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.