



ATSE

SUBMISSION TO THE

Senate Community Affairs Legislation Committee Inquiry into the Medical Research Future Fund Bill 2015 and the Medical Research Future Fund (Consequential Amendments) Bill 2015

JULY 2015



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President
Dr Alan Finkel AO FTSE

10 July 2015

Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Committee Secretary,

**Medical Research Future Fund Bill 2015 and Medical Research Future Fund
(Consequential Amendments) Bill 2015**

I write on behalf of the Australian Academy of Technological Sciences and Engineering (ATSE)¹ regarding the inquiry into the Medical Research Future Fund Bill 2015 and Medical Research Future Fund (Consequential Amendments) Bill 2015.

ATSE agrees with the Government that future discoveries in medical research will contribute to improving the health and wellbeing of all Australians. ATSE also believes that such discoveries in medical research require translation into medical services, technologies and devices. This may be achieved through established or start-up firms which will gain commercial benefits, grow the sector, create jobs and ultimately strengthen the economy.

Within the Bill, *medical innovation* is defined as “*the application and commercialisation of medical research, and the translation of medical research into new or improved medical treatments, for the purpose of improving the health and wellbeing of individuals*”. We suggest amending this definition in order to include medical technologies and devices. While medical treatments are necessary for improving the health and wellbeing of individuals, devices and technologies are powerful tools in the diagnosis and management of disease, and the ongoing monitoring and maintenance of health.

The MRFF is an opportunity to consider specific investment in multidisciplinary, project-driven research. Today’s healthcare system is technology dependent, and many of the future advances will depend not only on medical expertise but on collaborative contributions from

¹ ATSE advocates for a future in which technological sciences, engineering and innovation contribute significantly to Australia’s social, economic and environmental wellbeing. The Academy is empowered in its mission by some 800 Fellows drawn from industry, academia, research institutes and government, who represent the brightest and the best in technological sciences and engineering in Australia. The Academy provides robust, independent and trusted evidence-based advice on technological issues of national importance. ATSE fosters national and international collaboration and encourages technology transfer for economic, social and environmental benefit.
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engineers, computer scientists, physicists and chemists. Such research has high capacity for translation of research and innovation into end use products and processes.

While our medical research institutes are world class, so too are our universities. More than 75 per cent of all medical research is conducted in universities. Indeed, Australian universities have a proven track record in translating innovative medical research into end use applications for the economic and social benefit of Australia.

For example:

- Cochlear's bionic ear, now implanted in over 200,000 patients worldwide, was developed out of Melbourne University;
- Gardasil, the only human papilloma vaccine, now used in 120 countries with 170 million doses delivered worldwide, was developed at Queensland University;
- Relenza, used in the treatment and prophylaxis of influenza caused by influenza A and B viruses, was developed at Monash University in collaboration with CSIRO and the Victorian Pharmacy College; and
- IVF technology was pioneered at Monash University.

Funding should support the commercialisation of medical technologies from medical research institutes, universities and start-up firms. The key to maximising economic benefit from medical research is to ensure the MRFF harnesses all of Australia's medical research expertise and that clinical and market based outcomes are specifically pursued. To achieve this, MRFF funding allocations will need to be competitive, assessed by expert review and merit based. ATSE suggests that a significant proportion (at least 50 per cent) of the funding should be allocated for translational clinical trials and for project-driven multidisciplinary research (such as occurs for a bionic eye, limb prosthetics and other medical devices). This will ensure the Fund promotes not only improved health outcomes for all Australians but will also foster enhanced researcher-industry engagement, a highly skilled and innovative workforce, and profitable and competitive companies in the biomedical, medical technology and devices sectors.

For your reference, the ATSE Health Technology Position Statement and Action Statements accompany this submission.

Further to the comments raised in this submission, ATSE would be pleased to offer its considerable expertise. If ATSE can be of any assistance, please contact Ms Sarah Parker, Senior Research and Policy Officer

Yours sincerely,

Dr Alan Finkel

AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING (ATSE)



ATSE

HEALTH TECHNOLOGY

ADVANCED TECHNOLOGICAL SOLUTIONS FOR A HEALTHY AUSTRALIA

POSITION STATEMENT JULY 2014

This Health Technology Position Statement supports the ATSE 2013-2017 Strategy Plan which sets out the priorities and approaches the Academy will take to promote the application of technological sciences and engineering into innovation for the benefit of Australia.

ATSE CALLS FOR THE DEVELOPMENT AND DEPLOYMENT OF ADVANCED TECHNOLOGICAL SOLUTIONS FOR A HEALTHY AUSTRALIA.

Healthcare must be effective and affordable. To deal effectively with changing demographics and patterns of disease, Australia must develop and deploy advanced technologies that are effective across all populations, including the aged and people with disability. Technologies can play a major role in reducing healthcare costs when they are socially accepted and widely adopted. Such technologies can also enhance Australia's economy if they are developed from a strong Australian industry base which draws on world-class research and development.

WORLD DEMOGRAPHIC CHANGE

The world is undergoing unprecedented demographic change. The global population is currently 7.2 billion, with United Nations projections that it will reach 9.6 billion by 2050. This growth will place greater demand on resources, infrastructure and expenditure. Further, globally, the number of those over the age of 60 is expected to double from 2013 to 2050, by which time around 21 percent of the population will fall in this age category.

The pattern of morbidity is also changing from predominantly acute or infectious diseases to chronic disease such as many cancers, cardiovascular disease and dementias, alongside dramatic increases in the rates of obesity and diabetes. The aged population in particular often suffer from multiple chronic diseases, which pose serious long-term impacts on healthcare demand, creating an urgent need for new innovative approaches to healthcare design and delivery.

Visionary health policy is central to economic outcomes and sustainability. Much will depend, for both economic growth and health budgets, on the wellbeing of large cohorts of people as they age. If effective health innovation allows individuals to stay healthier and active for longer, labour supply can increase and future health and social support costs be contained.

CHALLENGES FOR AUSTRALIA'S HEALTHCARE SYSTEM

Australia's population is currently around 24 million people and is projected to grow to around 36 million by 2050. Australia's growth will occur against the background of a continuing demographic transition from a predominantly younger population to a much larger population of those over 65 by 2050 (13 per cent to about 22 per cent). These population changes pose significant economic implications in terms of increased healthcare expenditure, infrastructure requirements and the increased need for healthcare and aged care workers across larger cities and remote and regional Australia. The challenges for the healthcare system also present economic opportunities via Australia's new wave of medical device industries. This industry sector, if adequately supported, has enormous capacity to translate the considerable investment being made in medical research into practical end use processes and products that enhance the lives of Australians.

Australia's total spending on healthcare in 2011-12 of \$140 billion accounted for 9.5 per cent of gross domestic product (GDP), slightly above the OECD average of 9.3 per cent. This has grown 41 per cent from \$82 billion in 2001-02. Increases in health expenditure are contributed to a range of factors, including more people of all ages who visit the doctor more often, having more clinical tests than before and being prescribed more prescription drugs.



Increased demand for medical services and the use of new and expensive technologies has seen the proportion of GDP expended on healthcare rise, and is projected to increase to about 11 per cent by the mid-2030s. This projected increase in expenditure can provide net gains in the health and quality of life of Australians and reduced healthcare costs in the long-term, but only if it includes substantial and widely implemented health measures.

Funding for high-level residential care is projected to double to about 2 per cent of GDP by the mid-2030s. This is largely due to increased rates of dementia in those aged over 85 years. There will be an increased need for carers at a time when the proportion of younger people is in decline.

The current model for healthcare delivery is unsustainable and alternative ways of addressing healthcare challenges are urgently needed.

PRIORITY FOCUS AREAS

The worldwide market for medical devices is very large. The application of new technologies such as biotechnology, nanotechnology, information and communications technologies, and cognitive science is leading to the development of smarter and more effective technologies, particularly for the aged and people with disability. New technologies are also leading to the development of diagnostic tools for personalised and preventive medicine. Greater diagnostics and treatments targeted at dementia and based on the use of new and emerging technologies can reduce healthcare costs.

Major breakthroughs in the future are likely to come from collaboration between research disciplines, where clinical research will be integrated with various engineering, information communications technologies and science disciplines. Improved mechanisms for funding and performing medical based interdisciplinary research will need to be developed.

Technology provides enormous opportunities to enhance the effectiveness of the healthcare system, such as:

- **Genetic diagnostic testing** – to accelerate the correct diagnosis and enable preventive action;
- **'On-the-spot' decisions** – to reduce errors, reduce wait times and unnecessary deaths;
- **Cloud computing** – to streamline patient records, practice management and care coordination;
- **Robotics** – to assist in day-to-day operational activities and assist training in remote and regional Australia;
- **Assistive health technologies** – to enable independent living by supportive, preventive and responsive mechanisms;
- **mHealth technologies** – to assist in the prevention and self-management of disease via mobile devices);
- **eHealth technologies** – telehealth and telecare to deliver health services at home and in the community and facilitate off-site education; and,
- **Effective information communications technologies systems** – that are standardised and interoperable across States are fundamental to delivering remote healthcare services.

While many countries are actively looking to new approaches to healthcare, it is important to recognise that application of smart technologies will be disruptive to current models of service delivery. ATSE aims to explore the broader aspects of the application of current and emerging health technologies and their effects on the health, social and economic wellbeing of Australians, which is necessary for widespread uptake.

THE WAY FORWARD

The Academy has identified priority focus areas in which world-leading research, knowledge generation and innovative technology can be applied to address our societal needs and demands into the future. From these, ATSE has identified three Health Priority Areas for action in order to advance technological solutions for a healthy Australia:

1. Deploy assistive technologies for the aged and people with disability to improve quality of life.
2. Develop technologies for personalised and preventive healthcare.
3. Grow and promote a globally competitive medical device industry in Australia.

ATSE has further developed a series of Action Statements setting out key priorities for the development and application of health technologies which can reduce the cost of delivering healthcare services.

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DEPLOY ASSISTIVE TECHNOLOGIES TO IMPROVE QUALITY OF LIFE

JULY 2014

The rapid national large scale deployment of assistive technologies is essential if the growth in healthcare costs is to be contained, to reduce unnecessary hospitalisation and enable the aged and people with disability to better self-manage their health and remain at home longer.

THE CHALLENGE

Chronic illness and aged care accounted for over 70 per cent of Australia's \$140 billion expenditure during 2011–12. The Australian economy cannot sustain this expenditure over the long term. Health is now the second largest area of Australian government expenditure. Hospitals, doctors and medicines dominate our national health spending. Prices for dental, hospital and medical services have risen more strongly than the consumer price index this decade.

Australia's hospital-centric public health system is designed for acute care and is unnecessarily burdened by the management of chronic disease. The delivery of chronic disease management could be shifted to home and community settings at a lower cost and with no loss of quality in services and treatments.

Telehealth and telecare technologies and services for the management of chronic disease at home and in the community have been of intense interest in developed western economies. This is because of unprecedented growth rates of the ageing population and increasing morbidity as population ages, which are placing great stress on established health care services. The result will be increasing deficits in clinical human resources, rapid expansion of disease management programs and increased patient demand for greater self-management.

Telecare and telehealth services delivered at home via information and communications technologies (ICT) have been demonstrated to deliver cost effective, timely and improved access to quality care. They also reduce social dislocation and enhance the quality of life within these communities by allowing chronically ill, the aged and people with disability to stay in their homes and communities longer.

Australia's experience with the deployment of telecare and telehealth services is limited. Most deployments are small scale and lacking detailed analysis of key success factors such as:

- Healthcare outcomes;
- Economic benefits;
- Impact on clinical work force availability and deployment;
- Acceptability and usability by patients, carers, nurses, General Practitioners and administrators;
- Workplace culture; and
- Organisational change management and business processes.

Despite large national investments in health ICT, very little policy work has been undertaken in Australia in deploying telecare and telehealth in the home as a solution to the increasing demands and costs of managing chronic disease.

Evidence for ageing demographics and the increasing burden of chronic disease is evident from the fact that Australians:

- aged over 65 are projected to increase from 3.2 million to 5.8 million in 2031, and that
- currently, 61 per cent have a single chronic condition and 22 per cent have multiple chronic conditions; and
- high care nursing homes in Australia have approximately 200,000 high care residents. There are also over 6,000 people with disability under the age of 65 in nursing homes, adding extra pressure to available services.

There is a need for policies and funding mechanisms to support efficient home services and the widespread use of assistive technologies. This could bring significant cost savings to both State and Federal Governments and health and age care consumers.

Policies and funding models are needed that are consistent, robust, auditable, long term and directed to those most in need must be developed. This will require:

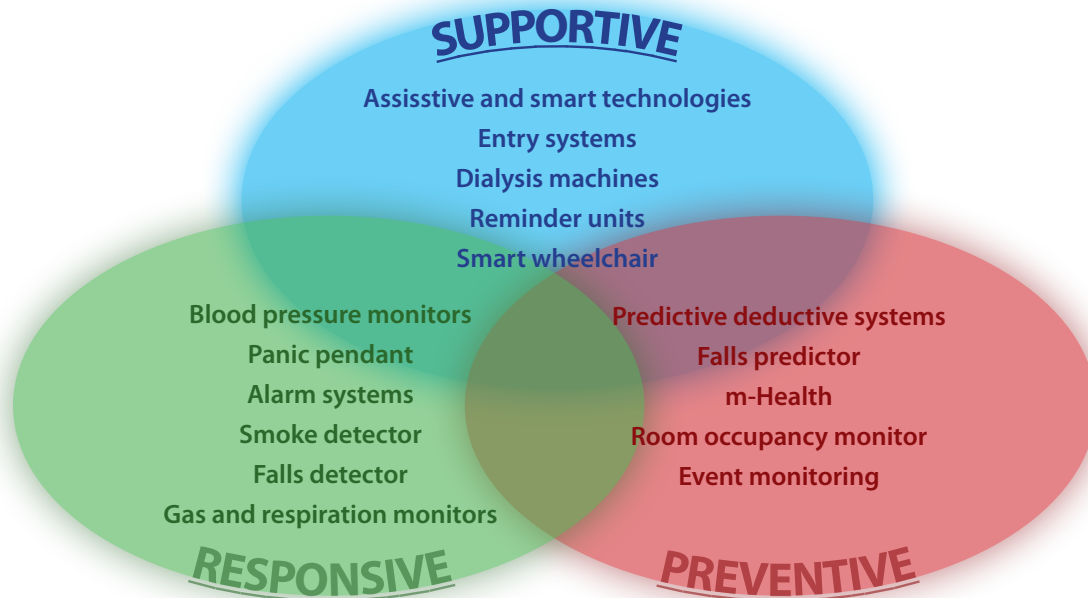
- Better coordination of State and Federal Government agencies;
- Better funding and re-imbursalment models; and
- Creation of new public and private sector markets and the participation of the aged care sector and not-for-profit sectors.

There is an urgent need for measures that reduce unnecessary admissions to hospitals particularly through active management of people needing aged care and people with disability.

THE VISION

- There is growing recognition that assistive technologies offers tools to reduce long term care costs by maintaining the aged in the community and reducing the cost of unnecessary hospitalisation.
- Citizens can remain healthy and well in their own homes for as long as possible supported by efficient home services and the widespread use of a range of assistive technologies (Figure 1).
- Large scale educational campaigns will inform citizens and service providers of the range of assistive technologies available and financial assistance they could be eligible for payment.
- Workforce development and capacity building should be a key platform for Governments of all persuasions.
- Significant increases in funding for research and development (R&D) and innovation in assistive technologies are needed.
- The use of ICT systems will be fundamental to monitor and deliver healthcare in remote settings, therefore systems will be interoperable, standardised and co-ordinated.

Figure 1: Assistive technologies can facilitate independence through supportive, responsive and preventive mechanisms.



Source: Adapted from 'Assistive Technology, Independence and Well-Being 4', UK Audit Commission, 2004.

RECOMMENDATIONS

ATSE believes that Australia can deploy assistive technologies to reduce healthcare costs and improve quality of life for the aged and people with disability by addressing these priority actions:

RECOMMENDATION 1:

State and Federal Governments should implement policies that facilitate a range of services and service delivery mechanisms that enable citizens to remain independent, safe and healthy in their own homes for as long as possible.

RECOMMENDATION 2:

Research funding agencies and the private sector should work together to support R&D and innovation across the whole range of assistive technologies, recognising the particular challenges and complexity of delivering healthcare services in unsupervised settings.

RECOMMENDATION 3:

Regulatory and ethical approvals processes should be streamlined to reduce costs of the design, development and marketing of new assistive technology products and to ensure the wide implementation of new health service delivery models that are safe and efficacious.

RECOMMENDATION 4:

Education and capacity building activities are needed throughout the aged care sector, including health care providers, carers, ICT specialists, service providers and members of the community.

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**HEALTH
TECHNOLOGY
ACTION STATEMENT**



**DEVELOP TECHNOLOGIES
FOR PERSONALISED AND
PREVENTIVE HEALTHCARE**
JULY 2014

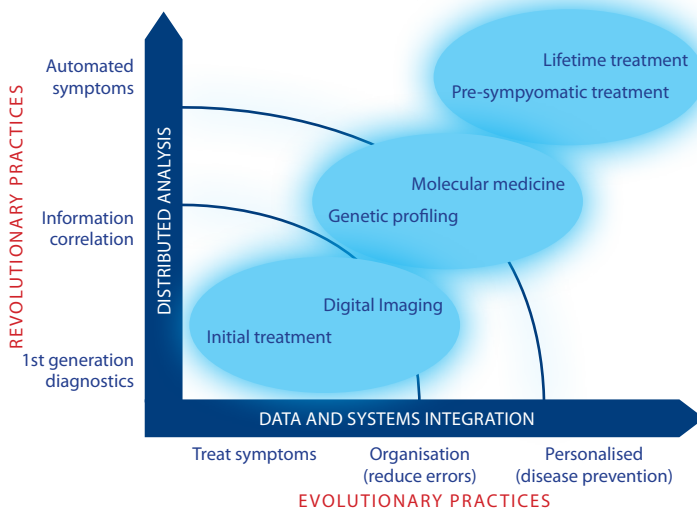
Interactive technologies are being developed to assess and improve the health of every Australian for earlier disease detection and diagnosis. Shifting the focus of healthcare towards prevention of disease could significantly reduce the high cost of long-term treatment of chronic disease and conditions. Helping clinicians and the end-users to understand the use and associated benefits of these new technologies will greatly impact on future health outcomes for Australians.

THE CHALLENGE

The cost of healthcare in countries like Australia is escalating with an ageing population and longer lifespans. The availability of treatments for chronic diseases and conditions is increasing. In Australia, the \$140 billion annual healthcare costs are dominated by cardiovascular disease and obesity (AIHW). The incidence of both cardiovascular disease and obesity can be reduced through preventable measures.

In the 21st-century, the focus of healthcare (Figure 1) will shift the current strategy of clinical diagnosis and prescription pharmaceuticals to a model that will provide more personalised healthcare. This will improve health outcomes and provide mechanisms to prevent disease and address consumer demand for an improved quality of life. Awareness campaigns are needed to inform the public on the benefits of new and improved health-related technologies. These campaigns will also need to address controversial aspects such as the safety of vaccines, the validity of genetic profiling and the security of electronic health records.

Figure 1: Market trends and drivers: revolutionary technologies and evolutionary practices



Source: Adapted from *Personalized healthcare 2010, Are you ready for information-based medicine*, IBM Life Sciences Solutions.

The use of genetic testing/profiling for disease prediction has become commercially affordable. This new approach integrates an individual's genetic profile with their physical characteristics, traits and metabolic status in order to assess an individual's overall health. Analysis of individual gene profiles can ultimately direct personalised nutrition and lifestyle programs to improve health, wellness and ageing. As a consequence, expenditure on healthcare assessments may increase, but these costs will be offset by net gains in productivity and quality of life. However, there are various ethical concerns surrounding security and privacy regulations for the large volumes of information obtained by genetic testing. This should be addressed.

The complexity of disease means that no single technique will be powerful enough to measure across a range of variables. This will require multi-parameter testing techniques and diagnostics to be developed. The analysis and potential for personalised treatments will rely heavily on more sophisticated information communications technology systems that can cope with the demands of masses of information

Advances in personalised medicine will engage a wide range of health and allied healthcare professionals in nutrition, psychology, information and communications technology (ICT), mobile health telephone applications (mHealth) and electronic health records and databases (eHealth). The greatest strength of genomic information lies in its personalised molecular information and predictive power. The use of mHealth technologies and related electronic devices that can track disease patterns, monitor medication usage and improve management of chronic disease offer preventive capabilities. These approaches will benefit both the young and aged populations, and can help reduce the rising incidence of obesity and diabetes.

Adoption and widespread use of personally controlled electronic health records has encountered multiple barriers. Healthcare providers need the necessary ICT infrastructure to store, mine and systematically integrate and analyse genomic information with other medical data. The successful integration and analysis of these data will drive beneficial health outcomes, while security and privacy measures are tightly regulated. Fundamentally, this will require the movement of hospital records to electronic format so efficient health information can be exchanged rapidly.

The use of mHealth technologies could be enhanced by evidence-based promotion of potential benefits applications by end-users to improve



their own health and wellbeing and enhance widespread adoption within the national healthcare system. Study outcomes should be supported by State and Federal Governments and private medical insurers. Pilot studies undertaken with these authorities can provide pivotal and validated evidence that will help to ensure public acceptance. Fast and reliable broadband connectivity across Australia will provide some technologies with the added capability to enhance health outcomes of individuals.

Transformation of the healthcare system depends largely on speed of uptake of these new technologies. Implementing them at multiple stages in both the prevention and the treatment of disease is a challenge that needs urgent attention.

- Health outcomes for individuals are enhanced because technologies are targeted and tailored to individual needs;
- Improved health and disease prevention is translated to increased productivity and economic benefit for the nation;
- Medical practitioners take up international best practice as new technologies are developed. Practitioners are encouraged to make best use of informatic and diagnostic data to apply these technologies in routine clinical practice;
- Individuals are better informed on the effect that personal lifestyle choices have on individual health (such as smoking, diet, alcohol and exercise) through community or educational approaches;
- Compliance rates for prescribed medication and diet and lifestyle are monitored effectively, both by the individual and by medical practitioners;
- Australia gains major benefits through the wider application of new preventive healthcare technologies. This would be assisted by the establishment of new and better regulatory routes to assist the approval process of the Therapeutic Goods Administration; and,
- Electronic health records and national databases are integrated to provide optimal translation of medical data for improved healthcare.

THE VISION

An Australian healthcare system in which:

- Individuals can obtain better health outcomes using a personalised and preventive approach that makes better use of new technologies and reduces healthcare costs;

RECOMMENDATIONS

ATSE believes Australia can develop technologies for application across personalised and preventive healthcare sectors. This can be achieved by addressing priority actions within a policy framework committed to drive health benefits by prevention strategies and via technology deployment.

RECOMMENDATION 1:

Encourage the Therapeutic Goods Administration and State Authorities to establish efficient policies and regulations for the deployment of new medicines and medical devices specifically related to personalised and preventive healthcare. These measures will enable rapid deployment of new technologies that focus on disease prevention and improved personalised healthcare.

RECOMMENDATION 2:

Ensure that new preventive healthcare technologies are rigorously evaluated and are effective. This will build confidence in and promote the net benefits of using personalised and preventive technologies. The outcomes from these studies should be disseminated through the media, public awareness campaigns, national advocacy forums, medical societies and government agencies.

RECOMMENDATION 3:

Facilitate the establishment of secure electronic databases of personally controlled healthcare records and ensure that the healthcare databases currently in development align with best clinical practice. Ensure that the priority outcome of these electronic health records and databases and the integration of health economic data is to support technology dissemination to improve healthcare for all Australians.

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GROW AND PROMOTE A GLOBALLY COMPETITIVE MEDICAL DEVICE INDUSTRY IN AUSTRALIA

JULY 2014

A robust Australian medical device industry has the potential for national economic and social benefits through job creation, export growth, and improved healthcare. Medical technologies can enhance workforce participation which also has substantial economic benefits. The industry draws from a wide range of expertise and utilises a range of engineering and advanced manufacturing capabilities.

THE INDUSTRY

Medical device products are wide-ranging and include complex equipment such as Magnetic Resonance Imaging scanners; sophisticated implantable devices such as cardiac pacemakers, cochlear implants and blood glucose monitoring devices; and insulin pumps. They also include simple devices such as syringes and bandages. The industry is characterised by a high level of innovation and relatively short product life cycles.

The medical device industry is growing rapidly around the world, driven by the increasing affluence of developed and developing countries, increases in life expectancy, and demands for a higher quality of life. The world market in medical devices is valued at around US\$325 billion. It is characterised by a small number of global multinational companies, a large number of small and medium sized enterprises, and a diverse manufacturing supply chain.

Australian medical device revenue is estimated at around \$10 billion. Australia has a net trade deficit in medical devices with exports representing only 42 per cent of imports. This is partly a result of the very broad spectrum of devices in the industry, and the limited niche product range developed locally. The industry has grown rapidly since 1990 with 62 per cent of companies established between 1990 and 2012, and 40 per cent established since 2000. More than half of Australian medical device companies have grown from start-ups. The industry is highly skilled and employs over 19,000 people, with over 50 per cent of employees having a tertiary qualification, and 21 per cent having a postgraduate qualification.

OPPORTUNITIES

There are opportunities for innovative Australian firms to compete in this market if the business environment is supportive and enables participation. Australia has all the building blocks to develop a robust medical device industry based on innovation, excellent research, a good healthcare system, a highly skilled workforce able to evolve with the new manufacturing technologies, an established regulatory system, and a healthy financial base. Australia has an appropriate manufacturing sector with strengths in medium-volume, high-complexity products and has a globally reputable biomedical sector.

There are two issues that, if addressed, could help grow the medical device industry in Australia and level the playing field for Australian manufacturers. Firstly, there is an inequality of regulatory approval processes in Australia that hinders the growth of the industry. If products are made overseas and have a CE Mark (European regulatory approval), the Therapeutic Goods Administration approval process is short and relatively easy. That fast approval is not available to Australian manufacturers and this is leading to companies manufacturing their products offshore or taking the whole company overseas, where economic growth and growth of the device industry will not be captured.

Secondly, introduction of the "Patent Box", a tax incentive on income attributable to developed patents, incentivises the manufacture of new-to-market products and supports research and development on-shore, rather than globalising and off-shoring manufacture. This would provide benefits to Australia by taking a product, process or service from concept to commercialisation, and assisting to grow the industry. The Patent Box concept was introduced by the United Kingdom in 2003 and adopted to date by Canada, the United States and several European countries.

PRIORITY FOCUS AREAS

To drive medical device innovation in Australia, an integrated system is required which:

- Connects all stakeholders along the innovation pipeline, by linking research translation and commercial development by industry with the healthcare system;
- Capitalises on new opportunities through short production runs and connected supply chains;
- Engages user communities and markets to deliver an enhanced customer experience;
- Develops and embraces an educated and productive workforce;
- Links technical and business development expertise;
- Supports business start-up and growth through the availability of capital, with a greater focus on establishing venture capital funds; and,
- Is supported by key government infrastructure, funding and policy programs.

THE VISION

An Australian healthcare system in which:

- Best use is made of technology to improve healthcare outcomes and reduce costs by tailoring technology use or development to particular problems and needs;
- There is effective interaction between clinicians, researchers and companies in the development and commercialisation of new technologies;
- The process of innovation for emerging medical devices companies is easy to navigate; and
- The development of medical and assistive technologies provides opportunities for the manufacturing sector to increase employment and expand exports.

RECOMMENDATIONS

ATSE believes that Australia can grow and promote a medical device industry by addressing these priority actions:

RECOMMENDATION 1:

Encourage and facilitate greater interaction between clinicians, researchers and technologists to develop devices and systems. These will be targeted to benefit Australian consumers and the Australian economy to reduce healthcare costs and ultimately grow a demand-driven medical device industry.

RECOMMENDATION 2:

Provide incentives applicable to the development of medical devices in Australia through measures such as the Patent Box, R&D Tax Incentive, tax concessions for early stage investors, and abolishing tax on share options prior to the realisation of financial benefits.

RECOMMENDATION 3:

Improve Australian regulatory processes applicable to medical devices to bring them into line with world's best practice. Significant benefits can be gained by addressing:

- CE Mark inequality;
- A government contribution to the Therapeutic Goods Administration budget which recognises the public good element of its work;
- Establish processes that enable simultaneous approvals where both a device and a medicine are involved; and,
- Assist early stage entrepreneurs and small and medium enterprises to help them through the regulatory process.

RECOMMENDATION 4:

Streamline approval processes and resolve issues of responsibility between government, insurance companies and individuals in regard to payment for new medical devices.

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