation 	<ul style="list-style-type: none"> support international collaboration
Health	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> TGA regulations 	<ul style="list-style-type: none"> clear health priorities 	<ul style="list-style-type: none">

			<ul style="list-style-type: none"> • duplication of processes and costs 	based on demographics <ul style="list-style-type: none"> • leadership across portfolios • culture change in adopting innovation • rural and remote access • industry/hospital partnerships which include research institutions, universities and medical/health workers 	
Infrastructure and Regional Development		infrastructure <ul style="list-style-type: none"> • working with industry to plan infrastructure for creation of technology parks planning <ul style="list-style-type: none"> • conducive environment for remote and in home care 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •
Industry	<ul style="list-style-type: none"> • research skills • commercialisation skills • linking collaboration opportunities physical virtual 		<ul style="list-style-type: none"> • R&D tax environment • adoption of Australian Innovation and Manufacturing Incentive • small business red tape • innovation red tape (IP protection) 	R&D <ul style="list-style-type: none"> • conducive environment (culture and finance) • development of hubs • linkages (education and industry) • partnerships – research/ medical/health/ and industry manufacturing <ul style="list-style-type: none"> • roundtable of med tech stakeholders to plan the “MedTech industry via a blue print” small business <ul style="list-style-type: none"> • effective small business environment 	<ul style="list-style-type: none"> •
Foreign Affairs and	<ul style="list-style-type: none"> • 		<ul style="list-style-type: none"> • adoption of Australian 		<ul style="list-style-type: none"> • access to fair trade

Trade			Innovation and Manufacturing Incentive		<ul style="list-style-type: none"> • develop export ready companies • access to networks (overseas) • inwards investment attraction • research institution/ industry international collaboration
Treasury/Finance	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • modelling and use of international experience in benefits of home/remote monitoring 	<ul style="list-style-type: none"> • taxation system review • adoption of Australian Innovation and Manufacturing Incentive 		<ul style="list-style-type: none"> •
Prime Minister and Cabinet	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • indigenous communities have access to health services and devices with remote monitoring 	<ul style="list-style-type: none"> • red tape • TGA white paper • adoption of Australian Innovation and Manufacturing Incentive 		<ul style="list-style-type: none"> •