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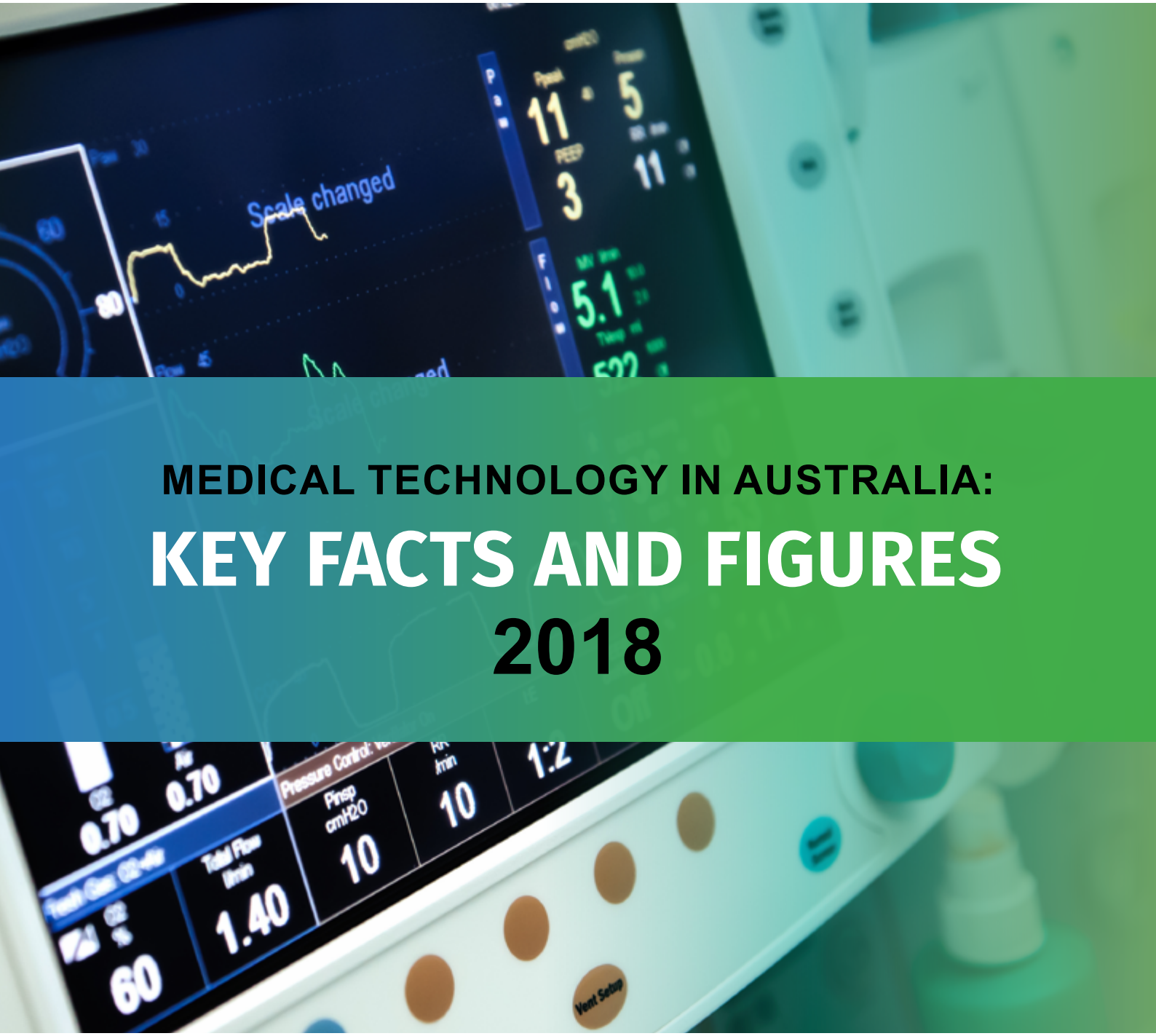

MEDICAL TECHNOLOGY IN AUSTRALIA:

KEY FACTS AND FIGURES 2018

Acknowledgements

The information in this factbook has been obtained from a variety of sources. These include Medical Technology Association of Australia (MTAA) members, the Australian Bureau of Statistics (ABS), the Australian Institute of Health and Welfare (AIHW), the Therapeutic Goods Administration (TGA), the Australian New Zealand Clinical Trials Registry (ANZCTR), BMI research, Evaluate MedTech, the Medicare Benefits Schedule (MBS), the Australian Prudential Regulation Authority (APRA) and the Independent Hospital Pricing Authority (IHPA). In some cases where direct data is not available, extrapolations have been made and noted.

Citation

Medical Technology in Australia: Key facts and figures 2018, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2018).

International Standard Serial Number (ISSN)

ISSN 2200-5668 (Print)

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Disclaimer

Every effort has been made to ensure the accuracy, correctness and reliability of the information provided in this report. MTAA does not claim that the information is free of errors.

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INTRODUCTION

Medical Technology in Australia: KEY FACTS AND FIGURES

The fifth edition of 'Medical Technology in Australia: Key facts and figures' provides updated data and statistics from 2018. The Medical Technology Association of Australia (MTAA) has been publishing this factbook since 2011 to summarise available information on the medical technology industry, aiming to provide a valuable resource for those wanting to gain a better understanding of the medical technology industry in Australia and globally.

MTAA

The Medical Technology Association of Australia is the national association representing companies in the medical technology industry. MTAA's objective is to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents 74 manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability.

MEDICAL TECHNOLOGY IN AUSTRALIA

This section provides an overview of medical technology, its characteristics and its contribution to healthcare.

MEDICAL TECHNOLOGY IN AUSTRALIA

The term medical technology is used to describe a broad range of products used in the diagnosis, prevention, treatment and management of disease and disability, such as medical devices, including in vitro diagnostic devices (IVDs), imaging equipment and dental equipment.

- A medical device is any instrument, apparatus, appliance, material or article which, without chemical action within or on the body, can diagnose, prevent, or treat a disease or other condition. Examples range from bandages, syringes and disposable gloves to pacemakers, surgical instruments, and hip and knee prostheses.

- IVDs are medical devices used to perform diagnostic tests on human specimens in vitro (outside the human body), for the purpose of diagnosing or monitoring a disease or other condition. Examples include home pregnancy test kits, blood glucose monitoring devices, and IVD systems used in the diagnosis of genetic diseases.

- Imaging equipment is used to capture medical images of patients for the purpose of diagnosing a disease or other condition. Examples include radiography (x-ray), ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI).

- Dental equipment includes products such as dentistry tools, alloys and resins that are used by dentists and allied oral healthcare professionals, as well as over-the-counter products used by consumers such as floss and brushes.

The majority of medical technologies are regulated by the Therapeutic Goods Administration (TGA) of Australia as medical devices. Medical technologies which are not regulated by the TGA as medical devices are generally subject to Australian competition and consumer legislation.

Given the diversity in the range of medical technologies in Australia, it is not surprising that the settings they are used in are also diverse: primary healthcare settings (where patients first interact with the healthcare system), secondary healthcare settings (where patients are referred following contact with a primary care provider) and various community care settings such as aged care facilities.

Primary healthcare settings include GP surgeries, dental surgeries, pharmacies, physiotherapy clinics and optometrist practices. Secondary healthcare settings include public and private hospitals and specialist healthcare providers such as cardiologists, orthopaedic surgeons and ophthalmologists.

BENEFITS OF MEDICAL TECHNOLOGY

Medical technologies benefit people's lives in many ways – through saving lives to improving the quality of life for a person living with a disease or disability. Notable examples include:

i

Between 1979 and 2010, mortality rates from coronary heart disease decreased by more than 70% for men and women aged 25 or over in Australia.[1] Similar findings were reported in the USA,[2] New Zealand,[3] the Netherlands,[4] England and Wales.[5] In the USA, up to 47% of the more than 40% fall in the death rate between 1980 and 2000 was attributed to medical and surgical therapies.[6] Revascularisation by means of coronary artery bypass graft (CABG) accounted for 7% of the decline.[7] CABG involves bypassing blockages in arteries by creating new pathways for the blood to travel to the heart, rather than removing the blockage. These new pathways are created through grafts, which are made from parts of healthy vessels, taken from either the patient's legs or chest. These grafts are then attached both above and below the blockage, allowing the blood flow to completely bypass the blockage and enter the heart.[8]

ii

As an alternative to open heart surgery, transcatheter aortic valve implantation (TAVI) was introduced in Australia in 2005 for patients suffering from aortic stenosis. With this new technology, there has been a decrease in mortality rates for aortic stenosis as patients who cannot undergo surgery are now able to receive treatment for their condition.[9] There have been more than 100,000 implants worldwide.[10]

iii

Treatment of hearing loss with hearing aids and cochlear implants have been reported to result in a significant increase in mental health quality of life, observed at 6 months and continuing to rise up to 12 months after the treatment.[11]

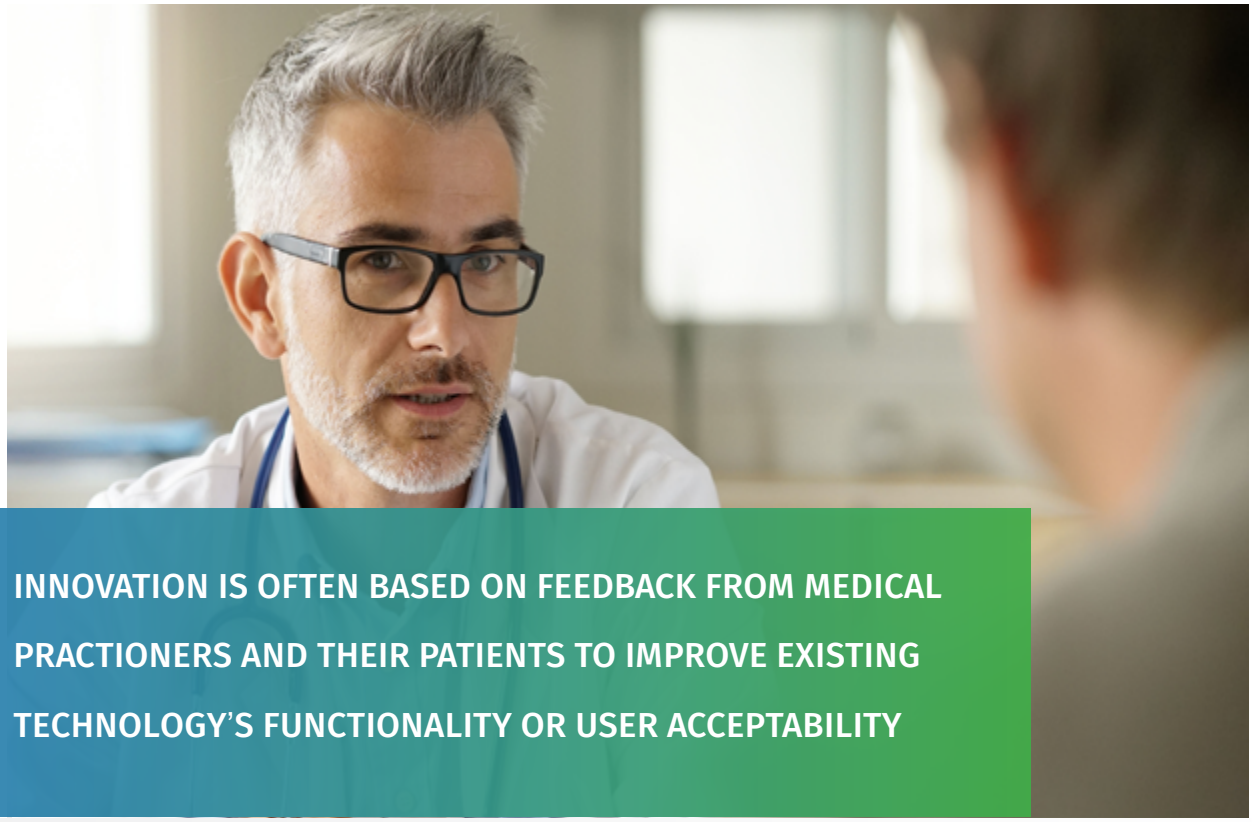
1. Australian Institute of Health and Welfare, Trends in coronary heart disease mortality: age groups and populations, in Cardiovascular Disease Series. 2014: Canberra.
2. Ford, E.S. et al., Explaining the decrease in US deaths from coronary disease, 1980–2000. New England Journal of Medicine, 2007. 356(23): p. 2388–2398.
3. Capewell, S. et al., Explanation for the decline in coronary heart disease mortality rates in Auckland, New Zealand, between 1982 and 1993. Circulation, 2000. 102(13): p. 1511–1516.
4. Bots, M.L. and D.E. Grobbee, Decline of coronary heart disease mortality in the Netherlands from 1978 to 1985: contribution of medical care and changes over time in presence of major cardiovascular risk factors. Journal of cardiovascular risk, 1996. 3(3): p. 271–276.
5. Unal, B., J.A. Critchley and S. Capewell, Explaining the decline in coronary heart disease mortality in England and Wales between 1981 and 2000. Circulation, 2004. 109(9): p. 1101–1107.
6. Ford, E.S. et al., 2007.
7. Ibid.
8. Alexander, J.H. and P.K. Smith, Coronary-Artery Bypass Grafting. New England Journal of Medicine, 2016. 374(20): p. 1954–1964.
9. Diez, J.G., Transcatheter Aortic Valve Implantation (TAVI). Texas Heart Institution Journal, 2013. 40(3): p. 298–301.
10. Thielmann M. et al. Transcatheter aortic valve implantation (TAVI) in patients with aortic regurgitation. Ann Cardiothorac Surg 2017;6(5): p. 558–560.
11. Contrera, K. et al., Quality of life after intervention with a cochlear implant or hearing aid. Laryngoscope, 2016. 126(9): p. 2110–2115.

INNOVATION AND MEDICAL TECHNOLOGY

Medical technology is characterised by a high rate of innovation, resulting in short life cycles for many products. This is a key difference between medical technology and pharmaceuticals and contributes, to some extent, to the differences in the generation of clinical evidence to support marketing approval and reimbursement.

Innovation is often based on feedback from medical practitioners and their patients to improve an existing technology's functionality or user acceptability. Innovation may result in simple changes to the technology where the design or materials used in manufacturing the technology are changed. While simple, these changes can still have a significant impact on health outcomes or a patient's quality of life.

Innovation may sometimes be more complex, and result in the development of technologies that fulfil an unmet clinical need or which revolutionise the way medical care is delivered.



INNOVATION IS OFTEN BASED ON FEEDBACK FROM MEDICAL PRACTIONERS AND THEIR PATIENTS TO IMPROVE EXISTING TECHNOLOGY'S FUNCTIONALITY OR USER ACCEPTABILITY

An excellent example of how innovation can transform a technology through a series of iterative changes, both simple and complex, relates to the development of pacemakers. The focus of the first products in the early 1950s was to save lives. The first electrical pacemaker was external to the body, required an external power source and was the size of a small TV. Patients could only walk as far as the electrical cord, which meant limited mobility and a reduced quality of life.[12] Subsequent incremental changes focused on improving a patient's quality of life and the device's performance, functionality and safety. These included reducing the current necessary for electrical capture of the heart (and thus improving patient comfort); allowing the pacemaker to adjust to a patient's activity and physical changes and thereby allow a more normal life; and allowing for both ventricles to be paced, improving patient survival and symptoms. The smallest pacemaker available today is the size of a vitamin capsule, completely leadless and has a 99.6% implant success rate.[13]

12. Aquilina, O., A brief history of cardiac pacing. Images in Paediatric Cardiology, 2006. 8(2): p. 17–81.

13. Diagnostic and Interventional Cardiology Safety, Performance of the World's Smallest Pacemaker Reinforced in Real-world Patients. 2017.

AUSTRALIA'S CONTRIBUTION TO INNOVATIVE MEDICAL TECHNOLOGY

Australia's contribution to medical technology innovation and healthcare has been significant. Below are some notable examples of Australian innovation.

1926

The world's first electronic heart pacemaker is developed at Sydney's Crown Street Women's Hospital by Dr Mark Lidwell and physicist Edgar Booth.

1930s

The humidicrib is developed in Tasmania in response to the polio epidemic and is a portable alternative to the 'iron lung' made from plywood. The technology is used to save premature babies.

1961

Drs George Kossoff and David Robinson build the first ultrasound scanner and pioneer the field of fetal ultrasound obstetrics.

1970s

The first person is implanted with a cochlear implant (bionic ear) developed by Professor Graeme Clark at the University of Melbourne.

1978

Professor Earl Owen and microscope manufacturers Zeiss pioneer microsurgery, which uses specialised microscopic instruments and equipment for precision surgery.

1980s

Dr Victor Chang pioneers modern heart transplantation in Australia. His work in conjunction with St Vincent's Hospital leads to the development of the artificial heart valve.

1981

Professor Colin Sullivan and co-workers at Sydney University invent the continuous positive airway pressure (CPAP) machine, which supplies pressure to keep the airways of sleep apnoea patients open during sleep.

2014

A handheld bio-pen is developed by the University of Wollongong, which will allow surgeons to design customised implants on-site and at the time of surgery. The BioPen prototype was designed and built using 3D printing equipment and will be suitable for repairing damaged bone and cartilage.

2013

A partnership between scientists at the University of Wollongong and St Vincent's Hospital in Melbourne leads to a breakthrough in tissue engineering, with researchers growing cartilage from stem cells in 3D-printed scaffolds to treat cancers, osteoarthritis and traumatic injury.

2011

Melbourne-based company Phosphagenics aims to offer patients with diabetes the world's first transdermally delivered insulin.

2010

An Australian hospital performs the Southern Hemisphere's first total artificial heart implant. The artificial mechanical device mimics the function of both heart ventricles, which are responsible for pumping blood.

2005

Dr Fiona Wood is named Australian of the Year for her work in burns treatment, including the development of spray-on skin for burns victims.

1999

The Solarscan™ device is developed, which scans the skin and compares the image to a database to determine whether sunspots are melanomas.

1998

Optical research scientist Stephen Newman develops the world's first multi-focal contact lens in Queensland, giving clear vision at all distances to individuals with presbyopia.

1992

Long-wearing night and day contact lenses that transmit an increased volume of oxygen and can remain in place for 30 days are developed by the Cooperative Research Centre for Eye Research and Technology in NSW.

1991

Drs Michael Ryan and Stephen Ruff from Sydney perfect the plastic rod bone repair, using plastic rods rather than metal pins and tubes, which interfere with scans such as MRI scans.

1990

Professor Fred Hollows is named Australian of the Year for his work in eye health, including the development of low-cost manufacturing of intraocular lenses.

HEALTH EXPENDITURE

This section provides an overview of international and national expenditure on healthcare and expenditure trends.

INTERNATIONAL HEALTH EXPENDITURE & TRENDS

Advancements in healthcare technology and increasing government intervention have improved the medical care system on a global level. Technological trends in the healthcare industry, coupled with highly trained clinical professionals, are driving an effective and efficient primary healthcare system for both patients and payers.[14] These new scientific developments have led to the rapid expansion of treatment possibilities, resulting in increased expenditure on healthcare. Additional factors also contribute to the increase in expenditure, including the ageing population and rising labour costs.[15] While increased costs are a great challenge for healthcare systems across the world, advancements in healthcare technology and stronger engagement by government in healthcare systems provides opportunities for economies to revolutionise the way care is delivered and as a result, transform their society.[16]

Overall, average global healthcare spending as a percentage of GDP is expected to remain steady in the next years, at 10.6% in 2018 and at 10.4% in 2021. Between 2017 and 2021, health spending is expected to rise by an annual average of 4.4% with growth higher in some regions (5.8% in Central and Eastern Europe and 5% in Asia).[17]

The US continues to dramatically outspend all other OECD countries[18] (Figure 1). The latest edition of OECD's Society at a Glance indicates that in 2016, the average health expenditure per capita for the United States (US$9,892) was around twice that of Australia (US$4,708).

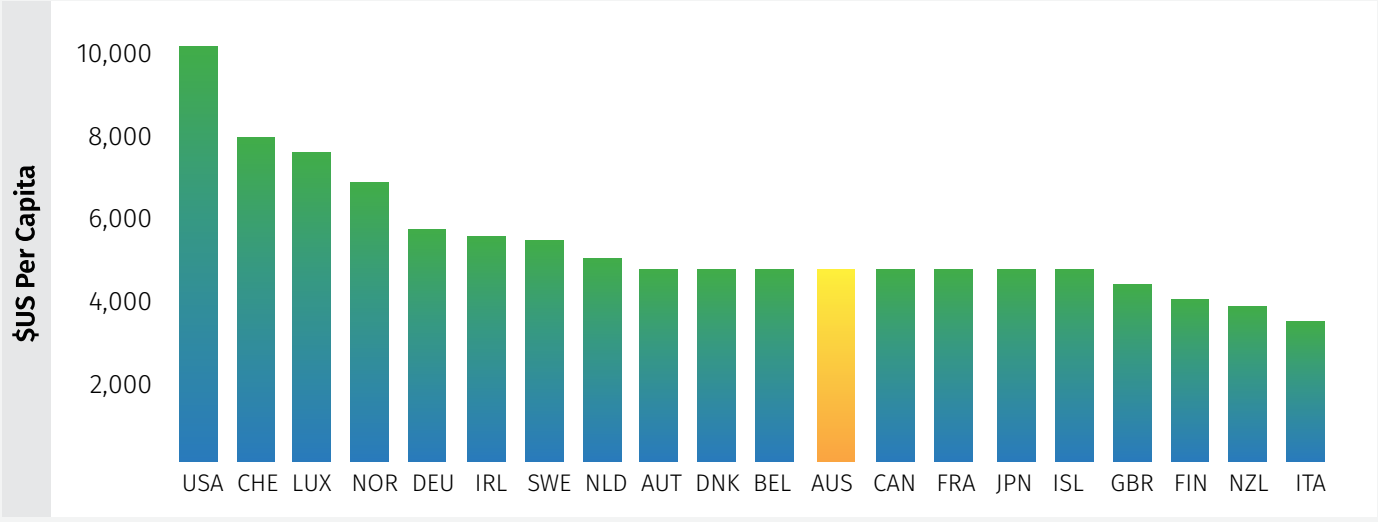


Figure 1. Country comparison of average health expenditure per capita $USD. Source: OECD.

14. Infiniti Research. Top 3 Technology Trends in the Healthcare Industry. 2017; Available from: https://www.infinitiresearch.com/thoughts/technology-trends-healthcare-industry.
15. The Economist Intelligence Unit, World Industry Outlook; Healthcare and Pharmaceuticals. December 2016.
16. CGI, Healthcare Challenges and Trends. 2014.
17. The Economist Intelligence Unit, World Industry Outlook, Healthcare and Pharmaceuticals. December 2016.
18. OECD, Society at a Glance 2016: OECD Social Indicators. 2016, OECD Publishing: Paris.

HEALTH EXPENDITURE IN AUSTRALIA

Using the latest data available, in 2015–16, total spending on health in Australia was $170.4 billion, representing a growth of $6 billion or 3.6% over the previous year in real terms. For the fourth consecutive year, the growth in spending remained below the decade average of 4.7% (between 2005–06 and 2015–16).[19] In comparison to other OECD members' health expenditure to GDP ratios, Australia has ranked above the OECD median since 2004 (9.7% versus 9.1%).[20]

Cardiovascular Disease (CVD) remains the disease group with the highest level of healthcare expenditure in Australia. In 2008–09, the most recent dates for which data is available, the estimated expenditure for CVD was $7.6 billion or 12% of all allocated healthcare expenditure. Coronary heart disease expenditure accounted for over one-quarter, 27%, of CVD expenditure in 2008–09.[21]

The Commonwealth Government is the major source of funding for Australian healthcare, with a contribution of $66.2 billion in 2014–15, or 41% of all spending. State and Territory Governments provided $42 billion (26%) and non-government sources (individuals, private health insurance and other non-government sources) $53.4 billion (33.1%) (Figures 2 & 3).

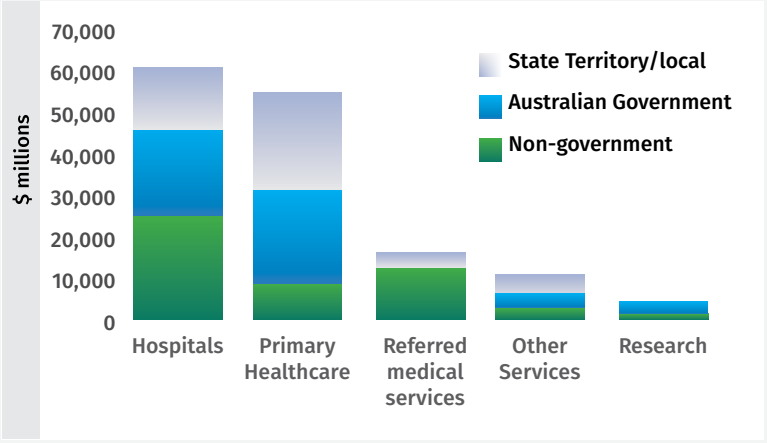


Figure 2. Recurrent health expenditure, by area of expenditure and source of funds in 2014–15. Source: AIHW.

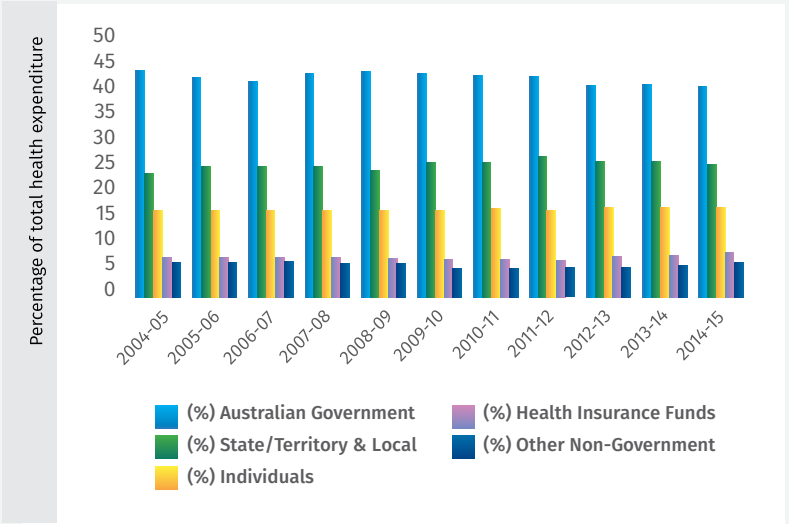


Figure 3. Total health expenditure, by source of funds as a proportion of total health expenditure, 2004–05 to 2014–15. Source: AIHW.

Individuals contributed around $28.6 billion in out-of-pocket costs for purchasing health services.[22]

19. Australian Institute of Health and Welfare, Health expenditure Australia 2015–16. Health and welfare expenditure series no. 58. Cat. no. HWE 68. Canberra: AIHW, 2017.

20. Australian Institute of Health and Welfare, Health expenditure Australia 2014–15. Health and welfare expenditure series no. 57. Cat. no. HWE 67. Canberra: AIHW, 2016.V

21. Australian Institute of Health and Welfare, Health-care expenditure on cardiovascular diseases 2008–09. Cat. no. CVD 65. Canberra: AIHW, 2014.

22. Australian Institute of Health and Welfare, Australia's health 2016. Australia's health series no. 15, Cat. no. AUS 199. Canberra: AIHW 2016.

THE MEDICAL TECHNOLOGY INDUSTRY

This section provides information on the key stages involved in bringing a medical device to market and supplying it in Australia. It also discusses the role of Health Technology Assessment (HTA) and the importance of clinical trials in these stages.

WORLDWIDE

The medical technology industry makes positive contributions to science, research and innovation, the economy, trade and manufacturing. It contributes to society through improved health outcomes, employment, education and training, and philanthropy. Advances in medical technology have led to important advances in the quality and effectiveness of healthcare, which have improved patient outcomes around the world.

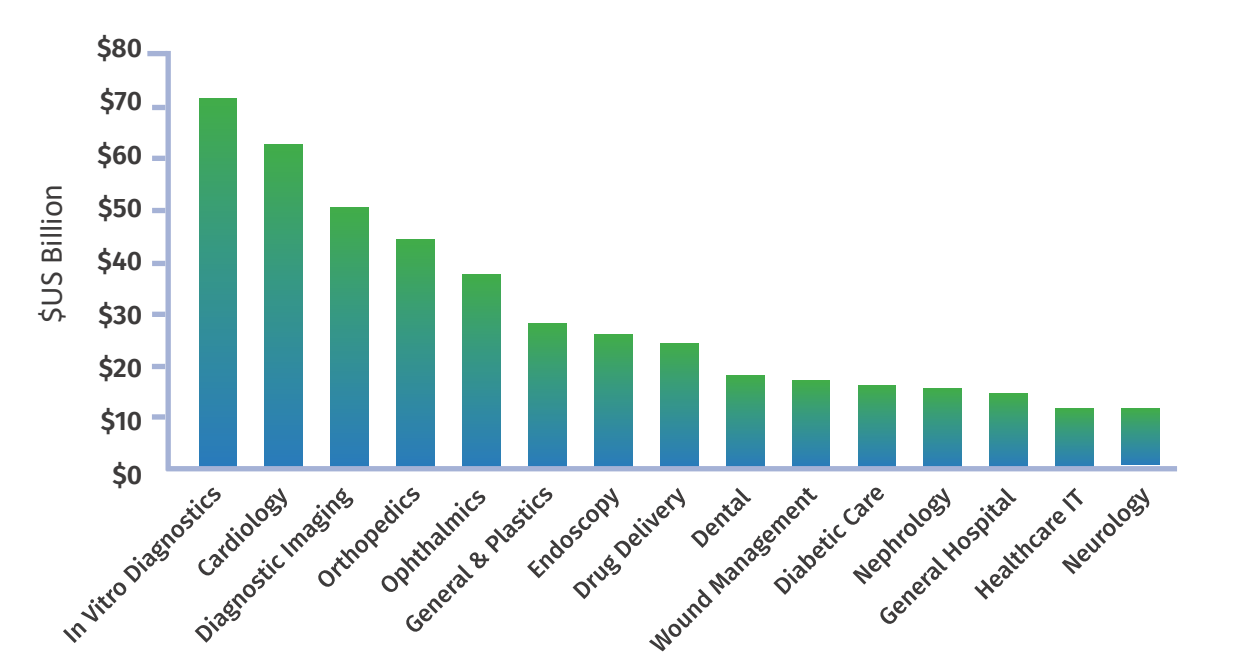


Figure 4. Forecasted sales by 2022 of medical devices in various medical technology segments. Source: Evaluate MedTech 2015.

The worldwide medical technology market is expected to achieve global sales of US$529.8 billion by 2022 and to grow at 5.2% per annum from 2015 to 2022. Analysis by EvaluateMedTech, based on in-depth forecasting models for the top 300 global medical technology companies, reported that medical technology is set to grow at a slightly lower rate (5.2% per annum) than the prescription drug market (6.1%).[23]

By 2022, in vitro diagnostics are expected to be the world's largest medical technology segment with sales of US$70.8 billion (Figure 4). Neurology is the fastest growing segment, with 7.6% growth per annum, while diagnostic imaging and orthopaedics are forecast to be the slowest growth segments with 3.8% growth per annum (Figure 5).[24]

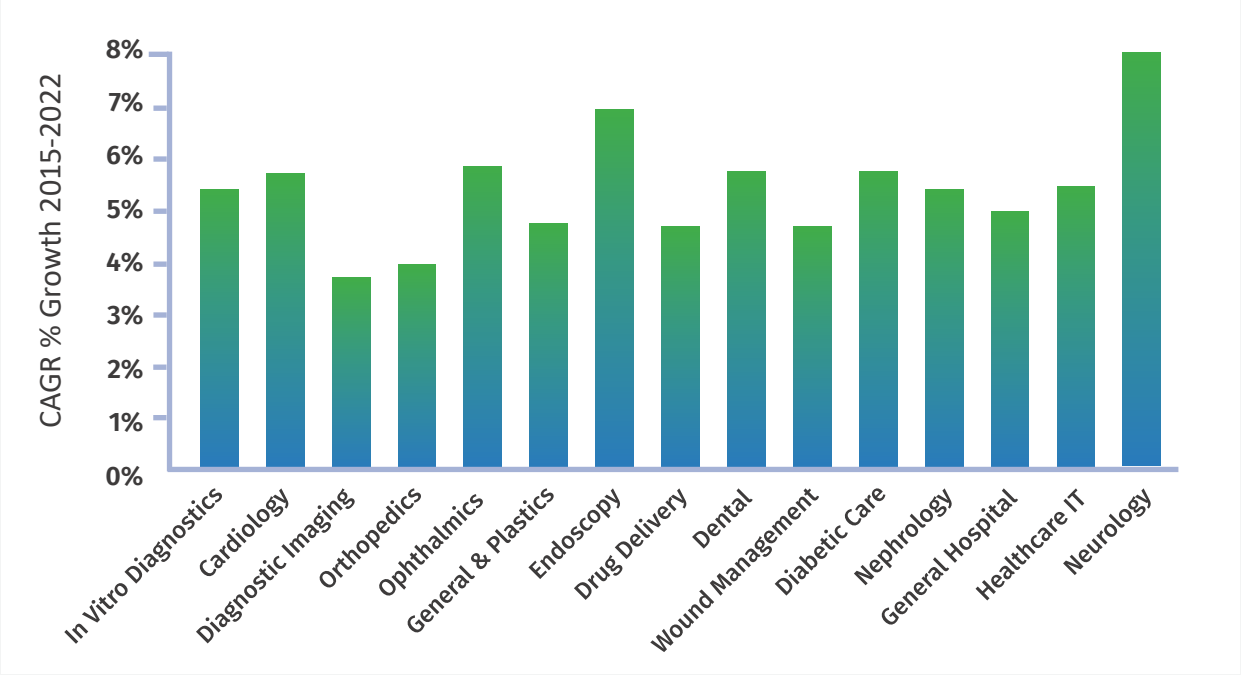


Figure 5. Forecasted CAGR for largest medical device areas from 2015–2022. Source: Evaluate MedTech 2015.

Forecasts predict MedTronic will hold the position as the largest medical device company by revenue come 2022, with sales estimated under US$38 billion.[25]

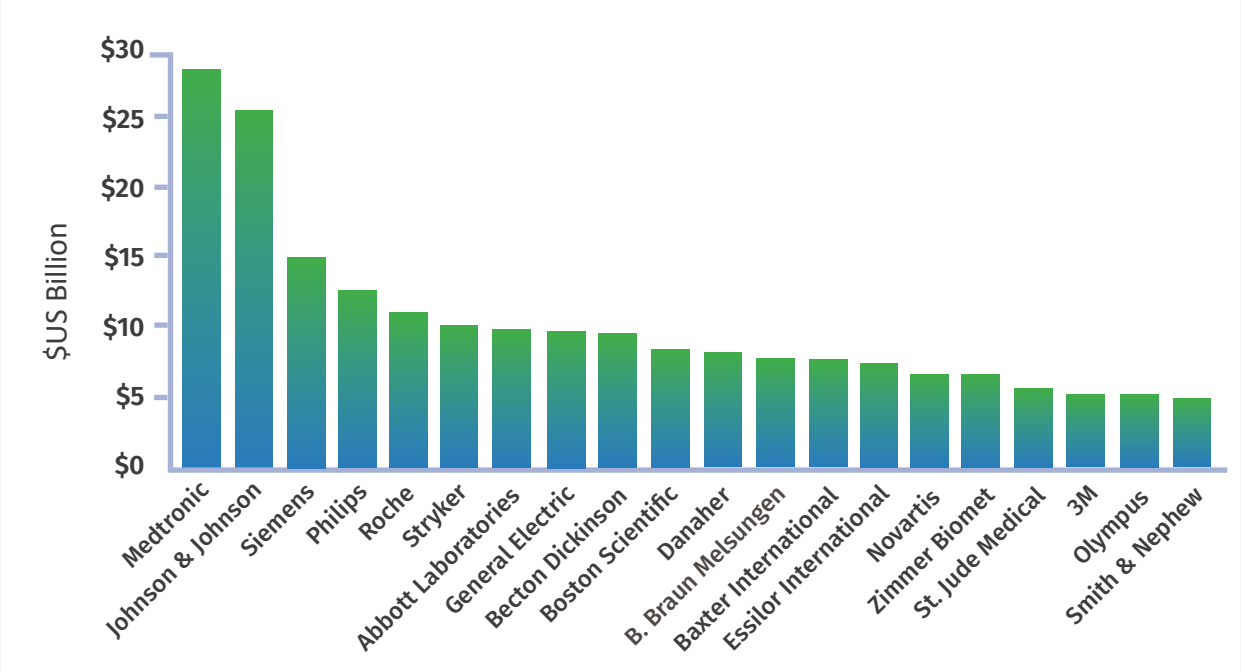


Figure 6. Medical technology sales for the top 20 international companies in 2016 Source: Evaluate MedTech 2015.

23. EvaluateMedTech, World Preview 2017, Outlook to 2022. 2017.

24. Ibid.

25. Ibid.

AUSTRALIA

The medical technology industry is one of the most dynamic manufacturing sectors in Australia and has the potential to provide substantial health gains and highly paid employment opportunities to Australians and add to Australia's export industry. Through new innovation, this industry could expand dramatically. Cochlear Australia and ResMed are two companies that have taken medical devices to the world from Australia. The Australian Bureau of Statistics (ABS) identified the industry as a growth sector, performing higher than average on indicators such as export, profitability, productivity and employment.[26]

For 2017, it was estimated that the total market (market size equals the total local production and imports minus exports) for medical devices in Australia was valued at US$4.6 billion.[27] Despite representing a small proportion (1.42%) of the world market, Australia compares favourably worldwide; according to the Worldwide Medical Device Factbook, Australia is ranked at 10th in terms of total market value.[28] Considering gross value added, which is a measure of the value of industry production, there has been a steady increase for the medical technology sector. In 2016, it was calculated that the gross value added for the industry was $1.9 billion, an increase from $1.5 billion in 2013.[29] In contrast, over the same period, the gross value added by the pharmaceutical industry has been steadily decreasing, dropping from $3.2 billion to $3 billion.[30]

With continual growth and advancements in the industry, all surgical operations performed in Australia involve some form of medical technology, helping more than 2.5 million patients per year, with assistive technology providing A$3.6 to $4.5 billion annual value to the community.[31] As a result of this, over the last 20 years, Australia has seen a 25% decline in annual mortality,[32] 25% decline in disability rates,[33] 56% reduction in hospital bed days and an increase in life expectancy by 4.6 years,[34] which can all be attributed to medical technology.

26. Australian Bureau of Statistics, Characteristics of Businesses in Selected Growth Sectors, Australia, 2013–2014. 2015, Australian Bureau of Statistics: Canberra.
27. https://www.statista.com/statistics/716902/medical-equipment-market-size-in-australia/
28. BMI Research, Worldwide Medical Devices Market Factbook 2016. BMI Research.
29. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.
30. Ibid.
31. MTAA, Medical Technology industry cautious of outcome for patients. 2017.
32. The World Bank, Mortality rate, adult. 2015.
33. Australian Bureau of Statistics, Disability, Ageing and Carers, Australia: Summary of Findings, 2015. 2015.
34. The World Bank, Life expectancy at birth. 2015.
35. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

SIZE OF THE INDUSTRY

MTAA estimates the industry comprises at least 2,976 companies and covers over one million distinct products in Australia. We have based our estimates on the following:

i. The number of medical devices included on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) in January 2017 is 54,555 and corresponds to at least 2,976 companies.

ii. Each entry included on the ARTG may cover a multitude of individual devices (in some cases one ARTG entry may cover several hundred individual products).

iii. There are some marketed medical technologies that fall outside the jurisdiction of the TGA as they may not meet the TGA's definition of what constitutes a medical device.

There are 91 ASX-listed medical technology and pharmaceutical companies in Australia, with a market capitalisation of $94 billion.[35] The number of listed companies has been steadily increasing since 2010 and if this trend continues, the contribution from the industry value to the Australian economy will continue to grow (Figure 7).

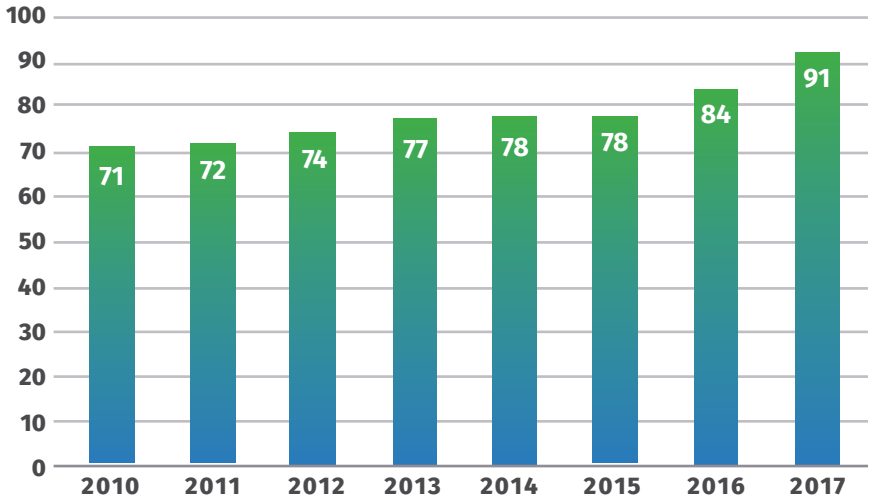


Figure 7. Number of ASX-listed companies in the medical technology and pharmaceutical industry. Source: MTP Connect.

LOCATION

The majority of medical technology companies (sponsors) are located in NSW (45%) followed by Victoria (28%) and Queensland (15%). ACT (n=14) and the Northern Territory (n=2) host the fewest medical technology companies. (Figure 8).[36]

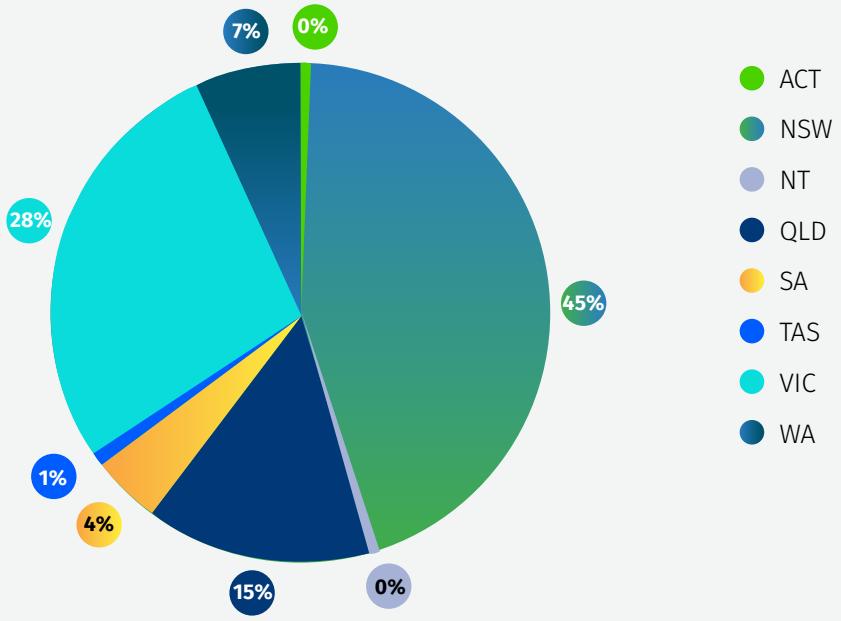


Figure 8. Percentage of medical technology companies by State, as a share of all medical technology companies in Australia. Source TGA, May 2017

Of all medical technology sponsors that have at least one medical device listed on the ARTG, only 861 manufacture in Australia. Of these, over two-thirds (n=592) are based in either NSW or Victoria (Figure 9).[37]

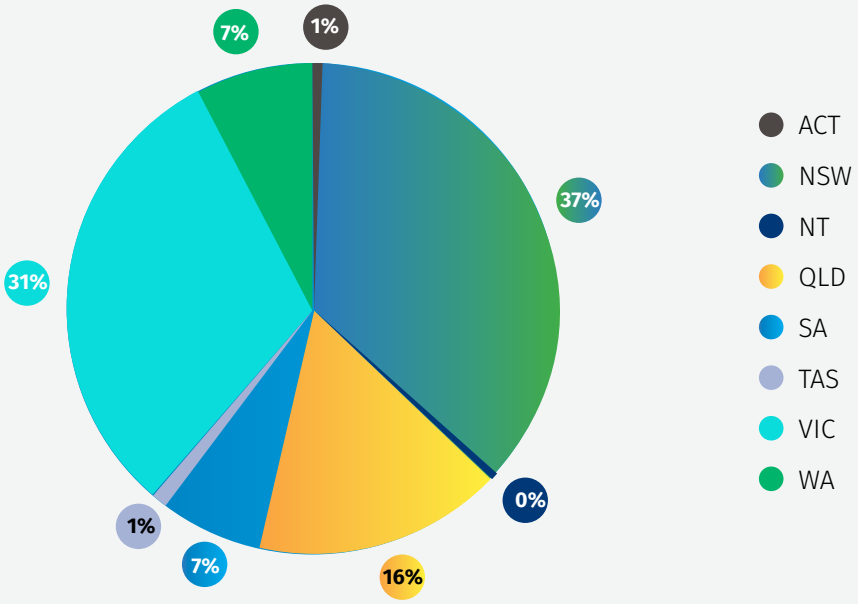


Figure 9. Number of manufacturers by State. Source: TGA

Medical technology manufacturers headquartered in Australia account for just 9% (n=861) of the industry (Figure 10).

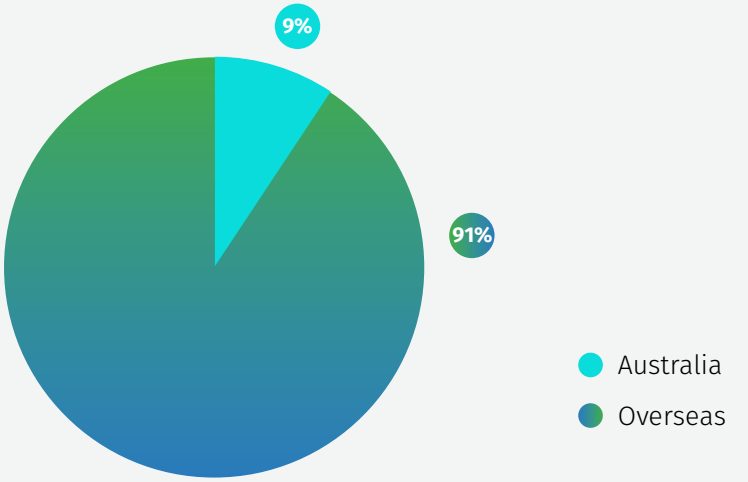


Figure 10. Number of manufacturers headquartered in Australia vs overseas. Source: TGA

Of the 2,976 medical technology companies in Australia,[38] 74 are MTAA members. Of all members, 58% (n=43) are multinational companies, 41% (n=30) are Australian and 1.4% (n=1) New Zealand-owned.

The Australia Bureau of Statistics (ABS) defines a large business as those employing more than 200 people, medium businesses as those employing between 20 and 200 people, and small businesses as those employing less than 20 people.[39] According to these definitions, the majority of MTAA members represent medium-sized business (46%; n=34) followed by small businesses (34%; n=25). Only 20% (n=15) of MTAA members represent large businesses (Figure 11).

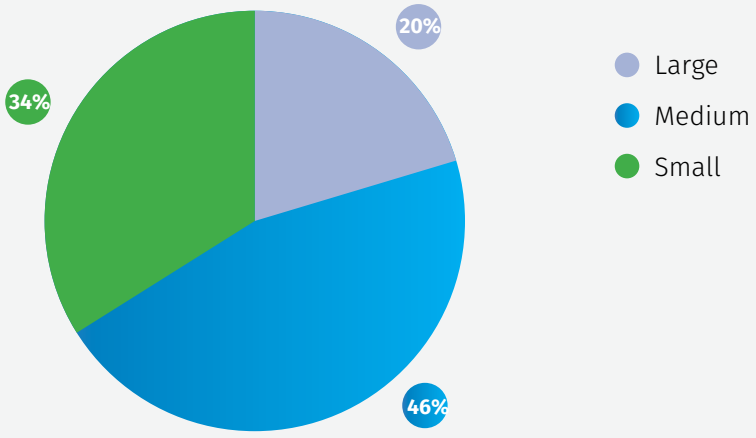


Figure 11: Breakdown of MTAA members according to business size. Source: MTAA

36. Therapeutic Goods Administration, Australian Register of Therapeutic Goods. 2017.

37. Ibid.

38. NSW Department of Industry. NSW medical technology industry development strategy 2018

39. Australian Bureau of Statistics. Small Business in Australia. 2001; Available from: http://www.abs.gov.au/ausstats/abs@.nsf/mf/1321.0.

EMPLOYMENT

The medical technology industry in Australia is a substantial employer. In 2016, it was estimated that the industry employs about 17,700 people.[40] Overall, 78% of all medical technology employees have graduated with a university degree, demonstrating the highly educated nature of the workforce. Of these employees, 52% earned an undergraduate degree and a further 25% completed a postgraduate degree.[41]

78% OF ALL MEDICAL TECHNOLOGY EMPLOYEES HAVE GRADUATED WITH A UNIVERSITY DEGREE

40. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

41. Deloitte, Medical technology industry workforce and skills review. 2015.

IMPORTS & EXPORTS

Most of the medical technology products manufactured in Australia are exported, while most products used in Australia are imported. This demonstrates the international nature of the industry and the need for Australia to remain internationally competitive. In 2016, the value of medical technology imports was A$7.3 billion and the value of medical technology exports was A$2.9 billion. From 2011–2016, imports and exports grew at a compound annual growth rate (CAGR) of 4.4% and 5.7% respectively (Figure 12).[42]

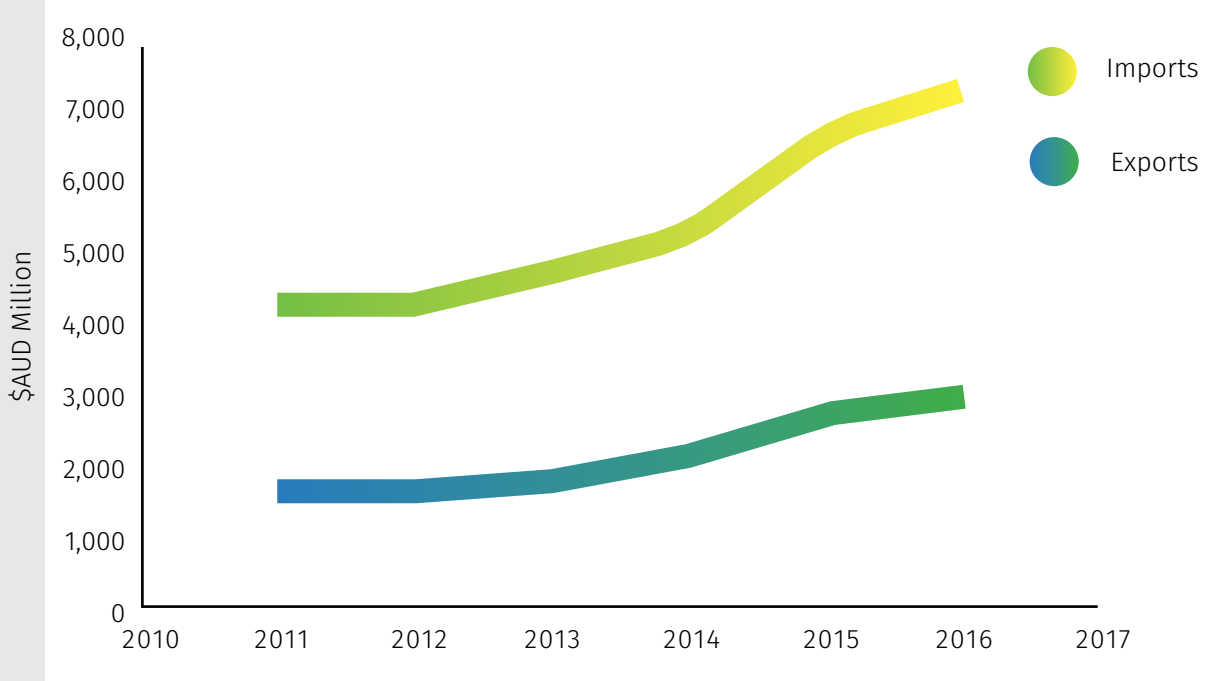


Figure 12. Medical devices trade, export and import growth from 2011-2016.
Source: BM Worldwide Medical Devices Market Factbook

Since Australia imports more medical devices than it exports in terms of overall value, this creates a net deficit in trade in medical technology. Several steps can be taken to increase the sustainability of the medical technology sector, which could contribute to a stronger healthcare system, better support Australian manufacturing and reduce external debt. These include improving the capability to identify, design, develop, make and sell products that are in demand, and maximise leverage from strong and sustainable partnerships through local and global supply chains, as well as increase industry support programs funded by government, and seek markets in emerging growth economies and market niches.[43]

40. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.
41. Deloitte, Medical technology industry workforce and skills review. 2015.
42. BMI Research, Worldwide Medical Devices Market Factbook 2016. BMI Research.
43. Future Manufacturing Industry Innovation Council, Trends in manufacturing to 2020 – A foresighting discussion paper 2011, Department of Innovation, Industry, Science and Research,: Canberra.

Exports for the entire medical technology and pharmaceuticals industry experienced a major downward trend between 2012 and 2015 but recovered strongly in 2016. Overall, the entire industry is the 10th largest in Australia by export value.[44] Medical device exports have grown steadily since 2012, reaching $1.5 billion in 2016 (Figure 13).

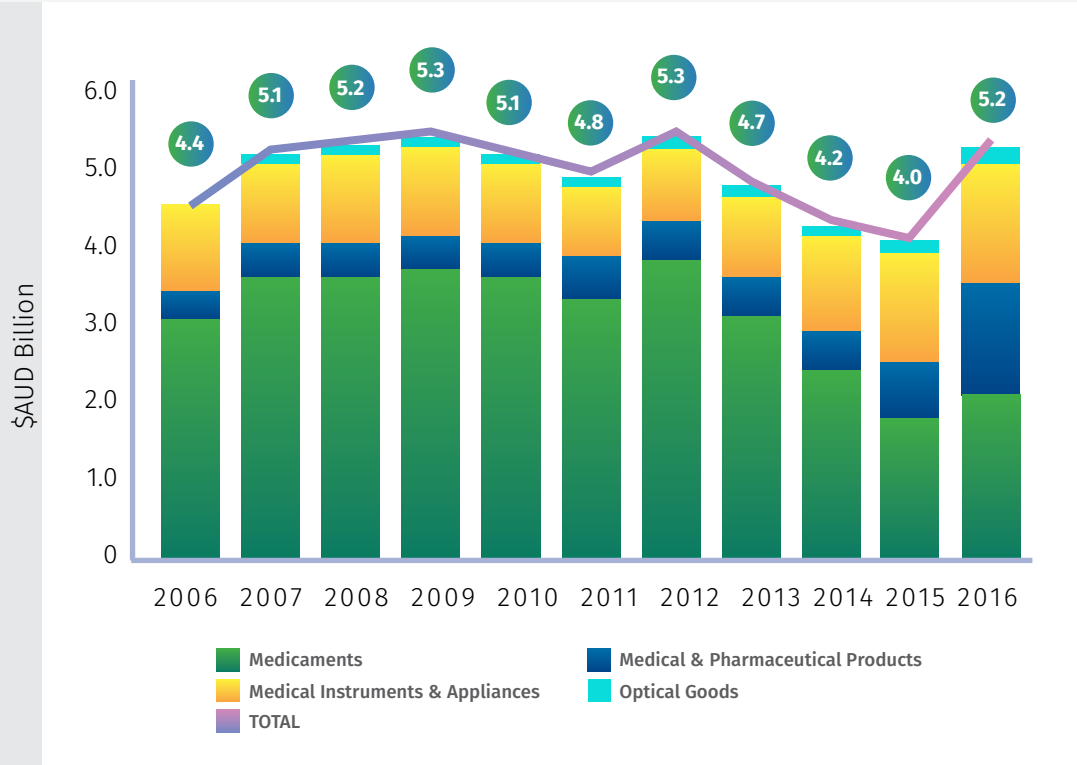


Figure 13. Manufacturing exports from the medical technology and pharmaceutical industry. Source: MTP Connect

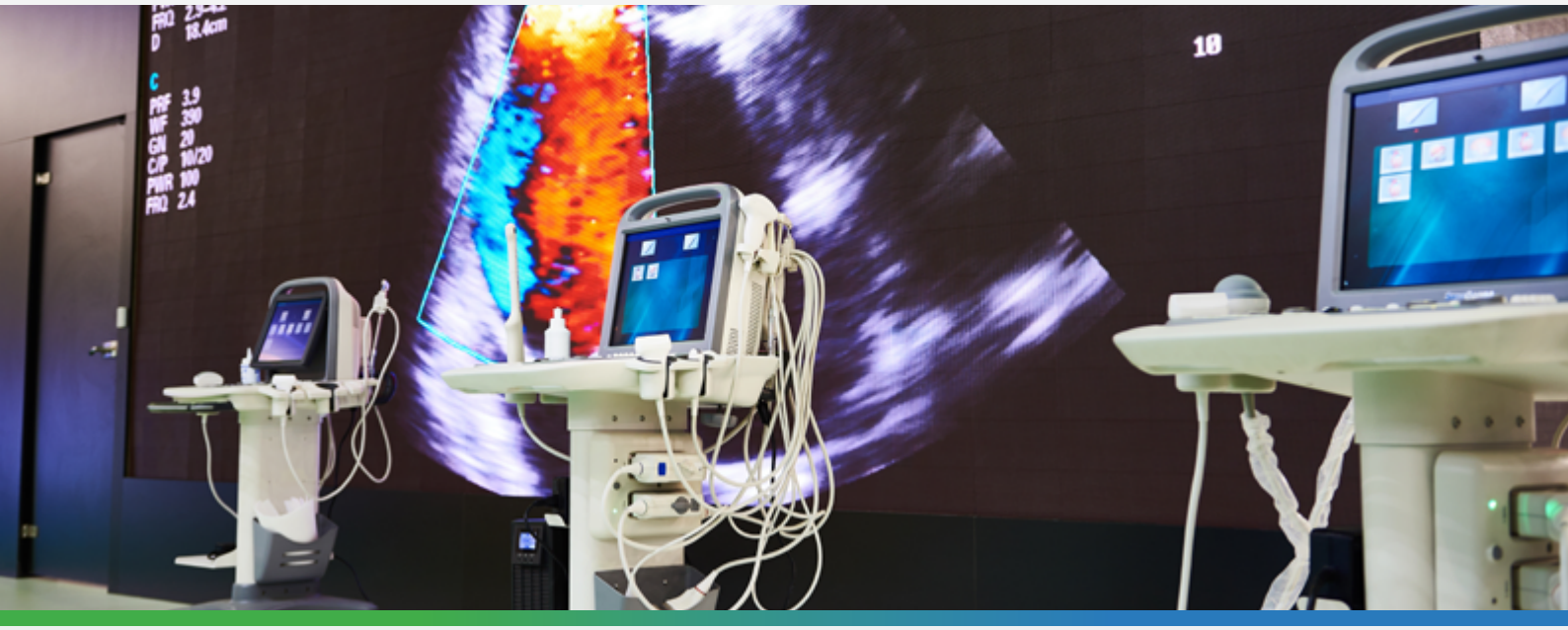
With the continuous growth of the industry in Australia, the net trade deficit may be reduced over the coming years. Australia's strong relationship with the Asia-Pacific market and a strong SME and start-up sector supported by government policy and highly skilled workforce, along with the increasing need for medical devices across the world, will likely provide Australian manufacturers with exciting trading opportunities in the future.

44. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

RELATIVE EXPENDITURE ON MEDICAL TECHNOLOGY IN AUSTRALIA

In Australia, medical technology is commonly blamed by some stakeholders for the high cost of healthcare.[45] However, a challenge to this thinking comes with recently published local and international data. Data from the World Medical Markets Fact Book 2015 (Espicom), which reports the latest available expenditure on medical devices in 74 countries, show that expenditure in Australia on devices is relatively low compared to other health costs.[46]

There was a very small decline in spending on medical devices from 3.8% of total health spending in Australia in 2006[47] to 3.6% in 2015.[48] Australia ranked only 42nd internationally for medical device spending as a percentage of GDP with only 0.33% of GDP spent per capita. This provides further evidence that in comparison to other countries, expenditure on medical devices is relatively low in Australia and has a minor impact on overall healthcare costs.



45. Australian Treasury, Australia to 2050.
46. Intelligence, E.H., The World Medical Markets Factbook 2015. 2015.
47. Skinner, B.J. and Canadian Health Policy Institute, Medical devices and healthcare costs in Canada and 65 other countries, 2006 to 2011. Canadian Health Policy, May 9, 2013. Toronto: Canadian Health Policy Institute.
48. Canadian Health Policy Institute, Medical devices and health care costs in Canada and 74 other countries, 2010 to 2015. Annual report. Canadian Health Policy, December 12, 2016. Toronto: Canadian Health Policy Institute.

In the most recent annual survey of manufacturing costs for medical devices published by KPMG, Australia was shown to be ranked fifth overall. In this group of countries, Mexico had the lowest manufacturing costs while the United States had the highest (Figure 14).[49]

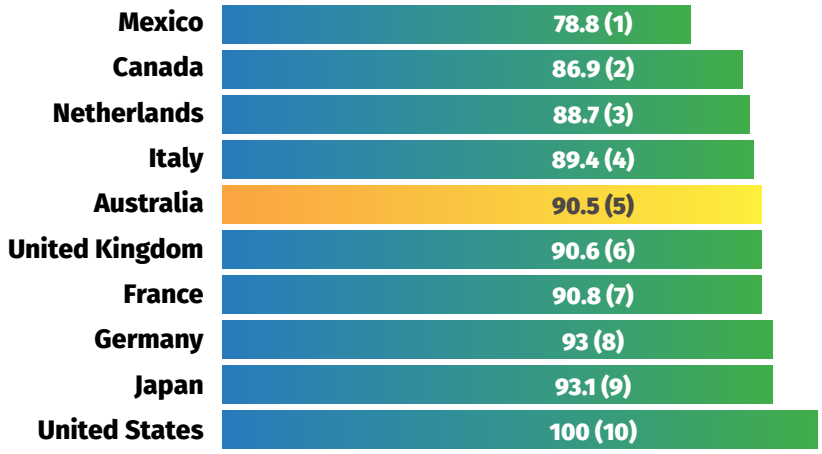


Figure 14. Medical device manufacturing costs in 2016. Source: KPMG.

Of the 74 countries for which data are available, Australia ranked 5th for total health spending per capita and 12th for medical device spending per capita. Australia was ranked only 64th when medical device spending was measured as a percentage of total health spending.[50] These results reveal that in comparison to other countries, spending on medical devices accounts for only a small percentage of total health expenditure. (Figure 15).

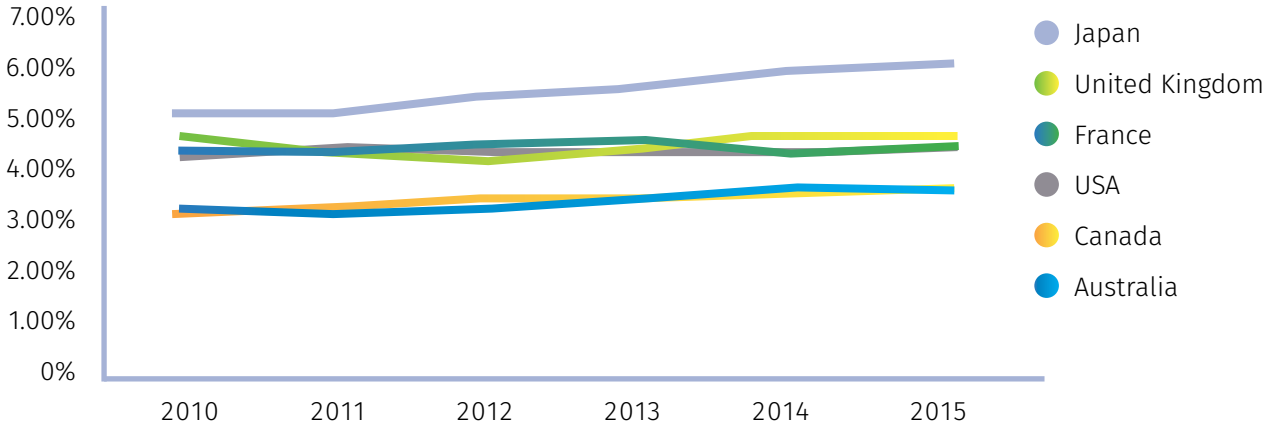


Figure 15. Medical technology expenditure as a percentage of total health expenditure in 2010-15 (per capita, current $US) for selected high GDP countries. Source: AIHW

49. KPMG, Competitive Alternatives 2016 Summary Report. 2016.

50. Canadian Health Policy Institute, Medical devices and health care costs in Canada and 74 other countries, 2010 to 2015. Annual report. Canadian Health Policy, December 12, 2016. Toronto: Canadian Health Policy Institute.

MEDICAL DEVICE LIFECYCLE AND THE ROLE OF HTA

This section provides information on the key stages involved in bringing a medical device to market and supplying it in Australia. It also discusses the role of Health Technology Assessment (HTA) and the importance of clinical trials in these stages.

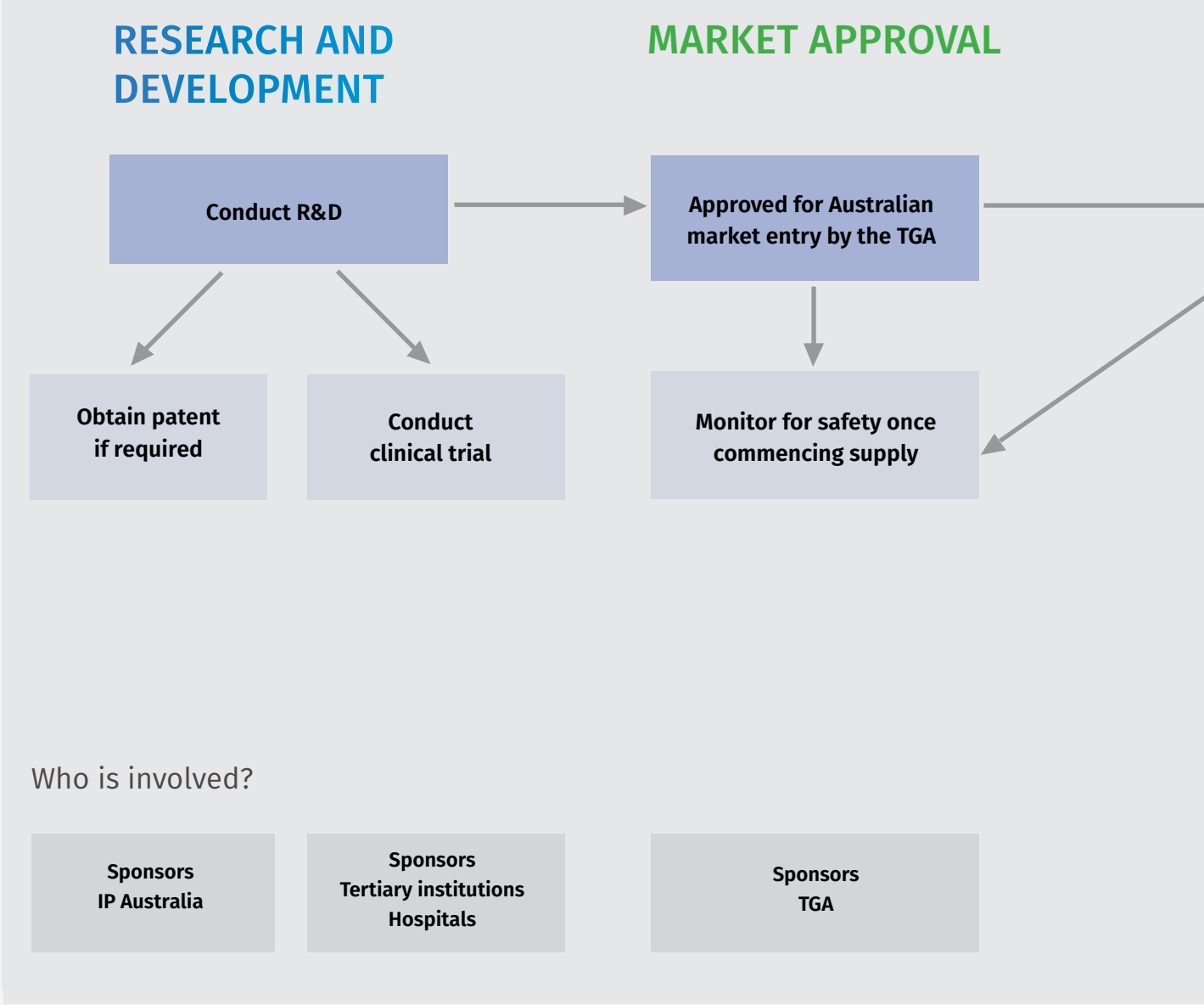
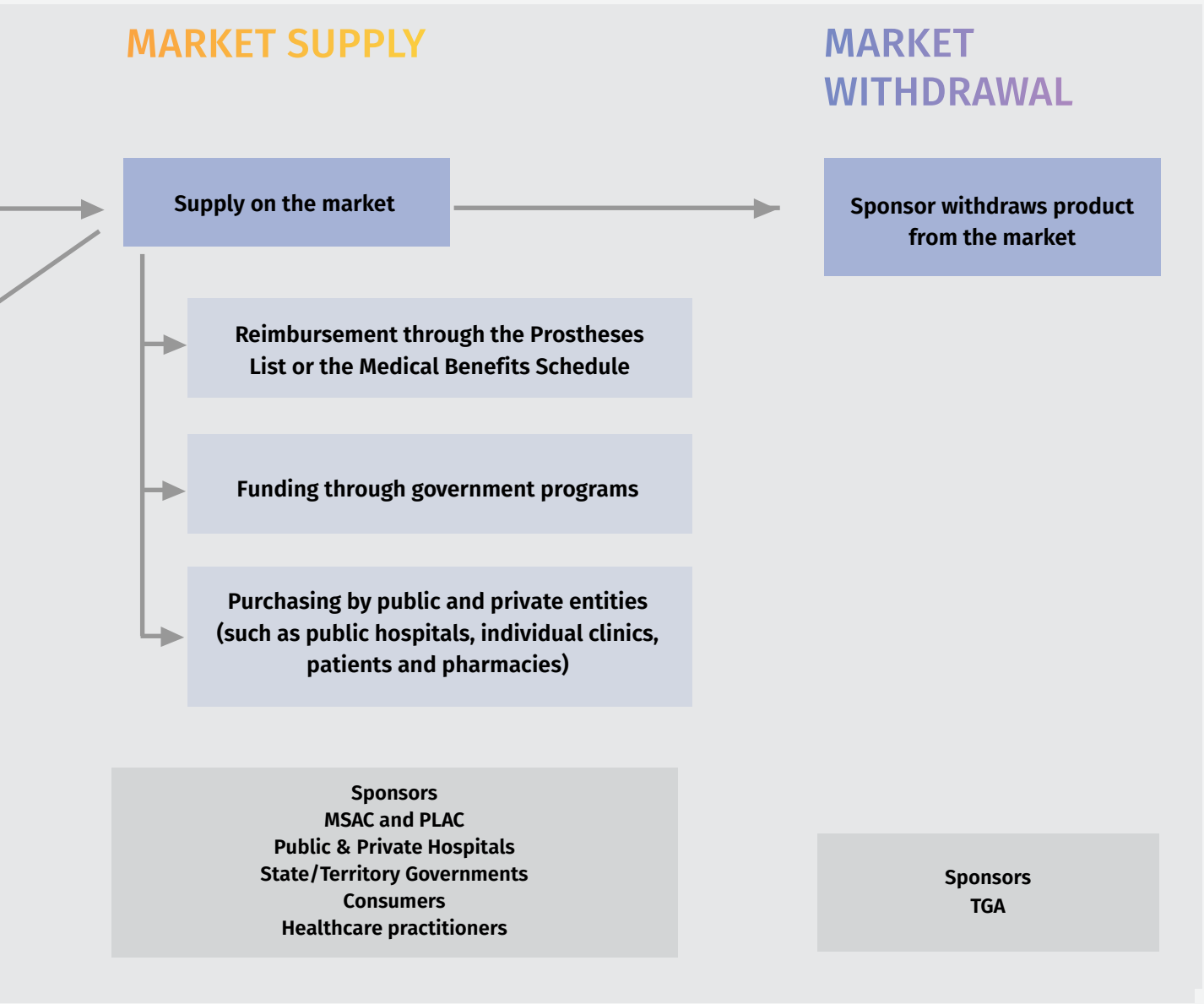


Figure 16. Medical Device Lifecycle. Source: MTAA
This diagram does not cover access to medical technologies that are not regulated by the TGA or that are approved for supply by the TGA under special circumstances such as the individual prescriber scheme.

MEDICAL DEVICE LIFECYCLE

The life of a medical device comprises the stages involving activities leading up to and including marketing approval by the TGA and the stages once marketing approval has been obtained and the product is being supplied on the market. This is shown in Figure 16 above.



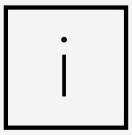
THE KEY STEPS INVOLVE:

- Undertaking research and development, which includes obtaining patents where no patent is currently in place and conducting clinical trials.
- Obtaining marketing approval from the TGA to enable the product to be legally supplied in Australia. Marketing approval imposes obligations on sponsors which they must adhere to while the device is being supplied on the Australian market, including monitoring for and reporting adverse events associated with their medical device.
- Supplying in the market, which involves a range of processes to enable purchasers/funders/payers to make decisions on which medical devices to purchase/fund or reimburse.
- Withdrawing the device from the Australian market based on individual company considerations.

THE ROLE OF HTA

In Australia, Health Technology Assessment (HTA) processes apply principally to diagnostic tests, medicines, medical devices, prostheses and surgical procedures. They operate with the objective of ensuring that only safe and effective health technologies are permitted to be sold in Australia and that Australian Government funding (in the form of subsidies) is directed to priority technologies that are both clinically effective and cost-effective.[51]

HTA processes can occur across the life cycle of a technology, and involve:



Horizon scanning to identify new and emerging health technologies for governments and health systems for planning purposes.

Market regulation to assess the intrinsic safety and performance of therapeutic goods, as intended for use by manufacturers.

HTA for reimbursement to assess the comparative safety, clinical effectiveness and cost-effectiveness of health technologies being considered for subsidy.

Post-market surveillance to monitor the impact of technologies in routine clinical use.

51 Department of Health, Review of Health Technology Assessment in Australia (HTA Review). Available from http://www.health.gov.au/htareview

The use of HTA is likely to have an increasing influence on decisions made to purchase, fund or reimburse medical devices in the future with the Commonwealth and State/Territory Governments considering the feasibility of establishing nationally cohesive HTA assessment processes as part of the negotiations of the National Health Agreement to commence on July 2020.

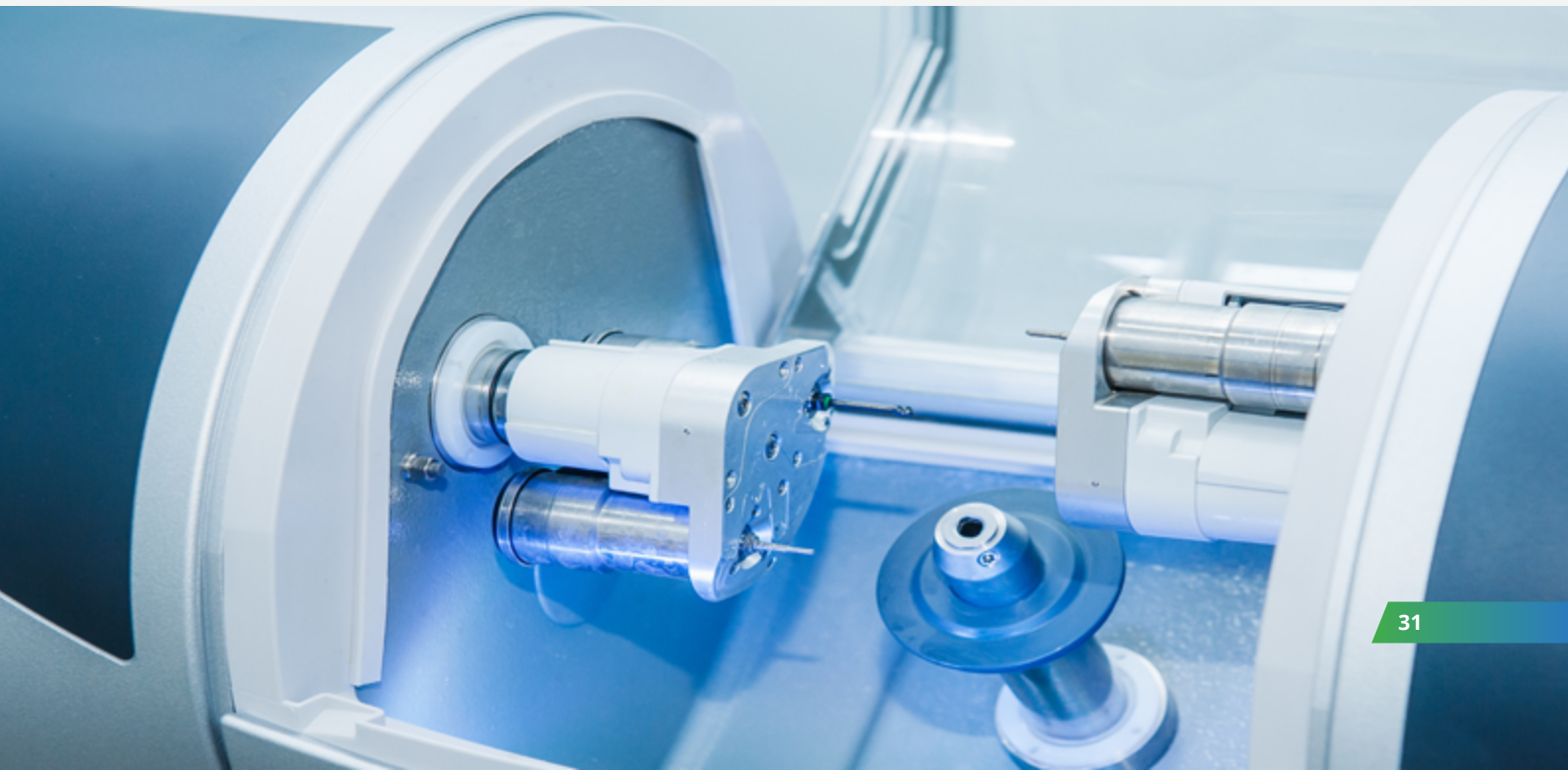
HTA for medical devices is provided by:

i. The TGA which assesses the safety and efficacy of medical devices to allow market entry and also monitors the safety of devices in use.

ii. The Medical Services Advisory Committee (MSAC) which recommends benefits for medical services, which may include medical devices, provided under the Medicare Benefits Schedule (MBS).

iii. The Prostheses List Advisory Committee (PLAC) which recommends the benefits payable by health insurers for prostheses included on the Prostheses List.

It is unclear whether any HTA beyond TGA assessment is undertaken by purchasers of medical technology outside the MBS and Prostheses List arrangements.



CHALLENGES FOR MEDICAL TECHNOLOGY

There are challenges for assessing the efficacy and cost-effectiveness of medical devices compared to pharmaceuticals under traditional HTA processes. While general methods of clinical and economic evaluation are already well-established, most international guidelines for evaluation, although appearing to be generic, have been written with pharmaceuticals in mind.[52]

At the same time, medical devices differ from other health technologies in a number of respects:

i. They often change rapidly.

ii. There are ethical considerations in conducting trials in a manner which reduces bias when assessing the effectiveness of implantable medical devices such as undertaking sham surgical procedures.

iii. Clinical outcomes often depend on the training, competence and experience of the end-user.[53]

iv. Costs often comprise both procurement costs (including the associated infrastructure) and running costs (including maintenance and consumables).[54]

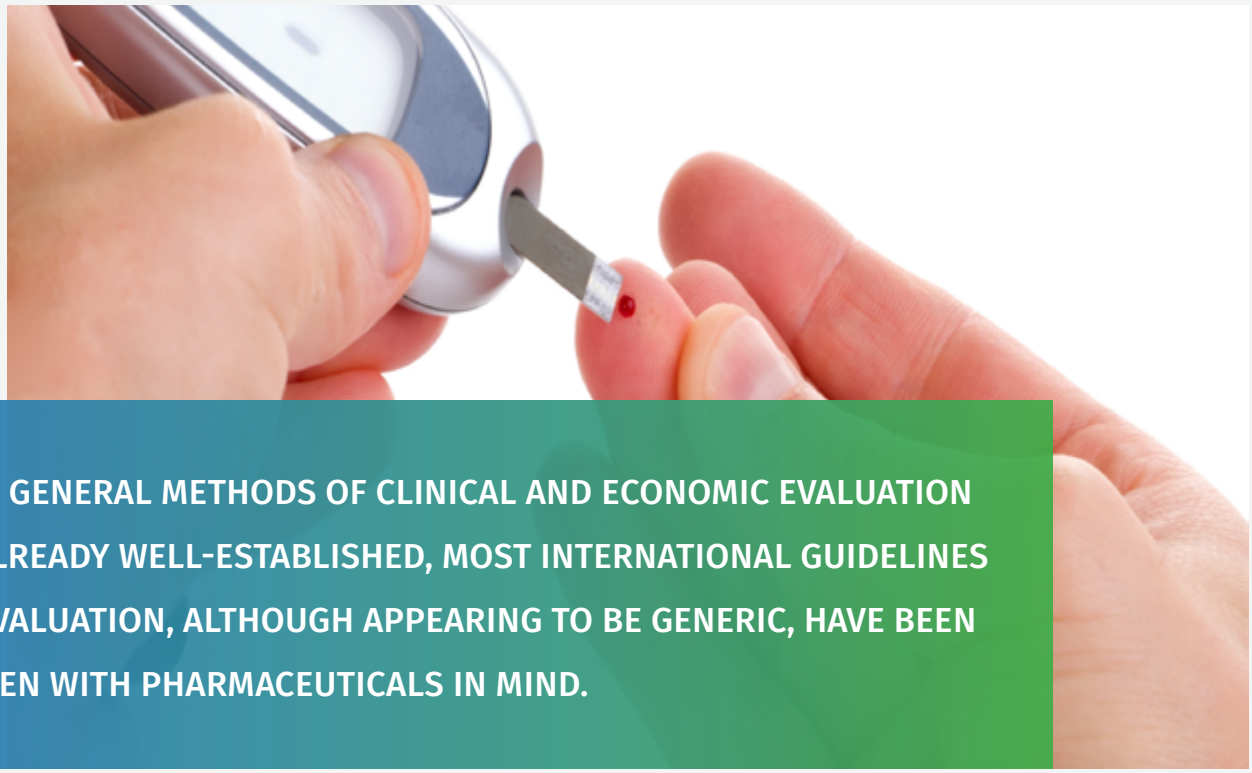
52. Drummond;, M., A. Griffin and R. Tarricone, Economic Evaluation for Devices and Drugs - Same or Different? Value in Health, 2009. 12(4): p. 402–404.

53. Ramsay, C. et al., Statistical assessment of the learning curves of health technologies. Health Technology Assessment, 2001. 5(12).

54. Tarricone, R., A. Torbica; and M. Drummond, Challenges in the Assessment of Medical Devices: The MedtecHTA Project. Health Economics, 2017. 26: p. 5–12.

These factors represent challenges for assessing the efficacy and cost-effectiveness of medical devices. For example, most guidelines for economic evaluation around the world require randomised controlled trials for the clinical assessment of devices. However, in contrast to pharmaceuticals and due to the peculiarity of medical devices, the studies on devices can be small clinical trials or even non-randomised clinical investigations. Therefore, the long-term efficacy data recorded is not generally obtained in the pre-marketing phase, thus reducing the knowledge base for subsequent HTA activities.[55]

Another key difference between devices and pharmaceuticals is that many devices are only used in the diagnosis of disease. This presents a major challenge for clinical evaluation, as the value of improved diagnosis cannot be separated from the value of the improvement in patient outcome that results from the subsequent treatment.[56] This makes it much more difficult to make a complete clinical evaluation of the patient outcomes and as a result, also impacts the subsequent economic assessment of the device.



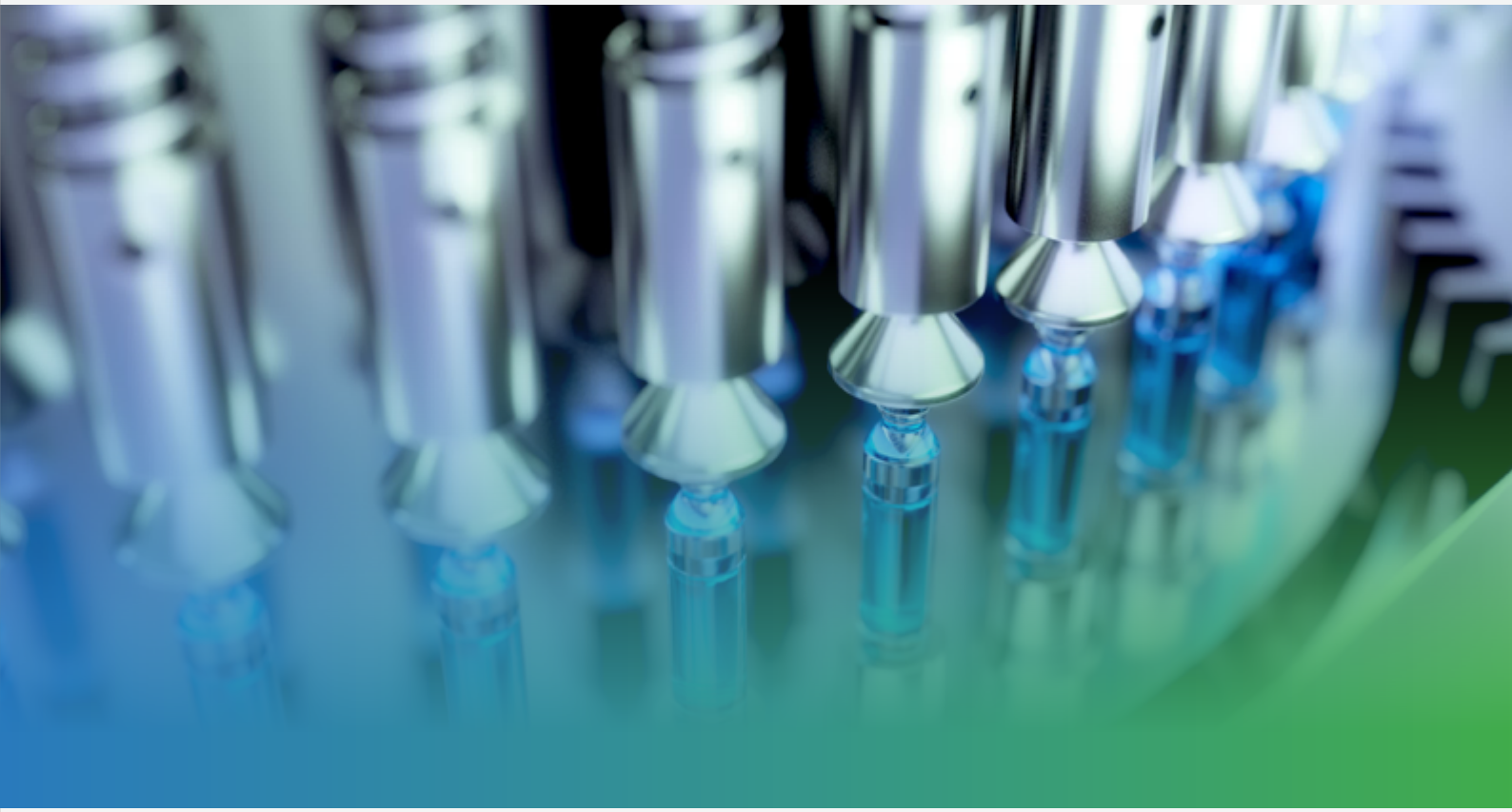
WHILE GENERAL METHODS OF CLINICAL AND ECONOMIC EVALUATION ARE ALREADY WELL-ESTABLISHED, MOST INTERNATIONAL GUIDELINES FOR EVALUATION, ALTHOUGH APPEARING TO BE GENERIC, HAVE BEEN WRITTEN WITH PHARMACEUTICALS IN MIND.

55. Ibid.

56. Drummond;, M., A. Griffin and R. Tarricone, Economic Evaluation for Devices and Drugs - Same or Different? Value in Health, 2009. 12(4): p. 402–404.

RESEARCH AND DEVELOPMENT

This section provides detail on research and development, including intellectual property considerations, and clinical trial activities in Australia.



Research and development (R&D) refers to the activities undertaken by firms to create new or improved products and processes and is regarded as one of the most important drivers of innovation.[57] Under this phase, companies undertake the research required to gather the clinical evidence to enable marketing approval of a medical device by the TGA. They also consider what other evidence is required to enable the device to be reimbursed or funded in Australia and undertake the research required.

Investing in R&D has resulted in everything from small commercial initiatives to growth in major technology industries, leading to the employment of millions of workers. The major impact on employment resulting from innovation affects not only global technology companies, but also other industries that benefit from increased capabilities and productivity. Reinforcing complementary investments in R&D by both the private and public sector helps encourage the development, production, and commercialisation of new products and services.[58]

57. Hall, B.H., Research and Development. International Encyclopaedia of the Social Sciences, 2006.

58. National Science Board, Research & Development, Innovation and the Science and Engineering Workforce. 2012.

EXPENDITURE ON R&D

Total R&D investment in the medical technology and pharmaceuticals sector was estimated to be $1.36 billion in 2016, with investment being flat since 2012.[59] While industry R&D spending is less than that of government grants, it still totals 45% of all R&D expenditure (Figure 17).

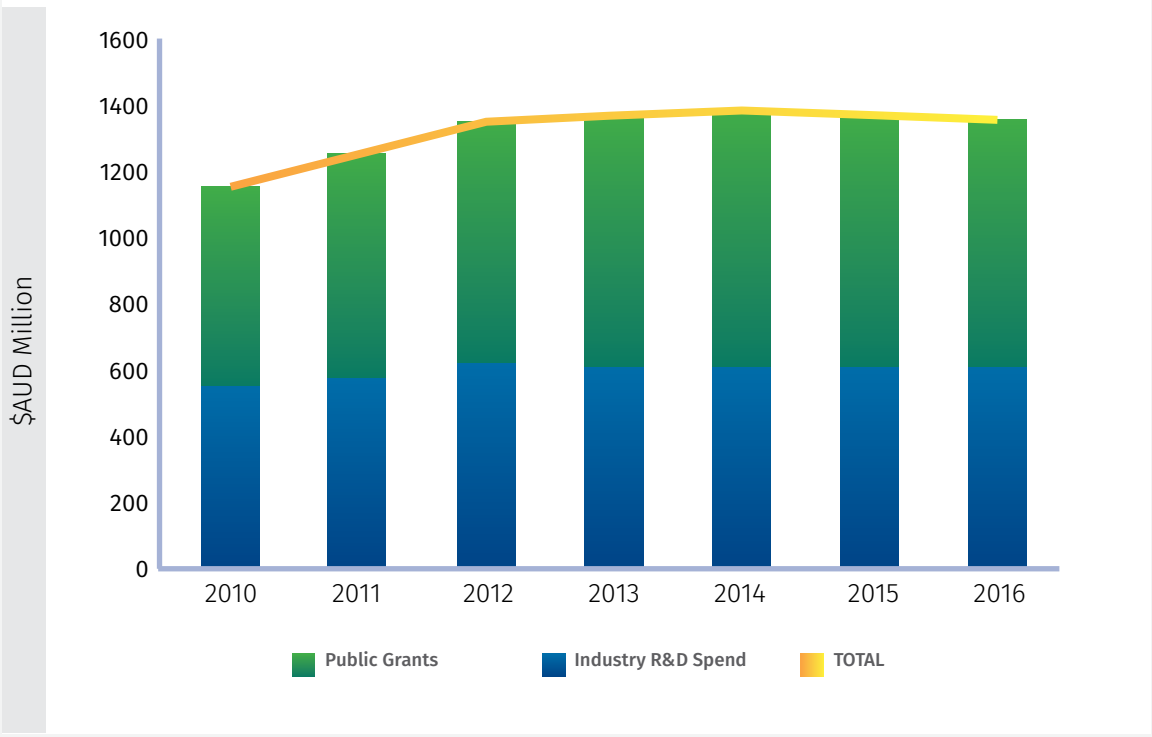


Figure 17. Research and development investment in the medical technology and pharmaceuticals sector. Source: MTP Connect

There is a range of government assistance and funding available for medical technology companies in Australia to support R&D, including the R&D Tax Incentive.

59. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

R&D TAX INCENTIVE

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.

Prior to 1 July 2018, the R&D Tax Incentive provided 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 their R&D costs.[60] It is a broad-based entitlement program open to companies of all sizes in all sectors that are conducting eligible R&D.

The R&D Tax Incentive was reviewed in 2016 by a panel consisting of Bill Ferris, Dr Alan Finkel and John Fraser to "identify opportunities to improve the effectiveness and integrity of the R&D Tax Incentive, including by sharpening its focus on encouraging additional R&D spending".[61]

As a result of the Review, from 1 July 2018, many changes will be made to the Incentive. These changes include abolishing the 43.5% tax offset to entities with a turnover of below $20 million and replacing this with an offset equal to their corporate tax rate plus a 13.5% premium. For entities with an annual turnover of $20 million or more, the tax offset is equal to the company's corporate tax rate plus a premium based on their level of incremental R&D intensity (i.e. the proportion of the spend on R&D compared to the total expenditure for the year).

Importantly, in considering the recommendations from the Review, the Government has recognised the critical role of clinical trials in developing life-changing medicines and medical devices. As such, it agreed to exempt R&D expenditure on clinical trials from a key change to the Incentive recommended by the Review which would have capped refunds on clinical trial expenditure to $4 million per annum. The legislation to give effect to these and other changes to the incentive is expected to be in place prior to the end of the 2018-19 financial year.

60. ATO. Research and development tax incentive. About the program. Available from: https://www.ato.gov.au/business/research-and-development-tax-incentive/about-the-program

61. Ferris, B., A. Finkel and J. Fraser, Review of the R&D Tax Incentive. 2016.

CLINICAL TRIALS

Clinical trials provide patients with access to new promising treatments with the potential to save or prolong their lives, or improve their quality of life. They are vital for advancing research and development of novel and high-tech medical technologies and provide an opportunity for doctors to learn about the latest methods of treatment and to improve healthcare in general.

For medical devices, a clinical trial is defined as a systematic investigation in one or more human subjects, undertaken to assess the clinical performance or effectiveness and safety of a medical device.[62]

The evaluation and appraisal of findings from clinical research leads to the assessment of current clinical practice and the adoption of the best scientific evidence, which translates into evidence-based practice.[63]

BENEFITS OF CLINICAL TRIALS

Clinical trials provide great economic benefits, such as vast employment in clinical research in medical technology, pharmaceutical and biotechnology companies, as well as reducing healthcare costs through providing sponsored treatment to patients which would otherwise have to be met through healthcare budgets. Flow-on benefits from clinical trials include timely access to innovative technologies, improved quality of life and reduced mortality for participants; training of research staff; and encouraging the culture of research in hospitals (Figure 18).[64]

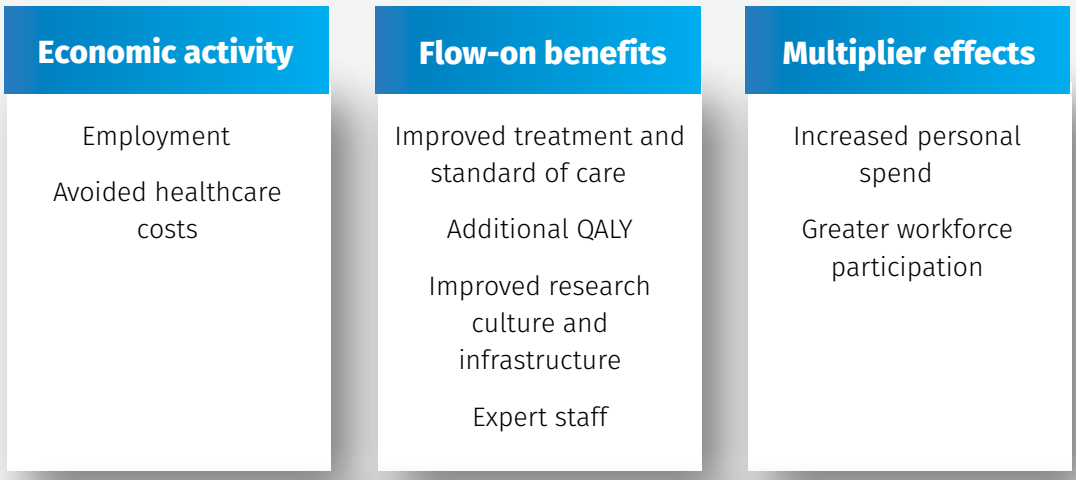


Figure 18. The benefits of clinical trials. Source: MTP Connect.

62. Medicines Australia, Clinical Trials – my health, my decision. Available from: https://medicinesaustralia.com.au/policy/clinical-trials/

63. Barbosa, D., The importance of clinical research in improving health care practice. Acta Paulista de Enfermagem, 2010. 23(1).

64. MTPConnect, Clinical Trials in Australia: The value and competitive advantage in the sector. 2017, MTPConnect.

Taking into account the estimated 2,200 jobs provided through clinical trials in the clinical setting, clinical trials employ over 6,900 staff.[65] A recent report by the Australian Clinical Trials Alliance and the Australian Commission on Safety and Quality in Health Care found that for every $1 spent on clinical trials there was a return on investment of approximately $5.80, and that there would be a gross benefit of approximately $2 billion measured through better health outcomes and health service costs.[66] Overall, total clinical trial activity in Australia contributed AU$1.1 billion of direct investment to the Australian economy in 2015,[67] of which AU$930 million was from medical technology, biotechnology and pharmaceutical companies.

CLINICAL TRIAL ACTIVITY

The number of new clinical trial notifications (CTN) in Australia continues to grow steadily. In July to December 2017, there were 252 notifications received by the TGA for new clinical trials involving at least one medical device, a growth of 22% from the same period in 2016.[68]

Overall, there has been a steady increase of clinical trials started in Australia between 2010 and 2015, with an overall compound annual growth rate of 2.2%. In 2015, a total of 1,357 clinical trials were started in the medical technology and pharmaceuticals sector, with 159 trials involving medical devices and a further 15 trials using both a drug and device (Figure 19).[69]

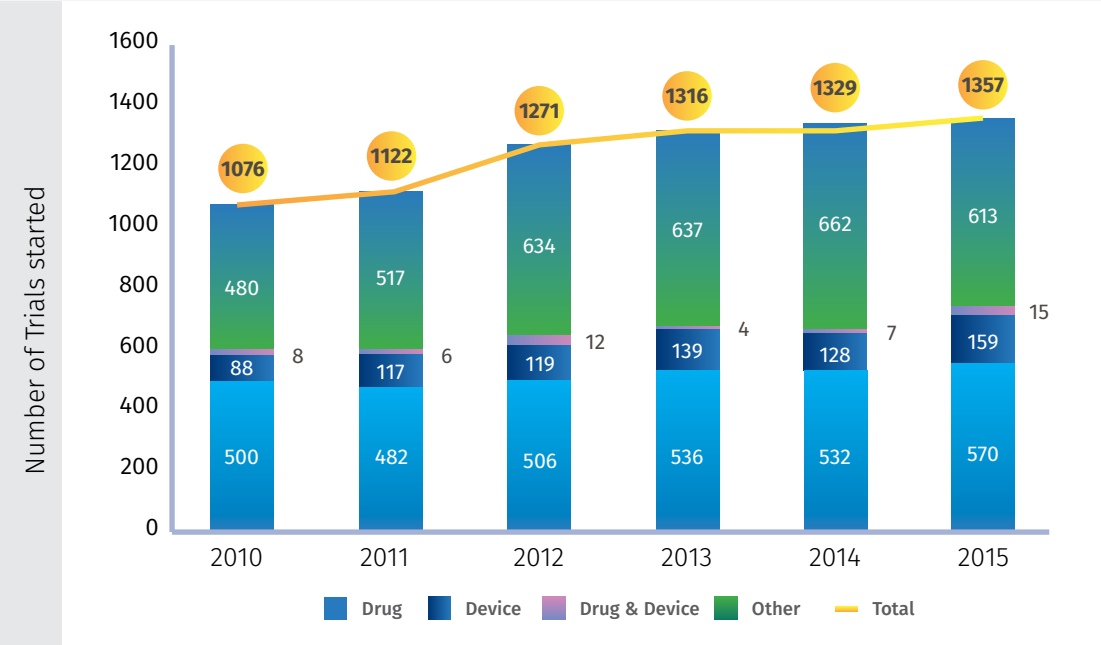


Figure 19. Clinical trials started in Australia by intervention type.. Source: MTP Connect.

65. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.
66. Australian Commission on Safety and Quality in Health Care, Economic evaluation of investigator-initiated clinical trials conducted by networks. 2017.
67. MTPConnect, Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector. 2017.
68. Therapeutic Goods Administration. Half yearly performance snapshot: July to December 2017. 3 April 2018. Available from: https://www.tga.gov.au/half-yearly-performance-reports.
69. MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

According to data from the Australian and New Zealand Clinical Trial Registry, since 2010 the number of clinical trials for medical devices has grown at a faster rate than for drugs or non-biological procedures – a compound annual growth rate of 13% versus 2.7% and 5% respectively.[70]

The largest number of studies are registered in Victoria (28%) and New South Wales (24%). The remainder are about equally shared between Queensland (16%), South Australia (14%) and Western Australia (13%) (Figure 20).

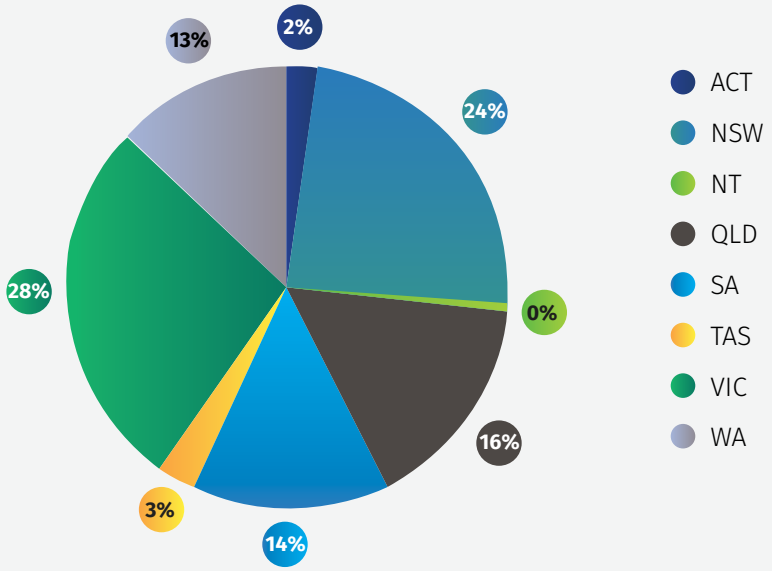


Figure 20. Cumulative number of clinical trials registered in Australia by state and territory. Source: ClinicalTrials.gov

REGULATORY REQUIREMENTS FOR CLINICAL TRIALS

Clinical trials conducted using therapeutic goods that have not been included on the Australian Register of Therapeutic Goods (ARTG) for general marketing are required to make use of the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes. This is because such products are considered experimental and do not have general marketing approval.. The CTN and CTX schemes provide two of these avenues for supply.[71]

70. MTPConnect, Clinical Trials in Australia: The value and competitive advantage in the sector. 2017, MTPConnect.

71. Therapeutic Goods Administration, Australian Clinical Trial Handbook, Version 2.0, March 2018; Available from: https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook-01.pdf

Under the CTN scheme, scientific and ethical review is provided by a human research ethics committee (HREC), with subsequent notification to the TGA. In the CTX scheme, the TGA has a direct role in the review of trial scientific data and must give 'approval' for the proposed trial program to go ahead; however, HREC review is still required.[72]

Clinical trials that only involve approved therapeutic goods do not need to go through the CTN or CTX processes. While both schemes grant exemptions for unapproved goods to be used in Australia, if a clinical trial only uses approved therapies then this exemption is unnecessary. In saying this, however, all clinical trials run in Australia still require review and approval by an ethics committee.[73]

CLINICAL TRIALS THAT ONLY INVOLVE APPROVED THERAPEUTIC GOODS DO NOT NEED TO GO THROUGH THE CTN OR CTX PROCESSES.

72. National Health and Medical Research Council. Australian Clinical Trials - The regulatory environment. 2015; Available from: https://www.australianclinicaltrials.gov.au/researchers/regulatory-environment.
73. Therapeutic Goods Administration, Australian Clinical Trial Handbook, Version 2.0, March 2018; Available from: https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook-01.pdf

OBTAINING PATENTS

A key component of the product development phase relates to companies obtaining patents for their products.

In Australia, there are two types of patents available: standard and innovation patents. Standard patents are for inventions that are completely original, include an inventive step, and last 20 years. For inventions that do not meet the inventive step requirement, an innovation patent applies. These are cheaper to obtain than the standard patent and only last for an eight-year period. They are more suited to inventions that are an advancement on an existing technology, rather than a ground-breaking invention.[74]

Australians looking to sell their invention globally are required to apply for patents in overseas markets, as intellectual property rights are only enforceable within the jurisdiction in which they are granted. To do so, Australians can either file separate patents in each of the countries they wish to sell their invention or file a single international application known as a Patent Cooperation Treaty (PCT) application. A PCT application gives intellectual property rights in over 140 countries and enables the filing of a single patent application across those countries simultaneously. The PCT application still requires the invention to meet all the different regulations and standards for each country, but any costs incurred can be deferred for up to 30 months.[75] While a PCT application allows companies to sell in a much larger market, filing separate patents in specific countries may be much more cost-effective. Therefore, the decision between filing for a PCT application or separate patents in each country is largely dependent on the invention and the business strategies put in place.

The World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) collaborate to respond to increasing demand for innovative medical technologies and to ensure access to these technologies. Patent applications by medical technology companies provide a good indicator of innovation.

74. IP Australia. Types of Patents. 2016 [cited 2017]. Available from: https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents#standard.

75. IP Australia, A guide to applying for your patent overseas. 2014: Canberra.

According to data analysis for innovation capacity of more than 100 countries worldwide in the Global Innovation Index 2016, Australia was ranked 19th, down from 17th place in 2015 (Figure 21).

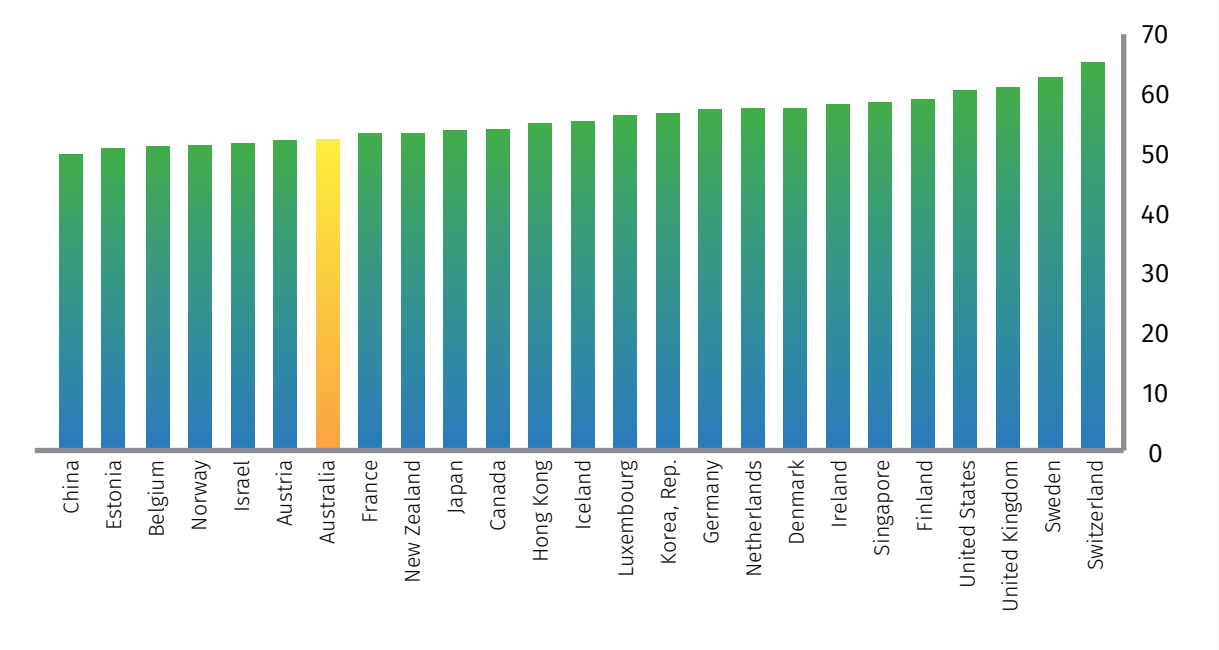


Figure 21. The Global Innovation Index of the top 25 countries. Source: WIPO

In Australia, medical technology innovation patent applications made up 8% of the total number of applications from 2001 to 2015, which is comparable to those pertaining to pharmaceuticals (6.4%) and civil engineering (8.6%).[76] The number of Australian medical technology patent grants has grown steadily since 2009 (Figure 22).[77]

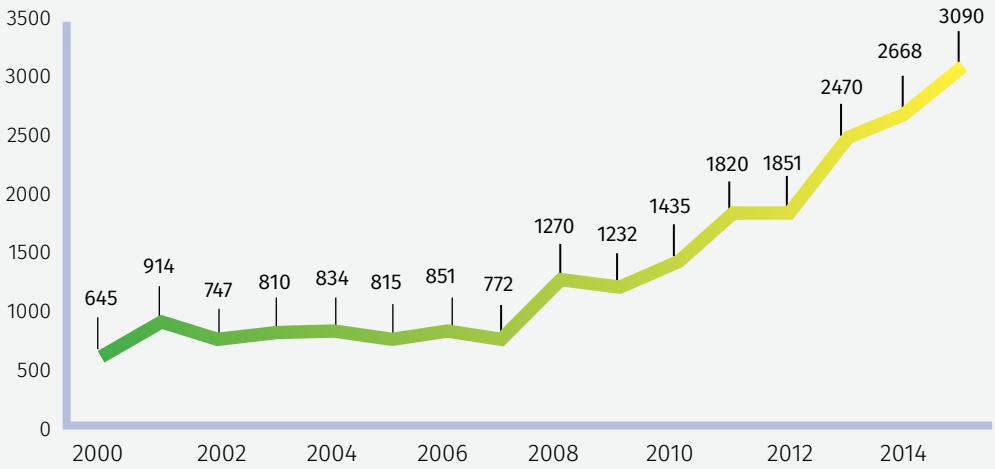


Figure 22. Number of Australian medical technology patent grants from 2000. Source: WIPO statistics database

76.. Statistical Country Profiles. Available from: http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=AU

77. WIPO IP Statistics Data Center. Available from: https://www3.wipo.int/ipstats/

TGA REGULATION OF MEDICAL DEVICES

This section provides information on key pre and post-marketing regulation of medical devices conducted by the TGA and provides some key regulatory statistics.

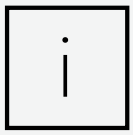
MARKETING APPROVAL

All medical devices supplied domestically must be approved for marketing in Australia following an assessment of the quality, safety and efficacy of the device by the TGA. Once approved, these devices are entered into the Australian Register of Therapeutic Goods (ARTG) and it is ARTG inclusion which allows therapeutic goods to be supplied in Australia.

It should be noted that TGA also has schemes which allow for unapproved medical devices to be supplied to individual patients or prescribers.

The TGA adopts a risk-based approach to regulation, where higher levels of evidence are required to obtain marketing approval for higher-risk devices (such as pacemakers) compared to lower-risk devices (such as tongue depressors).

The extent of regulation depends on:



The intended purpose of the device

The degree of risk the device poses to the patient

The degree of risk the device poses to the user and those in the vicinity

Whether the device is used internally or externally to the patient the duration of its use

RISK CLASSIFICATION

The TGA has adopted a classification system for devices based on the level of risk. The lowest-risk medical devices, Class I devices, are not assessed by the TGA prior to inclusion on the ARTG except for Class I devices which require sterilisation or have a measuring function (Class I(s)) (see Table 1).[78]

Examples of the classification of medical devices below.

Class	Risk	Examples of technology
Class I	Low	Non-sterile dressings, wheelchairs, reusable surgical instruments, devices for export only.
Class I(m)	Low to Medium	Class I devices with a measuring function, such as thermometers and patient scales.
Class I(s)	Low	Class I devices supplied sterile, such as sterile, adhesive bandages.
Class IIa	Low to Medium	Electrocardiographs, hearing aids, X-ray films, dental filings, TENS muscle.
Class IIb	Medium to High	PCA pumps, blood tags, orthopaedic plates and screws, device disinfectants.
Class III	High	Heart valves, breast implants, drug-eluting coronary stents, hip and knee replacements.
AIMD*	High	Pacemakers, implantable defibrillators, cochlear implants, ventricular assist.

Table 1. Classification system used for medical devices listed in the Australian Register of Therapeutic Goods. Notes: *Active implantable medical devices. Source: TGA.

78. Therapeutic Goods Administration, Australian Register of Therapeutic Goods. 2017, TGA.

78. Ibid.

KEY REGULATORY DATA

As of January 2017, there were 54,555 entries for medical devices in the ARTG,[79] all of which are categorised into classes according to their risk level (Table 1 & Figure 23).

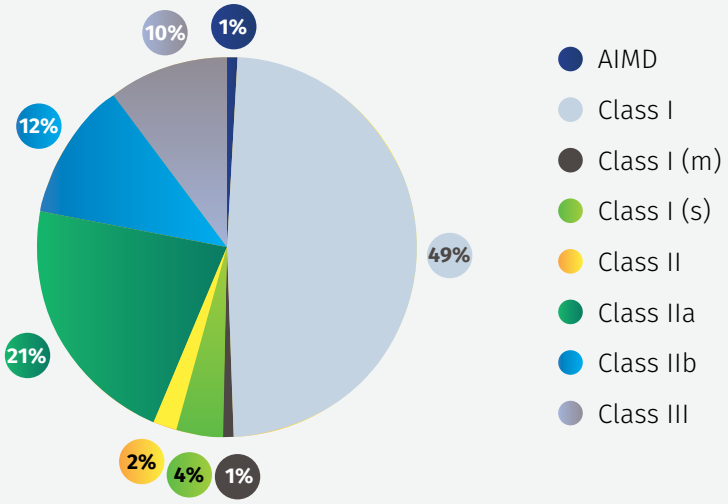


Figure 23. Australian Register of Therapeutic Goods medical device entries in January 2017 by device class.

There was a substantial increase in Class III (high) devices entered in the ARTG during 2013 (up 133% from the previous year), due to the reclassification of hip, knee and shoulder joint replacements in 2012, from Class IIb (medium to high) to Class III (high). However, as seen below, ARTG entries for all classes have seen little to no growth since 2015. Most significantly, Class I (low) devices have seen a sharp decline of 15% in 2016, after progressively increasing since 2012 (Figure 24).

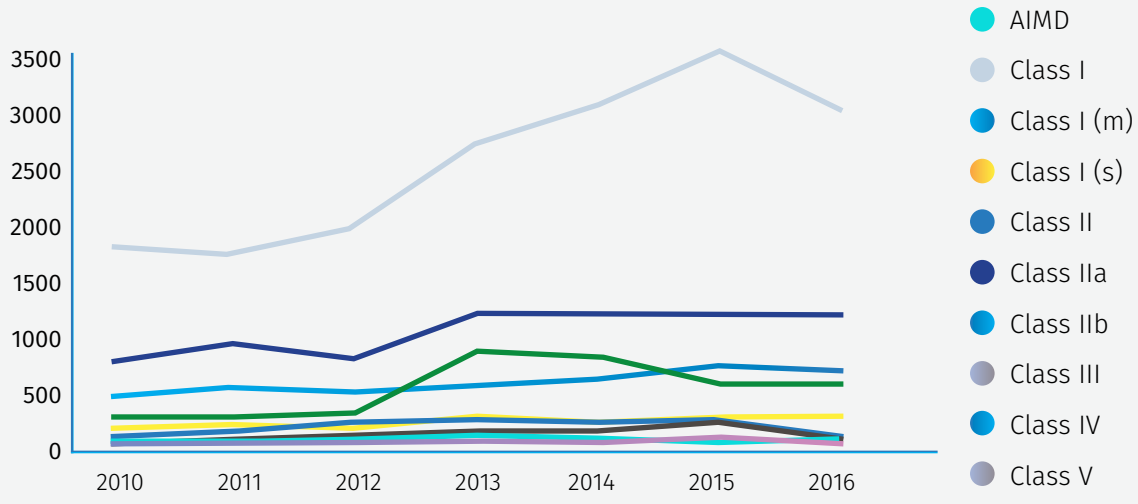


Figure 24. Australian Register of Therapeutic Goods licence-starting dates by device class. Source: TGA

POST-MARKETING

The TGA is also responsible for monitoring the safety, performance and quality of all devices, once listed on the ARTG and once the product is supplied on the market. The TGA's Incident Report and Investigation Scheme (IRIS) is a system in place that allows for anyone to report an adverse event related to a therapeutic item.

An adverse event is an event that has lead to either a death or a serious injury/deterioration to a patient, user or other person. Serious injuries include a life-threatening injury, permanent impairment of a body function, permanent damage to a body structure or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.[80]

As of 2015, the TGA has received more than 36,600 adverse event reports relating to medical devices since the commencement of IRIS in 1986.[81] In 2015, the TGA received 3,359 adverse event reports relating to medical devices, with 84% (2,817) of reports made by medical technology sponsors.[82]

It should be noted that device-related adverse event reports in IRIS are not necessarily linked to the medical device, but indicate that the device has been linked to the event by the reporter of the incident. Further investigation is required by the TGA to ascertain whether the event is caused by the device or whether there are other causes such as user error or the patient's physical condition or characteristics.

A better perspective on the overall safety of medical devices can be gained by reviewing the number of Class I, II and III recalls of medical devices reported in the System for Australian Recall Actions (SARA) and comparing that to the number of ARTG enties for medical devices.

80. Cornell University and INSEAD. Global Innovation Index 2016. 2016. Available from: http://www.wipo.int/publications/en/details.jsp?id=4064

81. Statistical Country Profiles. Available from: http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=AU

82. Ibid

The TGA classifies the types of recalls based on the consequence of the adverse event reported.

Specifically:

- Class I recalls are the most serious safety-related recalls where there is a reasonable probability that exposure to, or use of, the medical device will lead to significant adverse health outcomes, including death
- Class II recalls are urgent safety-related recalls where exposure to, or use of, the medical device may cause temporary or reversible adverse health consequences and these are unlikely to be serious in nature
- Class III recalls where exposure to, or use of, the medical device is unlikely to lead to adverse health consequences.

The data from SARA indicates that for the period of 1 July 2012 (the inception of SARA) to 30 June 2017, there were 2,985 recalls for medical devices, with 613 and 598 reported in the 2015–16 and 2016–17 financial years respectively. Class I recalls occurred for 19.7% of the recalls which occurred in 2015–16 and 19.1% for 2016-17.

In the context of the number of ARTG entries for medical devices, the total number of recalls annually in the 2015–16 and 2016–17 financial years involved only around 1% of ARTG entries and the number of Class I recalls around 0.2% of all ARTG entries.

IN 2015, THE TGA RECEIVED 3,359 ADVERSE EVENT REPORTS RELATING TO MEDICAL DEVICES, WITH 84% (2,817) OF REPORTS MADE BY MEDICAL TECHNOLOGY SPONSORS.

REIMBURSEMENT AND FUNDING OF MEDICAL DEVICES

Once marketing approval is granted by the TGA, sponsors are able to supply their device in the market. However, as medical devices are supplied in a diverse range of healthcare settings, the requirements or activities a sponsor needs to undertake to supply and be paid for their products in these settings are numerous and can vary significantly.

Sponsors can supply their devices under Commonwealth programs based on reimbursement or funding mechanisms (such as the Prostheses List and the National Diabetes Services Scheme). They may also supply their devices outside of Commonwealth programs where medical devices are purchased under normal commercial arrangements and which may involve some type of contractual arrangements.

Given the significance of this issue to many medical devices sponsors, this section discusses the key Commonwealth programs whereby reimbursement or funding of medical devices occurs.

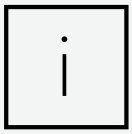
OVERVIEW

Medicare arrangements, including what is not covered, have a significant impact on the reimbursement, funding and purchasing arrangements for medical devices.

Reimbursement decisions under the Prostheses List and Medicare Benefits Schedule (MBS) are informed by HTA and are associated with established assessment processes. As such, they are a focus in this section. There is less focus on other programs or processes as it is not clear how funding or purchasing decisions are informed and there is significant variability in the processes that need to be followed.

MEDICARE

Medicare is the publicly funded universal healthcare scheme in Australia and provides patients with low cost or free access to the following:



Access to care in public hospitals

Access to some services in private hospitals

Access to medical services provided by general practitioners, specialists and some other healthcare practitioners outside the hospital setting as outlined in the Medical Benefits Schedule

Access to pharmaceuticals through the Pharmaceutical Benefits Scheme

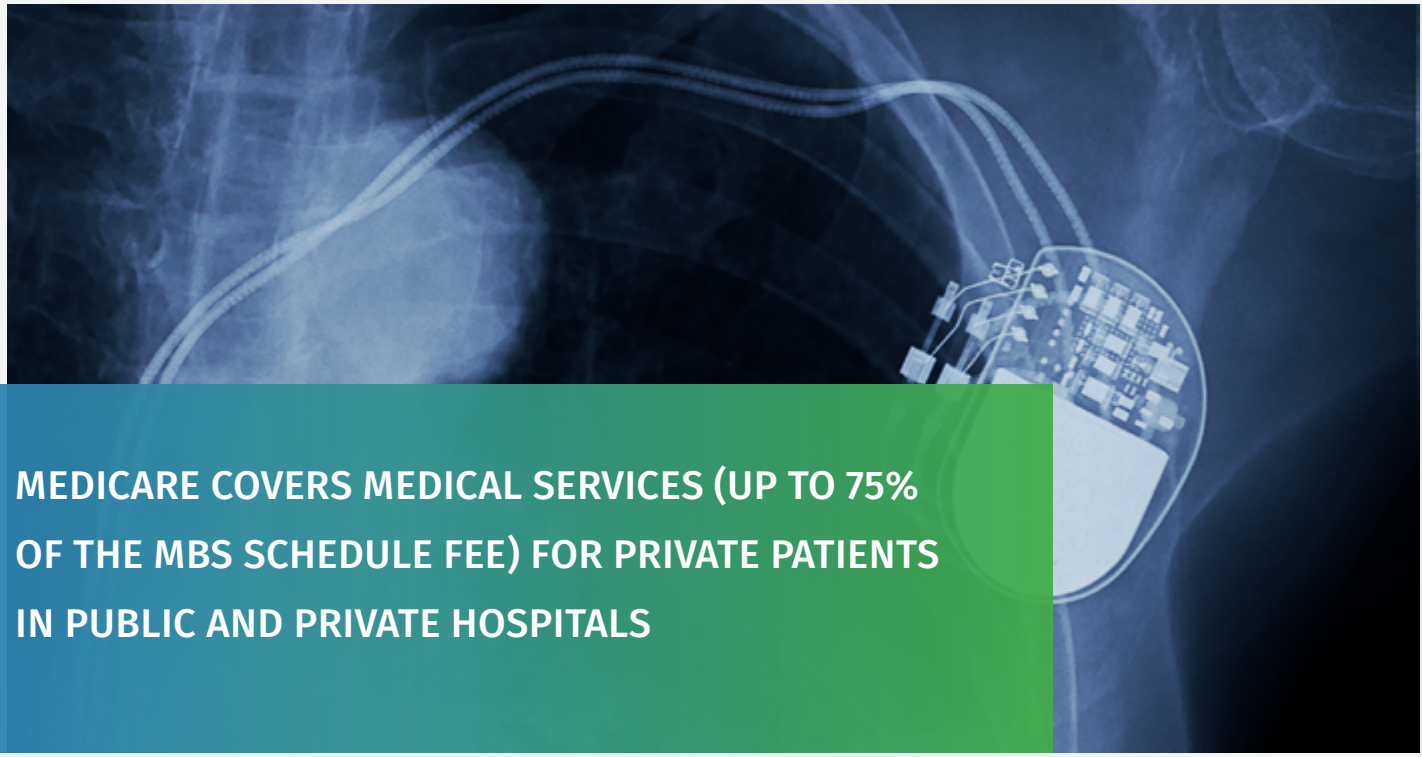
HOSPITALS

Medicare guarantees free treatment for public patients in public hospitals and provides for public hospitals to be jointly funded by the Commonwealth and States and Territories.

In public hospitals, medical devices used for public patients are generally purchased through a tender process conducted centrally by or on behalf of State/Territory Governments.

In private hospitals, Medicare covers medical services (up to 75% of the MBS Schedule fee) for private patients in public and private hospitals but excludes the cost of accommodation, theatre fees, medicines and medical devices. The costs of these 'shortfalls' are covered by private health insurers and are dependent on the contractual arrangements in place between the insurer, the hospital and the patient's level of insurance cover (although gaps in insurance coverage may lead to patient out-of-pocket expenses).

Medical devices are purchased directly by the private hospital. However, for some implantable medical devices associated with the provision of a service for which an MBS fee is payable, there are arrangements under the Prostheses List which guarantee that patients who are appropriately insured are covered for the cost of some of these devices, irrespective of the arrangements between the hospital and the insurer.



MEDICARE COVERS MEDICAL SERVICES (UP TO 75% OF THE MBS SCHEDULE FEE) FOR PRIVATE PATIENTS IN PUBLIC AND PRIVATE HOSPITALS

MEDICAL SERVICES

Medicare funds out-of-hospital medical services, including treatment by general practitioners and specialists and some diagnostic and pathology services. The cost of the medical device, if associated with the provision of the service, is included in the MBS Schedule fee.

Some of the medical services not covered by Medicare which involve medical technologies include most dental treatment, physiotherapy, podiatry, glasses and contact lenses, hearing aids and other appliances, and surgery for purely cosmetic purposes, which is not covered by Medicare. The purchaser or funder of the cost of these medical devices can be the consumer, the healthcare professional, private insurers or other Government programs designed to support a particular need.

OVERVIEW OF HTA COMMITTEES

Figure 25 below indicates the key Commonwealth committees which use HTA to inform reimbursement decisions.[83] While PBAC does not make recommendations in relation to medical devices, it has been included as one of the key HTA Committees.

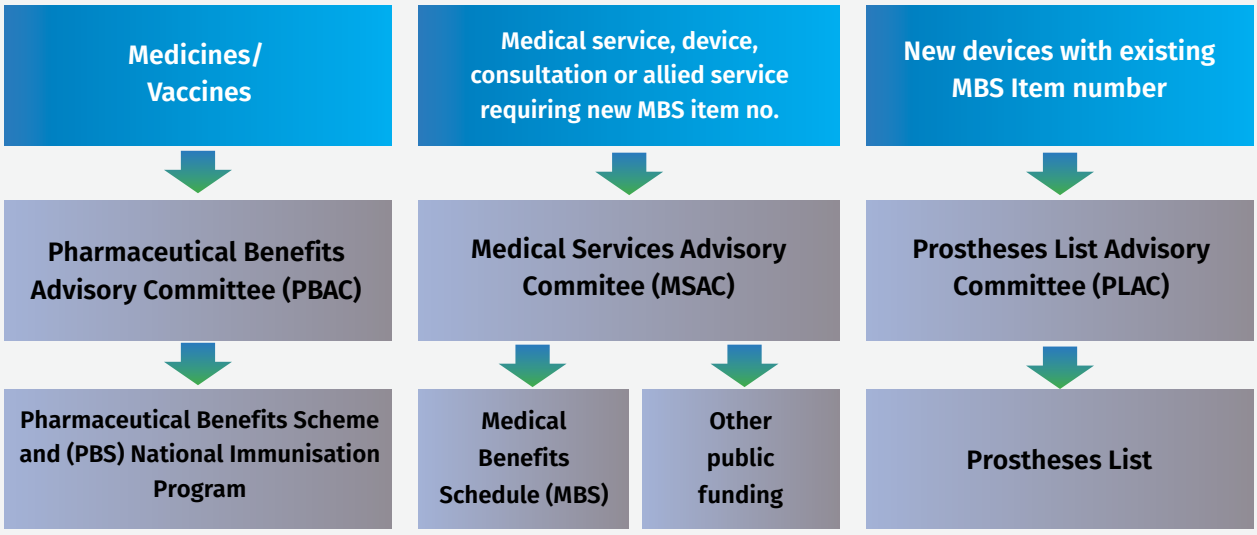


FIgure 25. Government committees which use HTA to inform reimbursement decisions

83. It should be noted that PBAC does not recommend reimbursement for medical devices but does make recommendations to list medicines which require the concomitant use of a medical device (such as a companion diagnostic test). As such, PBAC applications which include such devices are generally referred to MSAC for assessment while PBAC assesses the medicine. The medicine can generally not be listed on the Pharmaceutical Benefits Scheme unless the MSAC assessment of the medical device is favourable.

THE ROLE OF MSAC AND LISTING ON THE MBS

Medical services can be included on the MBS following successful evaluation of an application to the Medical Services Advisory Committee (MSAC). The cost of a medical device is included in the determination of the MBS benefit payable for the medical service.

The principal role of MSAC is to advise the Minister for Health on the strength of the evidence relating to the safety, effectiveness and cost-effectiveness of medical technologies and procedures.[84] Applications to MSAC are generally made by healthcare professionals, peak health bodies and the medical devices industry.

In recent years, the number of positive recommendations by MSAC has been on the decline. In the most recent analysis by MTAA, between 2013 and 2015, the rate of positive recommendations fell from 61% to 24%. Rejections rose from 14% to 48% (Figures 26 and 27).[85]

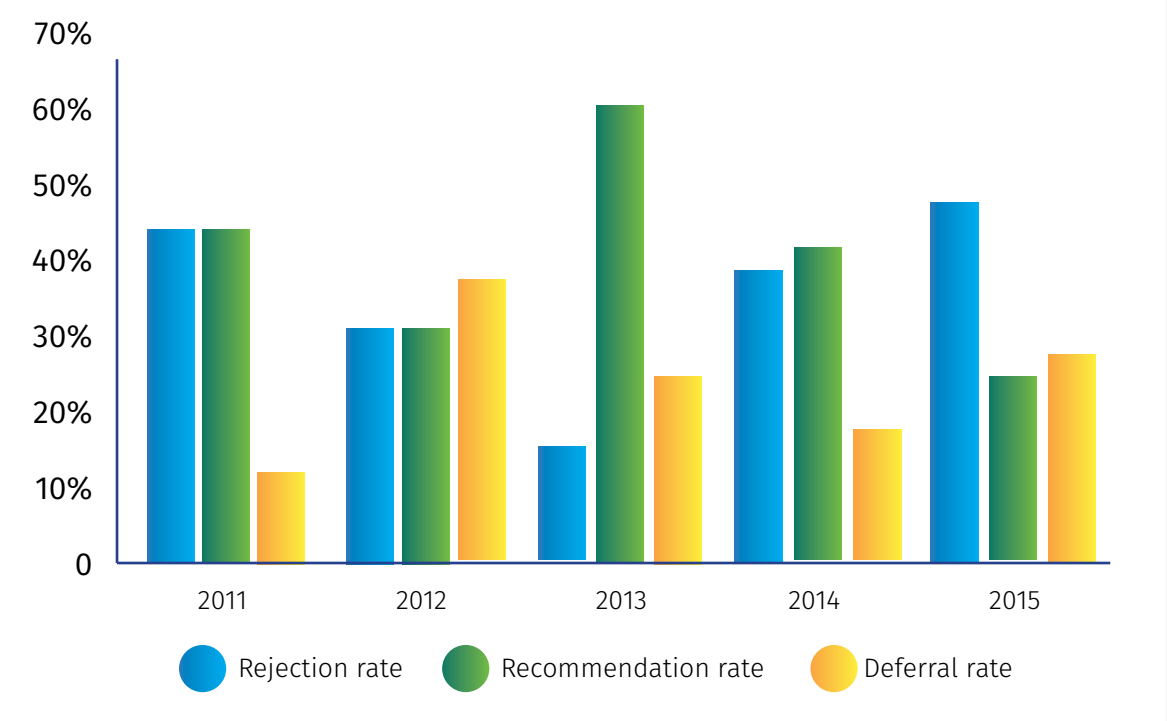


Figure 26. MTAA analysis of outcomes of MSAC applications from 2011–2015.

84. The Medical Services Advisory Committee (MSAC). Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/about-msac.

85. MTAA's analysis of outcomes of MSAC applications from 2011–2015 is based on 2016 analysis of information from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/application-page

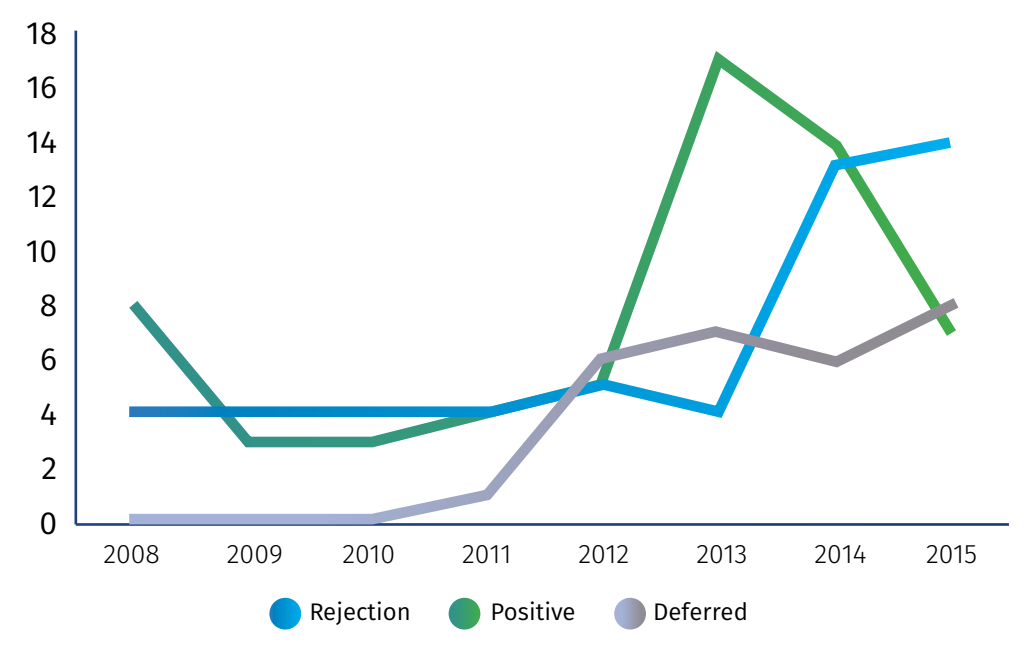


Figure 27. MTAA analysis of outcomes of MSAC applications from 2011-2015

PLAC ASSESSMENT AND LISTING ON THE PROSTHESES LIST

As outlined above, under Medicare, privately insured patients are not covered for the cost of medical devices associated with the provision of the hospital service.

This gap for private patients is addressed through the Prostheses List arrangements which are established under the *Private Health Insurance Act 2007* (Cth). Under this legislation, private health insurers are required to pay mandatory benefits for a range of prostheses (implantable medical devices) that are provided as part of an episode of hospital (or hospital substitute) treatment where a Medicare benefit is payable for the associated professional service and the product is included on the ARTG.

As such, the Prostheses List forms a key element of Australian private health insurance arrangements. However, prostheses costs only represent 14% of insurer benefit payments for hospital cover policies compared to 70% of hospital benefits and 16% of medical service benefits.[86]

Items are listed on the Prostheses List based on advice from the Prostheses List Advisory Committee (PLAC).

The PLAC makes recommendations to the Minister for Health about the listing of prostheses and their benefits on the Prostheses List based on assessment of comparative clinical effectiveness and cost effectiveness of medical devices.

In making its recommendations, the PLAC takes into account whether the prostheses meets the criteria for listing, the comparative clinical effectiveness against the comparator, the appropriate grouping and the benefit that should apply.

Economic assessments are generally undertaken for new technologies or where a higher benefit than the appropriate comparator is being proposed. In all other cases, a simple validation against the benefit of the appropriate comparator is undertaken.

86. Australian Prudential Regulation Authority. Private Health Insurance Quarterly Statistics. 2017. Available from: http://www.apra.gov.au/PHI/Publications/Documents/1705-QPHIS-20170331.pdf

Based on data from the Australian Prudential Regulatory Authority (APRA), in the four quarters spanning April 2017 to March 2018, Prostheses List expenditure was $2.08 billion for a total of 2,791,428 prostheses.

The proportion of expenditure for each category in the 12 months ending March 2018 is outlined below (Figure 28) as is the number of prostheses supplied (Table 2). It can be seen that the highest Prostheses List expenditure occurred in the cardiac category whereas the greatest volume of prostheses supply occurred in the general miscellaneous category.

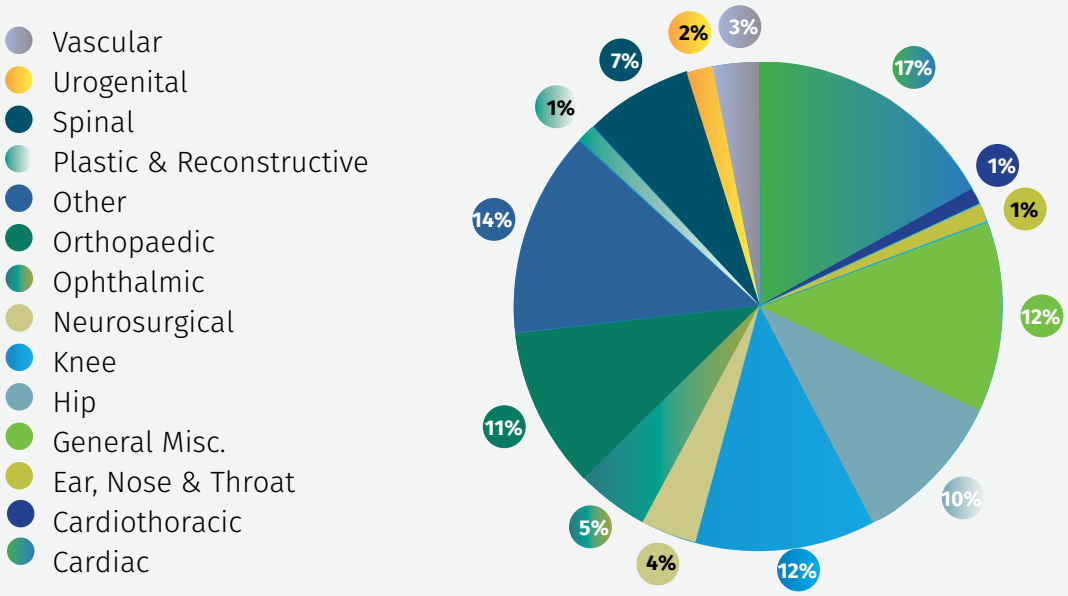


Figure 28. Proportion of benefits paid by insurers per Prostheses List category in the 12 months ending March 2018. Source APRA data

Product Category	No. of Prostheses	Percentage of total supplied
Cardiac	70,759	2.5%
Cardiothoracic	5,800	0.2%
Ear, Nose & Throat	37,270	1.3%
General Miscellaneous	847,352	30.4%
Hip	115,575	4.1%
Knee	129,893	4.7%
Neurosurgical	32,258	1.2%
Ophthalmic	336,792	12.1%
Orthopaedic	517,976	18.6%
Other	288,376	10.3%
Plastic & Reconstructive	87,325	3.1%
Spinal	201,859	7.2%
Urogenital	38,857	1.4%
Vascular	81,336	2.9%
Total	2,791,428	100

Table 2: Number of prostheses supplied per Prostheses List category in the 12 months ending March 2018. Source APRA data

In September 2017 (prior to the first tranche of Prostheses List benefit cuts referred to below on page 61), there were 11,240 items on the Prostheses List with around 94% of items included under Part A.

The minimum benefit amounts ranged from $7 to $100,000, with a median amount of $1,000. Items with a benefit of only $7 include insulin kits and accessories for infusion pumps, whereas a cardiac implantable device that restores the pumping of blood in people suffering from advanced heart failure had the highest minimum benefit. The majority of items on the Prostheses List have a minimum benefit amount between $1,001 and $5,000 (Table 3).

Minimum Benefit Amount	No. of items
$1 - $250	2,421
$251 - $500	1,460
$500 - $1,000	1,745
$1,001 - $5,000	4,827
$5,001 - $10,000	507
$10,001 - $50,000	275
Over $50,001	5

Table 3. Number of items per minimum benefit amount on the current Prostheses List

The largest categories under Part A by number of billing codes are specialist orthopaedic (3,183), spinal (1,803) and general miscellaneous (926) (Table 4).

Part A	
Product Category	**No. of devices**
01 - Opththalmic	317
02 - Ear, Throat and Nose	195
03 - General Miscellaneous	926
04 - Neurosurgical	475
05 - Urogenital	196
06 - Specialist Orthopaedic	3,183
07 - Plastic and Reconstruction	724
08 - Cardiac	364
09 - Cardiothoracic	102
10 - Vascular	497
11 - Hip	882
12 - Knee	883
13 - Spinal	1,803
Total	10,547
Part B	
Product Category	**No. of devices**
Cardiothoracic	20
Dermatologic	9
Ophthalmic	15
Orthopaedic	628
Total	672
Part C	
Product Category	**No. of devices**
03 - General Miscellaneous	9
08 - Cardiac	12
Total	21

Table 4. Prostheses List as of September 2017 by product category

In terms of the number of billing codes listed, both the Spinal and Orthopaedic product categories grew by 45% between 2012 and 2017 (Table 5).

Product Category	No. of items in 2012	No. of items in 2017	Percentage Change
Cardiac	317	376	18.6%
Cardiothoracic	98	122	24.5%
Ear, Nose & Throat	182	195	7.1%
General Miscellaneous	804	935	16.3%
Hip	1,167	882	-24.4%
Knee	1,093	883	-19.2%
Neurosurgical	424	475	12.0%
Ophthalmic	430	332	-22.8%
Orthopaedic	2,635	3,811	44.6%
Plastic & Reconstructive	898	724	-19.4%
Spinal	1,247	1,803	44.6%
Urogenital	214	196	-8.4%
Vascular	507	497	-2.0%

Table 5: Number of items in each product category on the Prostheses List

THE HISTORY OF THE PROSTHESES LIST

Prior to 1985, private insurers made individual decisions on which prostheses they would cover and the value of the benefit. This led to uncertainty in access to and the cost of prostheses for physicians and patients. Consequently, in 1985, the Australian Government intervened and introduced Schedule 5. This Schedule listed the prostheses and the benefits that should be paid by private health insurers.

Changes were made to the Schedule 5 arrangements in February 2001 to allow private health insurers to negotiate prostheses benefits in an effort to address inflation. However, this accelerated inflation to the point that by 2003–2004, the average price paid per benefit under the revised Schedule 5 arrangements had doubled.[87]

The Australian Government then introduced the Prostheses List (PL) framework in 2005 where prostheses and the associated benefits were included on a list based on an assessment linking improved health outcomes with the value of the prosthesis.

The introduction of the PL framework successfully addressed the earlier policy failures relating to certainty, cost and inflation. Analysis conducted by MTAA, based on APRA data, indicates that if the average (quarterly) benefit growth rate remained at the average level of 1.74% from 1999, the average Prostheses List benefit in December 2016 would have been 8% greater (i.e. $850 compared to the $794) (Figure 29).

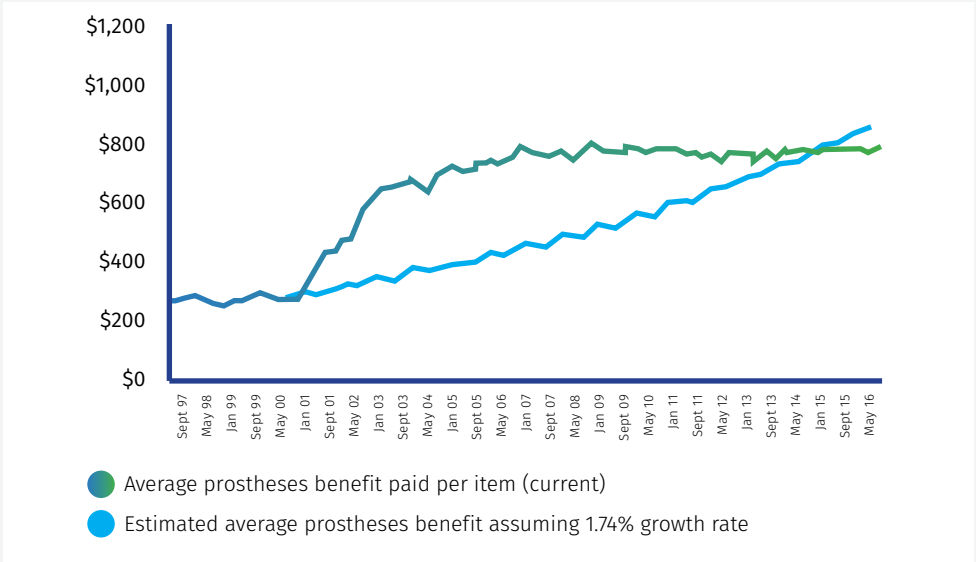


Figure 29. Average prostheses benefits paid per year. Source: MTAA analysis based on APRA data.

87. Report of the Review of Prostheses List Arrangements October 2007 – Robert Doyle on behalf of the Australian Government

Additionally, in real terms, the average prostheses benefit decreased by 20% between March 2007 to May 2016 ($997 in March 2007 versus $794 in May 2016) (Figure 30).

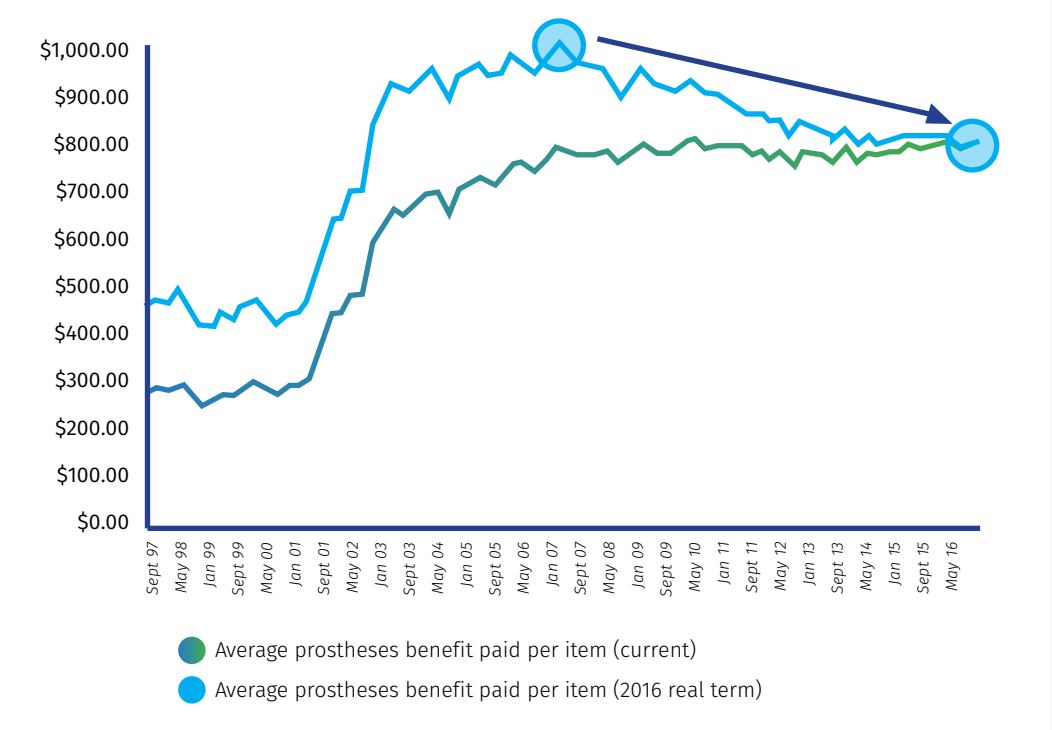


Figure 30. Average prostheses benefits paid vs real-term average prostheses benefit paid. Source: MTAA analysis based on APRA data

INDUSTRY AGREEMENT WITH GOVERNMENT

In 2017, MTAA and the Commonwealth entered into a historic four-year agreement (15 October 2017 – 31 January 2022). Under this agreement, the industry agreed to reductions in the benefit amounts on the Prostheses List and to participate in a process to reform the way benefits are set and reviewed in exchange for pricing and policy stability for the sector and a number of improvements to the Prostheses List arrangements.

Sector agreement to the cuts followed a period of significant pressure which had already seen significant cuts to certain Prostheses List categories in February 2018.

The total cuts to the Prostheses List benefits are estimated to deliver over $1 billion in savings to insurers over the life of the agreement.

OTHER GOVERNMENT PROGRAMS THAT FUND OR REIMBURSE MEDICAL TECHNOLOGY

There are numerous Commonwealth and State/Territory-based programs or schemes that provide access for patients to subsidised equipment and devices (Tables 6 & 7). These are generally associated with the provision of medical aids, appliances and consumables to assist people with impairment or disabilities in day-to-day living and community participation.

These programs or schemes vary in what is provided and how it is provided and the rationale for the decisions underpinning these.

Federal schemes	
National Disability Insurance Scheme (NDIS)	The NDIS supports Australians with disability, their families and carers at a cost of around $22 billion by 2019, of which the Australian Government is responsible for half of the annual costs.[88]
Repatriation Pharmaceutical Benefits Scheme (RPBS)	Administered by the Department of Veterans' Affairs (DVA), the RPBS provides access to certain medications, dressings and assistive devices for the treatment of entitled veterans and war widows.
Rehabilitation Appliances Program (RAP)	The RAP provides aids and appliances to eligible members of the veteran community to help them maintain their independence. A range of appliances are provided through six product groups. Administered by Diabetes Australia, this scheme delivers diabetes-related products at subsidised prices, information and support services to over 1 million people with diabetes each year. Products include blood glucose testing strips, insulin pump consumables, sharps and urine testing strips and products. For 2015–2016, the latest dates available, there were over 1.3 million people registered and the Australian Government spent over $200 million on the scheme that financial year.[89]

88. Buckmaster, L., Paying for the National Disability Insurance Scheme. Parliament of Australia. Available from: https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/BriefingBook45p/NDIS
89. Department of Health. National Diabetes Services Scheme (NDSS). 2017; Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-healthpro-supply-ndss.htm.

Federal Schemes	
Type 1 Diabetes Insulin Pump Program	The Type 1 Diabetes Insulin Pump Program is the result of collaboration between the Australian Government and the Juvenile Diabetes Research Foundation (JDRF) to provide subsidies for insulin pumps for people less than 18 years of age.
Stoma Appliance Scheme (SAS)	SAS provides entirely subsidised stoma-related products (medicines and appliances) to individuals who have undergone either a temporary or permanent surgically created body opening (stoma). The Commonwealth expects to save $9.5 million from 2017–18 to 2020–21 through the scheme.[90]
Continence Aids Payments Scheme (CAPS)	CAPS assists individuals with permanent and severe incontinence to meet some of the costs of continence products.
Epidermolysis Bullosa Dressing Scheme	This is the only federal scheme for modern wound care devices and assists patients with Epidermolysis Bullosa.
Australian Government Hearing Service Program	This program provides access to hearing devices and services.
External breast prostheses reimbursement program	This program assists women who have had a mastectomy due to breast cancer with reimbursement for new or replacement external breast prostheses.

Table 6: Federal schemes providing medical aids and appliances in Australia

90. Australian College of Nursing. Australian Government Health Budget Overview 2017–18. 2017; Available from: https://www.acn.edu.au/australian-government-health-budget-overview-2017–18

Accurately estimating the relevant expenditure on aids and equipment products in Australia is difficult due to the substantial number of consumers and products, multiple sources and types of supply, along with different definitions of aids and appliances. Based on the Australian Government definition, aids and appliances are durable medical goods that are not implanted surgically (such as glasses, hearing aids, wheelchairs and orthopaedic appliances and prosthetics). In 2014–15, an estimated $4.2 billion was spent on aids and appliances.[91]

It appears that the funding of aids and appliances is much more heavily reliant on individuals than other Commonwealth programs which provide access to medical devices. Individuals made up 65% of the total aids and appliances expenditure of $4.2 billion in 2014–15.[92] (Figure 31).

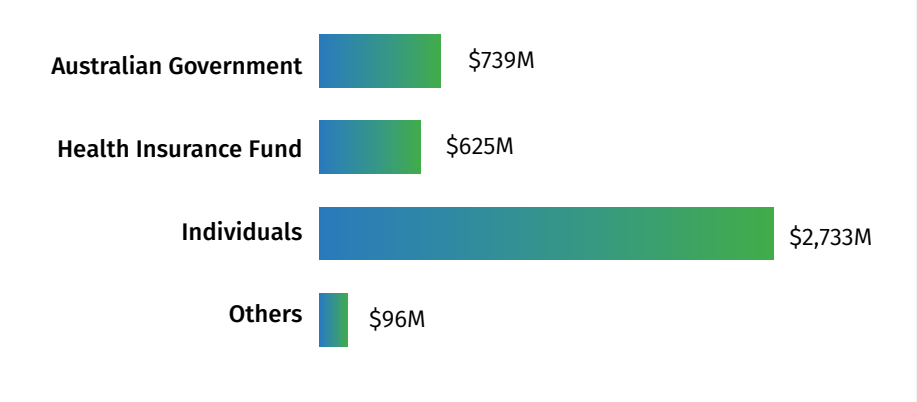


Figure 31. Expenditure on aids and appliances in 2014-15 by source of funds in Australia. Source: AIHW

91. Australian Institute of Health and Welfare, Australia's health 2016. Australia's health series no. 15, Cat. no. AUS 199. Canberra: AIHW 2016.

92. Ibid.

Major state/territory schemes	
ACT	ACT Equipment Scheme (ACTES) provides state funding to assist ACT residents with a long-term disability to obtain and maintain a range of equipment to assist them to live at home in the community.[93]
NSW	EnableNSW is a NSW Government scheme that provides a subsidy towards the cost of equipment covering disposable and reusable aids for eligible people living in the community.[94]
NT	The Disability Equipment Program (DEP) is operated by the Northern Territory Department of Health, and aims to provide prescribed equipment, aids and appliances to assist with safety, independence and participation in the community.[95]
QLD	The Medical Aids Subsidy Scheme (MASS) funded by the Queensland Government provides funding for medical aids and equipment to eligible Queenslanders with permanent/stable conditions or disabilities.[96]
SA	The Government of South Australia facilitates access to specialist equipment and assistive technology to help people with a disability manage their personal care, communication, mobility, safety and comfort.[97]
TAS	The Community Equipment Scheme (CES) is managed by Tasmania's Department of Health & Human Services to reduce the cost of aids.[98]
VIC	The Statewide Equipment Program (SWEP) provides Victorian people who either have a permanent or long-term disability or are frail aged with subsidised aids, equipment and home and vehicle modifications to enhance their independence and facilitate community participation.[99]
WA	The Community Aids and Equipment Program (CAEP), funded by the Western Australia state government, provides equipment and home modifications to benefit people with a long-term disability living at home in the community.[100]

Table 7: State and territory schemes providing medical aids and appliances in Australia

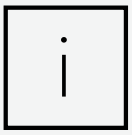
93. ACT Government, ACT Equipment Scheme, 2012. Available at: https://www.assistance.act.gov.au/adult/health_and_dental/act_equipment_scheme
94. NSW Government, HealthShare, EnableNSW. Available at: http://www.enable.health.nsw.gov.au/
95. Intouch Direct, NT-DEP Funding Schemes. Available at: http://www.intouchdirect.com.au/nt-dep
96. Queensland Government. Medical Aids Subsidy Scheme. Available at: https://www.health.qld.gov.au/mass
97. Government of South Australia. Equipment and assistive technology for people with a disability. Available from: http://www.sa.gov.au/topics/care-and-support/disability/disability-equipment
98. Tasmanian Government. Community Equipment Scheme (CES)/TasEquip. Available from: http://www.concessions.tas.gov.au/concessions/health/community_equipment_scheme_ces
99. Ballarat Health Services (Government of Victoria). State-Wide Equipment Program (SWEP). Available from: https://swep.bhs.org.au/
100. Government of Western Australia Department of Communities. Community Aids and Equipment Program (CAEP). Available from: http://www.disability.wa.gov.au/services-support-and-eligiblity/services-supports-and-eligibility-new/services/services-provided-by-the-commission/equipment-and-technology/community-aids-and-equipment-program-caep-/

FUTURE CHALLENGES

The overall affordability of healthcare in Australia, including the ongoing sustainability of private health insurance arrangements, will continue to drive healthcare policy and reform measures.

However, there are developments which will shape the future of healthcare and policy settings, thereby impacting on the operating environment of the medical device sector.

Some of the most significant include:



The roll-out of MyHealth Record and the capacity for the data collected to be used to improve health outcomes through a range of measures including informing areas of potential research and monitoring real-world device performance.

Increased digitalization of healthcare leading to different ways of delivering healthcare and the regulatory and reimbursement challenges this will pose.

Increased personalisation of healthcare treatments and growing use of artificial intelligence and robotics and the regulatory and reimbursement challenges this will pose.

It is important that stakeholders work together to maximise the healthcare value that the exciting possibilities from these changes can bring.

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