MTAA Submission to the Inquiry into approval processes for new drugs and novel medical technologies in Australia

November 2020

Medical Technology Association of Australia

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

MTAA represents manufacturers and suppliers of MedTech used in the diagnosis, prevention, treatment and management of disease and disability. The range of MedTech is diverse with products ranging from everyday items such as syringes, through to high technology implanted devices such as pacemakers, and orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and MRI machines.

MedTech helps more than 2.5 million patients per year. In 2019 over 3 million medical devices were used just to treat Australians with private health insurance.

MTAA members distribute the majority of products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure the safe and effective use of MedTech.

MedTech

The MedTech industry is one of the most dynamic manufacturing sectors in Australia and has the potential to provide substantial health gains and highly skilled employment opportunities to Australians and add to Australia's export industry. There are 91 ASX-listed MedTech and pharmaceutical companies in Australia, with a market capitalisation of $94 billion.

It is estimated that the total market for medical devices in Australia was valued at US$4.6 billion

The MedTech industry in Australia is a substantial employer. It is estimated that the MedTech industry employs about 19,000 people[1].

It is also estimated that the total market for medical devices in Australia is valued at over US$4.6 billion. Despite representing a small market, Australia compares favourably worldwide; according to the Worldwide Medical Device Factbook, Australia is ranked 10th in terms of total market value.

With continual growth and advancements in the industry, all surgical operations performed in Australia involve some form of MedTech, 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. Globally we have seen a 25% decline in annual mortality[2], 25% decline in disability rates[3], 56% reduction in hospital bed days and an increase in life expectancy by 4.6 years[4]. MedTech has played a central role in delivering these improvements.

[1] Deloitte Access Economics, MedTech Industry Workforce and Skills review, 2015. https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-au-economics-medical-technology-industry-workforce-skills-review-30516.pdf

[2] The World Bank, Mortality rate, adult. 2015.

[3] Australian Bureau of Statistics, Disability, Ageing and Carers, Australia: Summary of Findings, 2015. 2015

[4] The World Bank, Life expectancy at birth. 2015

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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Executive Summary

The COVID-19 pandemic is a profound reminder that the performance of our health system matters. It is also a reminder that MedTech (Medìcial Technology) is a core contributor to the health system's ability to deliver for patients. Australia's MedTech sector worked in collaboration with the Australian Government to deliver essential medical supplies to test for and treat COVID-19.

In light of this, MTAA welcomes this Inquiry. The opportunity to create a research and development, regulatory and reimbursement framework to deliver novel medical technologies to patients particularly in areas of high unmet need should be the core aspiration of Australia's health sector and governments.

MedTech encompasses a broad array of non-pharmaceutical medical technologies whose effect is typically by physical or interactive means, rather than biological. Devices range from hip replacements and pacemakers to MRI machines, telehealth and artificial intelligence programs.

Modern medicine, including MedTech, stands on the edge of a revolution which Australia needs to participate in both as an end user and inventor of technology. MedTech will profoundly transform the way health is practiced and patients are diagnosed and treated in the years to come. Digital technology will play a key role in this.

Cancer, heart conditions, organ failure, diabetes, degenerative diseases and many other high burden diseases will be better treated or even prevented in the future by MedTech as well as pharmaceutical therapies.

Australia's healthcare system performs well, but it could be better. Access to health technology is good, but clinically meaningful technology still does not reach all patients whenever it is needed. Incentives for R&D and clinical trials for novel MedTech can also be improved. This submission lays out MTAA's view on the problems and the real opportunities for change. COVID-19 is a reminder that this is not an academic exercise, but patients' lives depend on it.

Recommendations below are listed in summary form. A full list of recommendations follows the Executive Summary.

Novel medical technologies in development

While the fast-paced nature of MedTech makes it impractical to attempt to predict, or even list all emerging technologies, there are a number of areas of significant future transformation, which include:

- 3D printing including bioprinting of human tissue material
- Artificial intelligence
- Digital therapeutics
- Robotic surgery
- Neurological stimulation
- Physiological and neurological monitoring
- Telehealth and augmented reality

Furthermore, many of the devices with which we are familiar will continue to be enhanced through developments in digital technology, bioengineering materials, design innovation and our understanding of disease pathways.

Summary recommendations

- *Re-establish an effective horizon scanning process for MedTech in Australia*

Incentives to develop novel medical technologies

MedTech is a global industry and a large proportion of novel medical devices will continue to come through global supply chains. However, COVID-19 has highlighted space in the market for Australia to deliver some of its core MedTech needs. It also represents a very significant opportunity for economic growth. A strong, competitive local industry delivers health benefits for Australians as well, through early exposure to innovation and sharing of information between industry and clinicians.

The measures to support medical research and advanced manufacturing are welcome. However, there is opportunity to further enhance the local industry's ability to address unmet clinical need. In particular, the current strong financial incentives at the early stage research end need to be matched with better incentives at the commercialisation end.

Summary recommendations

- *Health procurement selectively purchase some essential devices from local companies where the global supply chain is unable to meet needs. A cross-portfolio review consider core expertise required to advance R&D in medical devices and ways to address gaps*
- *Lead a discussion with Australian fundholders to promote investment in medical R&D*
- *Provide tax credits for commercialisation advice to start-ups*
- *Audit technology needs in hospitals and provide this to Australian companies*
- *Reset government grant programs for the MedTech sector to more explicitly support commercialisation by start-ups*
- *Provide a patent box to reduce marginal tax on beneficially owned IP*

Boosting clinical trials of novel medical technologies

If Federal and State Governments work closely together to harmonise processes for faster and more efficient start-up of trials – ethics, governance and recruitment – then MTAA members and other research-based organisations will be better equipped to attract clinical trials and FDI into Australia. Each State should be commended for their interest and efforts to attract clinical trials at an individual State level. The key to take advantage of this opportunity is to streamline and harmonise efforts across the States to harness efficiencies for multi-state and multi-site large clinical development programs, growing the national footprint in clinical trial and drug development pathways.

These steps include, among other things, national messaging that Australia is open for business, a front door that streamlines ethics and governance processes (clinical trial harmonisation), and consistent standards on remote monitoring and utilising digital technology.

Summary recommendations

- *update public health policies and ensure they are mutually accepted by all parties involved in a clinical trial*
- *ensure HREC and SSA submissions are harmonised into one Australian online platform*
- *develop and implement sustainable national patient awareness campaigns for those seeking clinical trials information*
- *in consultation with industry, invest in and develop a national standard approach*

- *adopt and invest in technologies and associated practices to ensure the use of eMR for effective remote monitoring of patients*

Approval processes for novel medical technologies

The regulatory and reimbursement processes are critical factors determining whether Australian patients are able to get the benefits of new MedTech in a timely and affordable way.

The majority of new medical device applications for inclusion in the ARTG consist of incremental improvements to existing technology. These go through the standard TGA processes that apply a level of scrutiny commensurate with the risk class of the medical device. The TGA medical device regulations have been aligned with the EU medical device regulations for the past twenty years. For moderate and some lower risk medical devices TGA requires evidence of manufacturers' quality management system compliance with regulations. For high risk devices the TGA requires additional evidence that the design of the medical device compliance with applicable essential principles of safety and performance.

Since the 2015 Medicines and Medical Devices Regulatory independent review, the TGA has been implementing major regulatory reforms in consultation with stakeholders including the MTAA. Some of these reforms include expanding the acceptance of evidence from international comparable regulatory bodies for applications to include medical devices into the ARTG. Currently, the TGA accepts evidence issued by the EU Notified Bodies (as before), the U.S. FDA, Health Canada and Japan's Pharmaceutical and Medical Devices Agency. The highest risk medical devices such as drug device combination implantable devices must undergo a conformity assessment by the TGA.

Another reform implemented by the TGA is the introduction of a priority review for novel medical devices that meet certain eligibility criteria (address an unmet need in the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition) to ensure faster patient access to breakthrough technologies. The U.S. and China have similar pathways for novel or breakthrough medical technologies.

Regulatory reforms need to be supported by adequate resources, such as sufficient number of TGA specialist reviewers and state-of-the-art TGA IT systems, local infrastructure needed for medical devices commercialisation, sustained and long-term investment in research and development of medical technologies.

In addition, State and Territory governments need to eliminate red tape and duplicative requirements for medical devices that increase the cost and burden to industry with no added benefit to patient safety, such as compulsory registration to commercial databases Recall Health and National Product Catalogue. TGA regulations, systems and processes should be adopted uniformly across Australia without duplication by State and Territory departments of health.

Reimbursement and funding of medical devices is far more fragmented than the regulatory process through the TGA. Mechanisms differ between public and private, and interventional and therapeutic devices. The success of these mechanisms in providing patient access to novel technologies depend on the funding models and the decision-making processes for reimbursing specific technologies.

The current AR-DRG funding framework for public hospitals can act as a disincentive to use of new technologies by paying an average for a hospital episode. State and territory funding arrangements are varied and often opaque. This has been recognised in the most recent *National Health Funding Agreement* 2020 Addendum.

Medicare Benefits Schedule (MBS) items frequently incorporate the cost of diagnostic devices but not therapeutic devices as part of the service fee. In private healthcare, therapeutic devices are typically covered by the Prostheses List, which ensures surgeons can choose the most appropriate device for their patient. Certain devices may not be covered properly by either.

Health Technology Assessment (HTA) for the MBS and the Prostheses List conducted using the Medical Services Advisory Committee (MSAC) and the Prostheses List Advisory Committee (PLAC) must work well to ensure patient access to novel technology. There are opportunities for improvement in timeliness, sponsor engagement, relevant expertise, evaluative approaches and timely government implementation with these processes.

Summary recommendations

- *Ensure that TGA has the human and IT infrastructure resources to fulfill its mission as the national regulatory authority for therapeutic goods*
- *TGA should continue improving and streamlining its internal processes to deliver consistently quick review times in line with international KPIs*
- *State and Territory governments should eliminate red tape and duplicative requirements affecting medical device industry, such as compulsory registration to commercial databases Recall Health and National Product Catalogue*
- *Access to capital for MedTech start-ups and implementing long-term investment strategies in medical technologies*
- *Implement training and educational programs for product development skills specific to medical devices*
- *Develop local infrastructure needed for medical device product development and commercialisation, such as specialised testing services, suppliers of medical-grade components and materials*
- *Ensure affordable access to technical standards needed for designing and testing medical devices, and ensure alignment of Australian standards with international IEC and ISO standards*
- *Create a national list of recently approved novel health technologies*
- *State and territory governments be required to report on their uptake of novel technologies*
- *Make evaluation processes at state and territory level fit-for-purpose*
- *IHPA process to better reflect the costs of new technology*
- *Clearly articulate that the PASC process is optional for sponsors*
- *Provide clear opportunities for pre-submission meetings with sponsors for MSAC and PLAC*
- *Sponsors/experts to appear at MSAC meetings*
- *Strengthen the knowledge base of MSAC and PLAC in bioengineering and digital technology*
- *Hold open workshops on patient preference and appropriate evidence standards for MedTech*
- *Government to commit to funding MSAC recommendations in a timely way, similar to PBAC*

- *Improved triage of applications for novel technology for the Prostheses List*
- *Reduce additional processing time for inclusion on the Prostheses List following positive MSAC recommendation*
- *Further guidance to avoid overlap in regulatory and HTA assessments*

The opportunity for MedTech

There is no question that the practice of modern medicine stands on the edge of a revolution with incredible opportunity driven by advances, such as genetics and artificial intelligence, to address unmet medical need in the Australian and worldwide community. Many of these advances are already with us. The broad array of MedTech, and the industry that discovers, develops and supplies it, will play a central role in this revolution. Along with more revolutionary advances, technology that has been found to work well and has greatly increased life expectancy and quality of life in recent decades will be enhanced by important incremental innovation that, over time, can amount to very significant improvements.

As this Inquiry has recognised, it is critical that Australian patients are able to take advantage of the revolution in medical care by having a regulatory, reimbursement, healthcare, research and industry environment that enables the effective and equitable diffusion and deployment of the next wave of innovation.

What is a medical device?

It may be helpful to the Committee to provide some background on types of MedTech. Broadly speaking, MedTech can be divided into medical devices and biopharmaceuticals.

The *Therapeutic Goods Act* 1989 41BD (1)(a) defines a medical device generally for the purposes of regulation as:

Any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination and including the software necessary for its proper application) intended….to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability

(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state

(iv) control or support of conception

(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;

and that does <u>not</u> achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means [emphasis added]

Medical devices therefore cover the spectrum of investigational and therapeutic technology usually unless they have biopharmaceutical properties. Typically, they work by physical, mechanical or chemical means, but increasingly they also use information technology and cognitive interface with the user.

Specifically, this includes:

- Diagnostics
- Imaging
- Radiotherapy
- Robotic surgery

- Implants
- 3D printing devices
- Artificial intelligence
- Software and Apps
- IT/interconnectivity innovation in any of the above
- Sensor technology

Devices are then often further differentiated into diagnostic or therapeutic devices

Well-known examples of medical devices that are diagnostic in purpose include:

- COVID-19 Testing Kits
- Magnetic Resonance Imaging (MRI)
- Computerised tomography (CT)
- Pap smears
- Biopsy

Well-known examples of medical devices that are therapeutic in purpose include:

- Pacemakers
- Heart valves and the devices used to implant them
- Insulin pumps
- Cochlear implants
- Hip and knee artificial implants
- Ocular lenses
- Neuromodulators (stimulators)
- Renal dialysis machines
- Robotic surgical systems
- Sleep apnoea machines
- Laser eye surgery technology

Increasingly in surgery diagnostic and therapeutic devices are being used in tandem, the one to guide the use of the other to achieve the therapeutic effect.

All software and artificial intelligence used for diagnostic or a therapeutic purpose is classed as a device.

Most health conditions are investigated or treated using some form of device. Conditions that are particularly reliant on devices for diagnosis and/or treatment include:

- Cancer
- Heart conditions
- Kidney failure
- Diabetes
- Hearing loss
- Traumatic injury
- Osteoarthritis and other musculoskeletal degeneration
- Vision impairment

Devices play a critical role in all forms of surgery, including in bleeding control (haemostasis) and wound closure. Bleeding is a major contributor to avoidable hospital re-admissions[5] which is an increasing focus in National Healthcare Reform Agreements over the last decade.

Devices already have delivered enormous strides in treatment of serious conditions, these include:

[5] W. C. Y. Lau X. Li I. C. K. Wong K. K. C. Man G. Y. H. Lip W. K. Leung C. W. Siu E. W. Chan. Bleeding-related hospital admissions and 30-day readmissions in patients with non-valvular atrial fibrillation treated with dabigatran versus warfarin. 2017 Journal of Thrombosis and Haemostasis Volume 15, Issue 10. https://onlinelibrary.wiley.com/doi/full/10.1111/jth.13780

Pacemaker:

Artificial pacemakers are devices that are implanted into the body, usually just below the collarbone, to take over the job of the heart's own electrical system and regulate heart rates. Arrhythmias (irregular heartbeat) are serious and potentially life-threatening conditions. The pacemaker creates electrical impulses that signal the heart to pump. They can be single chamber or dual chamber. Biventricular pacemakers are used to treat heart failure[6].

In 1926, Mark C Lidwill of the Royal Prince Alfred Hospital of Sydney, supported by physicist Edgar H. Booth of the University of Sydney, devised the first artificial pacemaker[7]. Two years later in 1928, the apparatus was used to revive a stillborn infant at Crown Street Women's Hospital, Sydney[8]. Early pacemakers were large devices that required connection to mains electricity. In 1958, Arne Larsson became the first patient to receive an implantable pacemaker. He survived a further forty-three years[9].

Modern pacemakers weigh less than 50 grams and are the size of a large wristwatch face. A pacemaker contains a small computer with memory and electrical circuits, a powerful battery, and leads with electrodes that attach to the heart. They also have remote monitoring capabilities, alerting cardiologists to potential issues and allowing them to monitor a patient's heart vitals[10].

Cochlear implant:

A cochlear implant is a small device that bypasses a severely hearing-impaired or deaf person's damaged ear and stimulates the auditory nerve directly to simulate the hearing function. It consists of a microphone, speech processor, transmitter and receiver, and electrodes. They were developed in the 1980s and are regarded as one of the great advances of modern medicine.[11]

The work of Professor Graham Clark and the Australian-based Cochlear company in pioneering multi-channel cochlear implants is well-known. They are increasingly used not only in fully deaf people, but in severely hearing-impaired patients. Two recent studies showed that people with Cochlear implants could understand sentences eight times better than they could previously with their hearing aids.[12] [13]

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[6] Pacemaker Insertion, John Hopkins Medicine. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/pacemaker-insertion

[7] Broughall, N. Australia's Top 10 Inventions: The Artificial Pacemaker, GIZMODO. 2011, January. https://www.gizmodo.com.au/2011/01/australias-top-10-inventions-the-artificial-pacemaker/

[8] Best Aussie inventions of all time, C NET. 2014, January. https://www.cnet.com/pictures/best-aussie-inventions-of-all-time/13/#:~:text=1928%3A%20pacemaker&text=Its%20first%20recorded%20success%20was,a%20stillborn%20infant%20in%201928.

[9] Broughall, N. Australia's Top 10 Inventions: The Artificial Pacemaker, GIZMODO. 2011, January. https://www.gizmodo.com.au/2011/01/australias-top-10-inventions-the-artificial-pacemaker/

[10] Pacemakers and Defibrillator Implantation, Miami International Cardiology Consultants. https://micc.com/service/pacemakers-and-defibrillator-implantation

[11] Eshragi, A, A., Nazarian, R., Telischi, F, F., Rajguru, S., M., Truy, E., and Gupta, C. The cochlear implant: Historical aspects and future prospects, US National Library of Medicine National Institutes of Health. 2012, October. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921065/

[12] Gaylor JM, Raman G, Chung M, et al. Cochlear Implantation in Adults. A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. 2013;139(3):265–272.

[13] Runge CL, Henion K, Tarima S, Beiter A, Zwolan TA. Clinical Outcomes of the Cochlear™ Nucleus® 5 Cochlear Implant System and SmartSound™ 2 Signal Processing. Journal of the American Academy of Audiology [Internet]. 2016 [cited 2018 Oct 25]; (6):425.

Linear Accelerators:

A medical linear accelerator (linac) customises high energy x-rays or electrons to conform to a tumour's shape and destroy cancer cells while sparing surrounding normal tissue. The linac uses microwave technology (similar to that used for radar) to accelerate electrons in a part of the accelerator called the wave guide, then allows these electrons to collide with a heavy metal target to produce high energy x-rays. These high energy x-rays are shaped as they exit the machine to conform to the shape of the patient's tumour and hit a pinhead-sized target.

In 1956 a physician at Stanford University first used a linac from the Physics department to destroy a tumour in the eye of a two year old, which was causing blindness.[14] Linacs became commercially available in the 1990s. Modern devices have moved well beyond early devices and now offer highly targeted and powerful dosing. Linacs are also used to quell the rejection of an organ transplant, suppress the immune systems of patients undergoing blood and marrow transplantation, and correct certain neurological and cardiovascular disorders.[15]

[14] Baker, M. Medical linear accelerator celebrates 50 years of treating cancer, Stanford Report. 2007, April 18. https://news.stanford.edu/news/2007/april18/med-accelerator-041807.html#:~:text=A%20linear%20accelerator%20was%20co,for%20patient%20therapy%20in%201994.

[15] ibid

Term of Reference 1 What is the next wave of medical device technologies?

Medical device technologies are so diverse that it is difficult to sum up the manifold ways in which we can expect them to advance in the future. However, there are some fields under development which will produce particularly striking change in the years ahead, whether sooner or later:

- 3D printing including bioprinting of human tissue material
- Artificial intelligence
- Digital therapeutics
- Robotic surgery
- Neurological stimulation
- Physiological and neurological monitoring
- Telehealth and augmented reality

3D printing and bioprinting

3D printing of medical devices is already a reality in the Australian health system. 3D printing allows customised bone and joint replacement implants to be created by orthopaedic and craniomaxillofacial (skull and jaw) surgeons that reflect the patient's body and the nature of the damage. Typically, they are combined with customised surgical guides, which are 3D models of the patient's relevant anatomy, and used to plan the surgery and the implant placement.[16] Continued growth in utilisation and sophistication of these techniques is expected to continue.

3D Bioprinting is an additive manufacturing process where biomaterials, such as cells and growth factors, combine to create tissue-like structures that imitate neural tissue. The process that occurs is like 3D printing and uses the technology bioink to produce the composite layers always in a sterile environment[17].

Potential applications of 3D bioprinting into the future include:

- Artificial organ creation to treat vital organ failure at a much speedier pace than traditional methods. This is still largely experimental but would make a profound difference to the thousands of patients waiting for organ donors
- Medical Device and pharmaceutical testing reduce ethical issues (speeding up the research process) and is more cost-effective than traditional methods of testing.
- Cosmetic Surgery: for plastic surgery & skin grafting – clinically necessary in Australia, granted our high incidence and prevalence of skin cancer, particularly in older age[18] and specific cultural cohorts[19]. 3D bioprinting can also be used for burns victims and patients with traumatic skin injuries.

[16] Daniel, D. 3D printing implants and organs is the new reality, Healthcare IT News. 2018, December 17. https://www.healthcareit.com.au/article/3d-printing-implants-and-organs-new-reality

[17] Mashambanhaka F. What Is 3D Bioprinting? – Simply Explained. 2018 Nov. https://all3dp.com/2/what-is-3d-bioprinting-simply-explained/#:~:text=Bioprinting%20is%20an%20additive%20manufacturing,structures%20that%20imitate%20natural%20tissues.&text=In%20essence%2C%20bioprinting%20works%20in,object%20layer%2Dby%2Dlayer.

[18] Curchin DJ, Harris VR, McCormack CJ, Smith SD. Changing trends in the incidence of invasive melanoma in Victoria, 1985–2015. Medical Journal of Australia. 2018 Apr;208(6):265-9. https://onlinelibrary.wiley.com/doi/abs/10.5694/mja17.00725

[19] Watts CG, Madronio C, Morton RL, Goumas C, Armstrong BK, Curtin A, Menzies SW, Mann GJ, Thompson JF, Cust AE. Clinical features associated with individuals at higher risk of melanoma: a population-based study. JAMA dermatology. 2017 Jan 1;153(1):23-9. file:///C:/Users/KatrinaBirrell/Downloads/jamadermatology_watts_2016_oi_160047.pdf

- Bone tissue regeneration: for use in conditions like paediatric osteosarcoma (a rare disease[20]) as well as prosthetic and dental applications.

Artificial intelligence

The European Commission states that 'Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals'.[21] It is more than just the use of algorithms.

The use of (AI) is growing rapidly in healthcare for its ability to improve population and individual health. AI takes advantage of the significantly increased data available in health care combined with massive increases in computational power to detect what might take many years to detect with other methods. This includes earlier disease detection, more accurate diagnosis, identification of new observations or patterns on human physiology, and development of personalised diagnostics and therapeutics.[22]

Uses of AI in health include:

- Computer-aided detection (CAD) systems to help doctors interpret medical images
- Prediction of certain negative events, such as falls in the elderly, based on past patterns
- Autonomous diagnostic decision-making systems help detect signs of diabetic eye disease (retinopathy)
- Machine learning algorithms to help assess the risk of sudden cardiac death or other heart diseases based on electrocardiograms and cardiac MRI images
- AI in endoscopy to automatically detect colorectal polyps of many different types (Medtronic GI Genius™ intelligent endoscopy)
- Personalised health guidance based on patient data captured by apps added to genetics and blood markers
- Support clinicians in telehealth consultations by combining patient-reported and sensing data

Case study: Ai To Detect Colorectal Cancer

Medtronic is using artificial intelligence to improve patient outcomes, including recently launching the first system worldwide using artificial intelligence to detect colorectal polyps.

The TGA has approved the use of Medtronic's GI Genius™ intelligent endoscopy module for use in Australia. This device uses artificial intelligence to provide real-time automatic detection of colorectal polyps of all shapes, sizes, and morphology. The module uses advanced artificial intelligence to highlight the presence of pre-cancerous lesions with a visual marker in real-time – serving as a vigilant second observer.

Studies have shown that every 1 percent increase in adenoma detection rate reduces the risk of colorectal cancer by 3 percent.

(Corley et al 2014. Adenoma Detection Rate and Risk of Colorectal Cancer and Death. NEJM 2014; 370(14): 1298-1306)

[20] Taran SJ, Taran R, Malipatil NB. Pediatric osteosarcoma: an updated review. Indian journal of medical and paediatric oncology: official journal of Indian Society of Medical & Paediatric Oncology. 2017 Jan;38(1):33. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5398104/

[21] Mashambanhaka F. What Is 3D Bioprinting? – Simply Explained. 2018, November. https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines

[22] Artificial Intelligence in MedTech: Delivering on the Promise of Better Healthcare in Europe, MedTech Europe. 2019, November. https://www.medtecheurope.org/wp-content/uploads/2019/11/MTE_Nov19_AI-in-MedTech-Delivering-on-the-Promise-of-Better-Healthcare-in-Europe.pdf

Digital therapeutics

Digital therapeutics have been on the market for about ten years but have only recently come into their own. In order to be called digital therapeutic a product has to be software driven, evidence-based, and make a claim to prevent, manage, or treat a medical disease or disorder.[23] Digital therapeutics include leading and emerging technologies such as virtual reality online therapies to help people to adopt healthy behaviours, and social robots[24]. Their greatest use is to stimulate behaviour change, which is very important for management of chronic disease, but can actually be used to treat mental health conditions whose burden is very large and growing. This can include treatment for substance abuse.

Robotic surgery

Robotic surgery is increasingly widespread globally and in Australia. It commonly involves use of a camera arm and mechanical arms which are controlled by the surgeon while viewing the surgical site in high-definition, magnified 3D images on a computer. It is typically used in minimally invasive surgery that involves only very small incisions. Surgeons have continually searched for less invasive approaches to surgery and the focus is increasingly on miniaturisation.[25]

While these systems seek to improve on existing approaches, there is a further area of development for microbots which are constructs at the sub-millimetre level with surgical functionality. Theoretically these constructs could be deployed into a patient's bloodstream through a conventional access, and then maneuvered to a specific destination to carry out a designated task without a surgeon even touching the patient's skin. These systems are still very early in their development, but individual areas of research are beginning to integrate into a more cohesive image of what microbots of the future may look like. Microbots represent a potential revolutionary concept in surgery.

Neurological stimulation

Neuromodulation is the treatment of neurological challenges through the stimulation of the brain or nervous system via targeted electrical pulses. Advances in both bioengineering and neurology has resulted in a fast-developing way to treat chronic diseases, sometimes known as bioelectronic medicine. Scientists are able to identify specific nerves and implant devices that can be activated when needed to change their activity and so control cells in organs targeted by those nerves that regulate the body's many immune and metabolic responses.[26]

Neuromodulation is already a safe and effective treatment, largely deployed for movement disorders including Parkinson's disease tremor and dystonia, as well as epilepsy, psychiatric disorders such as depression/obsessive compulsive disorder/Tourette's, and a variety of previously intractable chronic pain syndromes as well as loss of bladder control.[27]

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[23] Makin, S. The emerging world of digital therapeutics, Nature. 2019, September. https://www.nature.com/articles/d41586-019-02873-1

[24] NATURE, S106, Vol 573, A smarter way to treat, Makin S, 2019

[25] Annals of Laparoscopic and Endoscopic Surgery, Emerging surgical robotic technology: a progression toward microbots, Khandalavala K, et al, 2020 http://ales.amegroups.com/article/view/5499/html

[26] Park, A. Why it's time to take electrified medicine seriously, TIME. 2019, October. https://time.com/5709245/bioelectronic-medicine-treatments/

[27] Farrell, S, M., Green, A., and Aziz, T. The use of Neuromodulation for symptom management, US National Library of Medicine National Institutes of Health. 2012, September 19.

Conditions that have been treated or symptom-managed experimentally, and might be treated in the future using neuromodulation, include Alzheimer's disease, rheumatoid arthritis, Crohn's disease, additional types of untreated pain, cluster headaches and even cardiovascular disease. Particularly while pharmaceutical approaches to treating psychiatric and neurological disorders have been meeting with limited success[28] non-pharmacological ways of treating brain related pathologies may be of crucial importance if progress is to be made.

Among patients with anorexia nervosa, implanted deep brain stimulation has been able to successfully stimulate the regions of the brain controlling dysfunctional behaviour leading to reduced anxiety, improved wellbeing and mood, and increased Body Mass Index (BMI) score[29].

Physiological and neurological monitoring and control

Neurological monitoring and control devices are devices that are controlled via connection to the brain. Whilst still well beyond the horizon, neurological monitoring and control devices represent leaps in health outcomes that until recently was the basis of science fiction. Emerging research into brain-computer interface (BCI) technologies centre around the creation of a direct communication pathway between an enhanced or wired brain and an external device usually through the detection of electronic pulses within the brain. BCIs are often directed at researching, mapping, assisting, augmenting, or repairing human cognitive or sensory-motor functions.[30]

Case study: Neuralink Corporation

Neuralink Corporation is an American neurotechnology company founded by Elon Musk and others, developing implantable brain–machine interfaces (BMIs). Whilst Neuralink is reported to be still conducting pre-trial research they have demonstrated a concept that implanted very thin (4 to 6 µm in width) threads into the brain, the demonstration proved it could read information from a lab rat via 1,500 electrodes in the brain.

The initial goal of Neuralink's technology will be to help people with paralysis to regain independence through the control of computers and mobile devices. In July 2020, Neuralink obtained an FDA breakthrough device designation which allows limited human testing under the FDA guidelines for medical devices

Wikipedia. 2020 October. https://en.wikipedia.org/wiki/Neuralink

1Lopatto, E. Elon Musk unveils Neuralink's plans for brain-reading 'threads' and a robot to insert them https://www.theverge.com/2019/7/16/20697123/elon-musk-neuralink-brain-reading-thread-robot

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6769574/#:~:text=Neuromodulation%20(deep%20brain%20stimulation%2C%20motor,4%5D%2C%20psychiatric%20disorders%20such%20as

[28] Gribkoff VK & Kaczmarek LK (2017) The need for new approaches in CNS drug discovery: Why drugs have failed, and what can be done to improve outcomes. Neuropharmacology 120:11-19.

[29] Lipsman N, Lam E, Volpini M, Sutandar K, Twose R, Giacobbe P, Sodums DJ, Smith GS, Woodside DB, Lozano AM. Deep brain stimulation of the subcallosal cingulate for treatment-refractory anorexia nervosa: 1 year follow-up of an open-label trial. The Lancet Psychiatry. 2017 Apr 1;4(4):285-94.

[30] Krucoff, Max O.; Rahimpour, Shervin; Slutzky, Marc W.; Edgerton, V. Reggie; Turner, Dennis A. (1 January 2016). "Enhancing Nervous System Recovery through Neurobiologics, Neural Interface Training, and Neurorehabilitation". *Frontiers in Neuroscience*. **10**: 584. doi:10.3389/fnins.2016.00584. PMC 5186786. PMID 28082858.

Telehealth

It is well discussed that COVID-19 accelerated the introduction of telehealth into Australia and shows what can be achieved through political will and stakeholder collaboration. Through COVID-19, 32.8 million telehealth services were delivered (to 30 September 2020) at a cost of over $2.4 billion[31]. MTAA welcomes the Federal Government's extension of its COVID telehealth arrangements for an additional six months as the long-term plan is developed and implemented. Security is critical to the success of telehealth.

Telehealth goes beyond merely a video link when it begins to incorporate sensing and diagnostic technology that can be used in real time, including smart technology. This can also involve the use of artificial intelligence to process and report on significant patient information, as noted earlier in this submission.

Some notable examples of where medical technologies that could support telehealth are bio-sensing wearables such as digital blood pressure monitors, glucose sensors and even the latest Apple Watch.[32]

Case study: Apple Watch Series 4

Apple Watch included an ECG feature in 2018 as part of its Series 4. It's sparked a number of headlines for its role in saving people's lives due to falls or irregular heartbeats. However, because the feature acts like a medical device, monitoring your heart rate and providing health advice, it would require listing via the TGA on the Australian Register of Therapeutic Goods (ARTG). As of September 2020, Apple were yet to lodge an application to the TGA in regard to the listing of any of their products.

Emerging medical technologies in Australia

While many of these new and expanding fields are attention-grabbing, it is important to realise that many important strides in addressing unmet medical need will be through incremental innovation in more traditional spaces. This includes utilising new materials and creating greater interconnectivity for existing implants as well as utilising the technologies described above.

Many of these technologies could come to Australia in the next few years, or in some cases are already here. The Food and Drug Administration (FDA) Breakthrough Device Designation is for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Designation speeds up the review process for regulatory approval. More information will be provided on this pathway and the TGA equivalent Priority Review process under Term of Reference (4). However, it is worth noting that to May 2020 the FDA had already granted nearly 300 Breakthrough Device Designations since its predecessor began in late 2015, including 50 in the first

[31] Department of Health. Budget 2020-21: Record health and aged care investment under Australia's COVID-19 pandemic plan. 2020 October. https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/budget-2020-21-record-health-and-aged-care-investment-under-australias-covid-19-pandemic-plan

[32] https://www.gizmodo.com.au/2020/09/australians-are-still-no-closer-to-getting-apple-watchs-ecg-feature/

five months of 2020 alone.[33] This highlights the enormous rapidity and importance of developments in MedTech to address a range of unmet clinical needs.

[33] Kelly, S. FDA Breakthrough Devices Program nears 300 designations, MedTech Dive. 2020, May 27. https://www.medtechdive.com/news/fda-breakthrough-devices-orteq-archerdx-terumo-thermedical-helius-photopharmics/578562/

Examples of Breakthrough Device Designations issued by the FDA include:

Note: Products on this list have not been approved by regulatory authorities and inclusion does not imply endorsement of the product

Company and Link	Product description	Potential benefit	Designation month/year
Medtronic Press Release	(PLC) personalized close d loop insulin pump system	The technology is designed to automate insulin delivery in real-time while personalised and adapts to the user. The system will also provide insights and predictive diagnostics unique to the individual, the goal is to dramatically simplify diabetes management for the patient.	02/2019
Impulse dynamics Impulse Dynamics article	Cardiac contractility modulation (CCM) therapy	A treatment for Class III heart failure, CCM therapy is the first approach of its kind designed to improve contraction of the heart, allowing more oxygen-rich blood to reach the body. The therapy delivers precisely timed electrical pulses to the heart during the absolute refractory period of the beating cycle, just after the heart contracts.	03/2019
Fresenius Medical Care Press Release	Computer assisted ultrafiltration control software	Working with Fresenius' CLiC device which enables relative blood volume monitoring (RBV-M), the new software aims to create a dialysis machine with embedded intelligent diagnostics that will provide computer-assisted recommendations for achieving target levels of RBV. This improves fluid management during haemodialysis which is a serious issue for patient outcomes	03/2019
Boston Scientific Press Release	Pulse field ablation (PFA) system	For treatment of atrial fibrillation & cardiac arrhythmias, the PFA system is intended to ablate heart tissue via the creation of a therapeutic electric field instead of a thermal energy source like radiofrequency ablation or cryoablation, with the intention of preventing unnecessary heart tissue damage during ablation.	05/2019
B Braun Globe Newswire article	Drug coated PTCA balloon catheter	The latest generation coronary drug coated balloon that can be used in cases where there is gradual re-narrowing of a coronary artery (in-stent restenosis) following placement of a stent	08/2019
Medtronic Press Release	Fully Implantable Left Ventricular Assist Device (LVAD)	For patients with advanced heart failure, LVAD systems increase the amount of blood circulating through the body. This new system is fully implantable rather than requiring a cable to a controller external to the body	10/2019
Medtronic	Valiant Navion LSA branch thoracic stent graft system	For minimally invasive repair of thoracoabdominal aortic aneurysm (TAAA). Off-the-shelf endovascular solution with a size matrix to enable broad patient applicability for one of	10/2019

Vascular News article		vascular surgery's most difficult pathologies. Patients with open surgery for this condition have high mortality rates and surgeons have limited options for grafts	
Fresenius Medical Care Press Release	Dialysis system using anti-blood clotting agent Endexo®	Use of the antithrombogenic polymer Endexo® into the manufacturing process of dialyzers and bloodline to cut the risk of clotting, thereby reducing the need for physicians to administer potentially dangerous blood thinners such as heparin	10/2019
Smith & Nephew Press Release	Combination of anaesthetic Tymbion, tympanostomy tubes, and several devices needed for the delivery of the ear tubes and the anaesthetic into the ear drum	First device that can be used to place ear tubes in young children using local anaesthesia in the outpatient setting. The device enables more flexible treatment of recurrent/ persistent ear infections. The company who received this approval (Tusker Medical, Inc) were acquired by Smith & Nephew, who see the device as complimenting the companies ENT portfolio (the same patient and customer populations) and strategy to invest in innovative technologies that address unmet clinical needs	01/2020
Abbott Press Release	Fully implantable heart pump	The Fully implantable left ventricular assist System (FILVAS) improves quality of life for heat failure patients (diagnosed in 1.9% of the US population). Through the system, patients no longer have to carry external components – a requirement with other, older devices	02/2020
Medtronic Press Release	Symplicity Spyral	The Symplicity Spyral catheter positions electrodes which use a radiofrequency energy to ablate nerves in the renal artery to assist management of hypertension.	03/2020
Terumo Press Release	Stent	Single use device which combines a gelatin-sealed woven polyester graft with a self-expanding stent graft. For use in the surgical repair/ replacement of damaged/ diseases vessels of the aortic arch or descending aorta Reduces treatment most at risk of rupture from two procedures to one, which reduces patient mortality and potentially reduces overall operating theatre time & hospital costs. For treatment of thoracic aortic aneurysm (TAA)	04/2020
Terumo Press Release	Stent	Virtue® Sirolimus-Eluting Balloon (SEB) for percutaneous coronary interventions	04/2020

PhotoPharmics Press Release	non-invasive phototherapy device intended as an adjunct treatment to help people with Parkinson's disease improve overall function	The therapy targets photoreceptors in the eye that regulate circadian signalling to the brain.	04/2020
Helius Medical Technologies Press Release	PoNS™ device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS")	The Portable Neuromodulation Stimulator (PoNS) is an authorized class II, non-implantable medical device authorised for sale in Canada. The PoNS is used as a short-term treatment option for gait deficits due to symptoms from MS and is to be used in conjunction with physical therapy. The PoNS is an investigational medical device in the U.S., the EU and AUS; and is currently under review for clearance by the TGA. Treatment is currently not commercially available in the U.S., the EU or AUS.	05/2020
OncoSil Medical Ltd (ASX listed) Finfeed news article	OncoSilTM device for the treatment of unresectable locally advanced pancreatic cancer in combination with systemic chemotherapy.	OncoSilTM is a targeted radioactive isotope (Phosphorus-32) that's implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound. The treatment by this device delivers more concentrated and localised beta radiation compared with external beam radiation.	05/2020
Boston Scientific Press Release	Single use endoscope (Duodenoscope)	For use in endoscopic retrograde cholangiopancreatography (ERCP) – procedures which diagnose & treat disease in the pancreas and bile ducts. Previously design flaws made them hard to clean, leading to several outbreaks of antibiotic resistance superbug ingestions. The scope redesign to single use increases patient safety.	06/2020
Johnson & Johnson Vision Monday article	Myopia control contact lens	Contact lens used to slow the progress of myopia (near-sightedness)	06/2020
Neuronetics Inc	NeuroStar Advanced Therapy TMS System	The system uses transcranial magnetic stimulation (TMS), a non-invasive form of neuromodulation, to stimulate areas of the brain that are underactive in depression. The	06/2020

Press Release		breakthrough designation applies specifically to adult patients with bipolar I or II disorders who failed to show satisfactory improvement with prior pharmacological therapy.	
Johnson & Johnson (Ethicon) Press Release	Transbronchial microwave ablation technology using robotic-assisted bronchoscopy	Combines microwave ablation system with robotic-assisted bronchoscopy system to enable surgeons to remove lesions while performing robot-assisted bronchoscopy (procedure where the inside of the lungs, including the bronchi are examined by way of a thin tube containing a light and camera placed into the lungs through the nose or mouth to assist lung disease diagnosis)	07/2020
Synchron (Australian company) Neuro News article	Stentrode brain-computer interface	Uses brain-controlled handsfree app platform called brainOS to translate the brain activity into a standardised digital language, directly through thought, to control apps that restore communication and limb function. In addition, brainPort, a fully internalised, wireless solution implanted in the chest provides high-resolution neural data transmission. It is being evaluated for its ability to enable patients with paralysis to regain functional independence by control of digital devices through thought alone and does not require brain surgery	08/2020
Medtronic Press Release	TYRX™ Absorbable Antibacterial Driveline Wrap	Securely holds a percutaneous driveline in patients receiving a ventricular assist device (VAD) and is designed to reduce complications from infections by its unique mesh material and the release of antimicrobial agents	09/2020
GI Windows Medical Corp PR Newswire article	Self-forming magnetic compression anastomosis device	The self-forming magnetic compression anastomosis device is used for small bowel colorectal surgery to provide a less invasive solution and with the potential to lower the high rates of colorectal complications	09/2020
Abbott Press Release	Esprit BTK System drug eluting resorbable scaffold	Unlike traditional metal stents, this system provides temporary support to an artery immediately after balloon angioplasty, preventing the vessel from reclosing. Once implanted, the scaffold delivers a drug over a few months that promoted healing & assists the artery to reopen. This device addressed the poor short and long-term results of balloon angioplasty in patients with critical limb ischemia, a condition that can lead to amputation and limb loss	09/2020

SetPoint Medical Globe Newswire article	SetPoint bioelectronic platform	The company is developing a novel bioelectronic medicine platform that stimulates the vagus nerve to activate the inflammatory reflex to produce a systemic immune-restorative effect for patients who have moderate to severe rheumatoid arthritis and are inadequately treated with anti-rheumatic drugs	10/2020
Genetron Globe Newswire article	Blood-based next-generation sequencing (NGS) test HCCscreen™	HCCscreen™ for early detection of hepatocellular carcinoma in individuals who are designated to be at high-risk for HCC due to chronic HBV infection and/or liver cirrhosis.	10/2020

The above table provides just a sample of the spectrum of technologies that could be imminent for the Australian healthcare system. Some of these, such as Synchron's device, will come from Australia although this will be a small minority for the foreseeable future.

Nonetheless, it is important that Australia maximises its contribution to the development of these new technologies for patients here and worldwide. This question will be addressed in Term of Reference 2 below. Clinical trials are an important way in which clinicians gain early experience with new medical advances and in some cases allow patients facing very poor outcomes to access important advances earlier than otherwise might be the case. This opportunity is addressed in Term of Reference 3 below.

It is also critical that the regulatory and reimbursement systems are well designed and managed to incorporate these technologies. This also requires that the structures of health care in Australia allow these to be used effectively in practice so that patients actually benefit. This will be addressed in Term of Reference 4 below. However, it is clear that the range of new technologies that are developing will challenge our healthcare system, particularly for medical devices. Already medical devices are assessed and paid for in numerous different ways across the health system, Commonwealth and state, public and private, or not at all. Decentralisation is not inherently bad, but it exposed the risk of technology that could be of enormous benefit slipping through the cracks.

MTAA recommends the government re-establish an effective horizon scanning process which includes an assessment of the key enablers to uptake for each technology

Term of Reference 2 Incentives for new medical technologies for unmet need

Novel technologies and Australian industry

MedTech is a global industry and a large proportion of novel medical devices will continue to come through global supply chains. These remained remarkably robust during COVID-19 even in the face of sovereign risk and dramatic loss of air freight availability. This is a credit to the skilful work of local Australian operations and sensible decision making in global headquarters. However, COVID-19 has highlighted the need for Australia's capability to deliver some of its core MedTech needs. Furthermore, MedTech is an exciting, innovative industry that will deliver significant economic growth in the future to economies where the innovation and IP resides. Australia's home-grown global companies, as well as many smaller ones, are testament to the opportunity that Australian innovation has to market to the world.

Furthermore, there are health advantages to having commercial innovation coming out of Australia. Particularly in the case of highly novel MedTech, the first exposure patients have is through first-in-human studies after verification testing is complete. Being small, high value trials, these will typically be conducted in major clinical centres close to the innovation hubs of their sponsors. The greater the base of MedTech industry in Australia, the more likely these early studies will occur here. Similarly, there will be a bias for later phase studies to have a substantial number of centres in Australia in this case, even when other larger markets are included.

Finally, a local MedTech sector can improve clinicians' understanding and exposure to medical innovation. MedTech innovation is often dependent on a close relationship with clinicians, because it is the latter who employ and direct the technology particularly in cases of surgery. The clinicians see the practical problems faced by existing technology in achieving good patient outcomes and are able to provide very specific feedback to company bioengineers and researchers on what improvements are needed. Likewise, locally based MedTech companies can engage clinicians on innovation opportunities and give them early access to technological improvements. Partnerships between companies, researchers and clinicians are likely to be fostered.

More specifically, though Australia is a relatively small part of the global research community, it has often been stated that we punch above our weight in medical research, and incentives to specifically drive innovation in areas of high unmet need will benefit Australians as well as global populations. This will also drive the sector growth overall.

Driving commercialisation of novel technologies

MTAA welcomes the commitments in the Federal Budget 2020 to further reform the R&D Tax Incentive to insure it acts as a true incentive for industry. Notwithstanding this welcome commitment, MTAA believes there is opportunity to further promote growth in the Australian sector, and to encourage innovation in high unmet need areas in particular.

As a proportion of total government support, a large amount of funding is directed toward early stage research and start-ups in Australia. Relatively little funding is directed toward commercialisation. However, medical technologies are only good in theory until they are commercialised, and without launch and resulting revenue they don't generate the funding needed for further research investment. The Federal Budget has some welcome measures to address this, however some further recommendations are provided below.

Recommendations:

- *Health procurement agencies to consider policies to selectively purchase some essential devices from local companies based on an equitable process to grow local capability where strong global supply chains do not meet local needs*
- *A cross-portfolio review to consider the types of core expertise required to advance high quality R&D in medical devices, such as regulatory capability, and action ways to fill these both through visas and local skill development*
- *Lead a discussion with the investment community on why Australian fundholders are reluctant to invest in MedTech but consistently prefer lower technology industries and promote change in investment patterns*
- *Provide tax credits for commercialisation advice to start-ups that allow them to choose their own consultants but increase affordability*
- *Actively audit technology needs in hospitals as reported by clinicians and staff and provide these lists to Australian companies*
- *Reset government grant programs for the MedTech sector to more explicitly support commercialisation by start-ups*

Taxation of Intellectual Property

Australia's investment into R&D continues to lose traction. Australia is ranked 13th in terms of government tax and direct funding support for R&D, but its ranking for the outputs of this investment continues to slide 18th in 2011, 20th in 2018, and 22nd in 2019. This is leading to economic activity being lost to peer nations, lost opportunities for well-paid jobs in advanced manufacturing, and a loss in license and royalty payments.

Currently, the Commonwealth, via the R&DTI, the MRRF, and NHMRC, spends more than $3B p.a. to support medical breakthroughs. However, the process halts as there are currently no incentives for onshore commercialisation of the resulting intellectual property. In effect, this is leading to the exportation of this IP just as it is beginning to become profitable and deliver value to the Australian economy. The exact cost to the Government could only be calculated once the specific parameters of this policy are set. MTAA welcomes further discussion with the Government on this point.

MTAA recommends the Government to investigate international solutions such as the UK's Patent Box, Ireland's Knowledge Development Box, or section 238 of the French General Tax Code. By significantly reducing the marginal tax rate for income earned on locally developed and beneficially owned IP, these policies incentivise companies to:

- *Keep IP onshore;*
- *Expand local manufacturing of the IP; and*
- *Pay the taxable portion of the related review back to the country that invested in their initial R&D.*

Addressing high unmet needs

In terms of addressing areas of high unmet needs specifically, concentrated collaboration across sectors and up and down the innovation chain is very important. The research required to address high unmet needs also needs to be focused, sustained and predictable.

We strongly support the focus of the MRFF on long term outcomes and this should receive ongoing support and not be subject to continuous change.

Australia is not large enough to compete with itself to develop the next generation of innovation. We particularly welcome the end-to-end model of national collaboration championed by the Australian Cardiovascular Alliance, which has the breadth of expertise and commitment to consider all phases of technology development and to determine which gaps need to be filled. This is a model that should be encouraged in other disease states, potentially through linkage grants.

MTAA also considers not enough funding is allocated on the critical but unattractive work of tracking what happened to past research and commercialisation funding. Some of it may have paid dividends, and some of it may have not resulted in any health or commercial advances. However, it is very important not to hide 'failure' and to constantly look to the future, when many of the best lessons are in understanding what worked and what didn't and why. Research into highly novel technologies that will address unmet need is high risk and there will inherently be many stories of dead ends, as well as some gems that yielded very significant results. 'No fault' investigations of past grants and programs would be very beneficial for policy setting.

Recommendations:

- *Further incentivise cross-institution and cross state border collaboration through linkage grants and incentives for flagship programs, similar to the Australian Cardiovascular Alliance*
- *Actively co-locate science parks next to major hospitals and incentivise engagement between industry, researchers and clinicians*
- *Have a full time internal government capability undertaking 'no fault' and confidential reviews of the results of past grants and incentives for MedTech and related research on a case by case basis to build a systematic body of information for government policy action and for education of researchers, investors and companies engaged in the sector*

Term of Reference 3 Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies

Clinical trials provide benefit to Australian patients, our learning healthcare system, the broader medical research industry and the Australian economy. Australia currently enjoys a strong international reputation as a destination of choice for clinical trials. Sustaining our success will be a challenge as international competition for the placement of clinical trials has begun to erode Australia's historical advantages.

In 2019, there were 1,820 ongoing trials in Australia: a 22% increase on 2015. This contributes an estimated $1.1 billion a year to the economy. This figure could easily be doubled over the next 5 years by industry working with governments to create the right settings to realise this ambition.

In order to remain a world leader in the delivery of clinical trials, and to attract more clinical trials to Australia, we must be able to:

1. commence trials quickly and in a consistent and efficient manner across multiple centres around Australia
2. increase the ability for patients to participate in clinical trials. In particular, ensure there is equitable access to clinical trials for patients located in regional areas, through building tele-trials capabilities. This will ensure that clinical trials recruitment is similar to, or greater than, that seen in other countries
3. adopt modern and future-ready technologies to enable clinical trial processes to be conducted efficiently, cost-effectively and, where possible, remotely

Faster and more efficient Start-up of Clinical Trials

The start-up of a clinical trial involves a range of activities, the most significant of which is the ethical review and approval of the trial by a Human Research Ethics Committee (HREC) and the Research Governance review and approval via a Site-Specific Assessment (SSA). These processes are almost always managed consecutively at present, despite local evidence that parallel review significantly increases start-up times[34].

For multi-centre trials conducted across sites residing in different jurisdictions, it is usual to require the services of more than one HREC and each trial site conducts its own Research Governance review. The timelines for review and approval of the trial by both HRECs and Research Governance offices (RGOs) are variable and unpredictable.

The start-up of trials is therefore duplicative, inefficient, costly and unpredictable in its timeframe, despite reform work that has been undertaken. This is not limited to the start-up of a clinical trial; given both the HREC and RGO will need to continue to be involved in review of certain aspects of the trial throughout its lifecycle this duplication, inefficiency and inflated cost continues throughout the study.

[34] NHMRC, June 2017, Streamlining the site assessment and authorisation of Clinical Trials, Final Report

National Harmonisation of Ethics Review

A series of national initiatives intended to contribute to the national harmonisation and streamlining of clinical trial start-up have been implemented at the state, territory, and local level with only limited success. These initiatives include:

- National Mutual Acceptance (NMA) scheme whereby ethical approval of a trial by one Human Research Ethics Committee (HREC) is accepted by others at participating public hospital centres[35]
- national certification by the National Health Medical Research Council (NHMRC) of ethics committees for multi-centre research[36] [37]
- Single point of contact or valet service for trial sponsors[38]

Success has been limited as public health policies do not allow the use of all ethics committees that have been nationally certified by the NHMRC for multi-centre research (eg. private ethics committees). In addition, public health policies do not routinely allow private research centres to be covered by public hospital ethics committees without a range of varying written agreements in place. As it is very common for a mix of public and private trial centres to be included in trials, at least two ethics committees are required, and possibly three if university centres are also involved. This leads to a duplication of effort, increased costs and inefficiency for the initial submission and delays in approval of a clinical trial, resulting in unnecessary delays in patient access to medical treatment.

MTAA in consultation with industry partners, recommends that:

- *Public health policies are updated to provide that the following are mutually accepted by all States, Territories and Universities participating in the clinical trial;*
    - *All nationally NHMRC accredited ethics committees can review and approve clinical trials at all public hospitals, private hospitals and trial centres, and universities.*
    - *That the approval granted by a nationally NHMRC accredited ethics committee will be mutually accepted by all clinical trial centres without exception and without additional written agreements being required.*
- *That the Australian Commission on Safety and Quality in Healthcare be tasked to facilitate processes on a national basis to address the items referred to in this recommendation.*

A National Platform for Ethics and Governance Submissions

The NHMRC developed a portal for the submission of HREC applications. In addition, there is a number of separate and siloed national and state-based portals for HREC and SSA submissions.

[35] NHMRC, National mutual acceptance of ethics review for multi-centre clinical trials. https://www.australianclinicaltrials.gov.au/ethical-review-process-each-australian-state-and-territory

[36] NHMRC, National Certification Scheme for ethics review of multi-centre research.https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research

[37] NHMRC, National Certification Scheme, Institutions with Certified Ethics Review Processes. 2020, January. https://www.nhmrc.gov.au/sites/default/files/documents/attachments/list-of-institutions-v42.pdf

[38] St Vincent's Hospital, Research Valet. https://www.svhm.org.au/research/industry/research-valet

This creates duplication of information and significant inefficiencies in HREC and Site-Specific Assessment (SSA) submissions. There are significant costs involved across Australia in managing a series of different software platforms that essentially fulfil the same tasks.

MTAA in consultation with industry partners, recommends that:

- *HREC and SSA submissions are harmonised into one Australian online platform, and that these are reviewed in parallel by HRECs and Research Governance offices. Further, that the development of this platform is within the purview of the Australian Commission On Safety And Quality In Health Care (ACSQH).*

Recruitment of Clinical Trial Participants

Australia competes in a regional and global marketplace for participation in the large number of industry-sponsored clinical trials conducted each year across the world. There are a range of factors considered when placing trials in countries including start-up time, cost and ability to deliver participant recruitment targets[39]. As many as 86% of clinical trials do not reach participant recruitment targets[40] and, as such, the ability of sites within a country to recruit to their contracted participant target is a key factor in study placement in the country.

The traditional methods of identifying patients for clinical trials, which take place mostly in large public and private health service organisations, have proven to be adequate at best, but often prove to be insufficient. In order to improve on the ability of investigational sites to recruit to target there needs to be an increase in awareness of the role and importance of clinical trials amongst the general public and the medical community. Clinical trials need to become part of the dialogue between patients and their healthcare providers as a first step towards seeking and identifying appropriate clinical trials. This will be more easily achieved when clinical trials become part of the standard of care in Australia's health infrastructure.

Additional focus on the decentralisation of clinical trials to regional centres, through the utilisation of tele-trials, will provide a broader pool of potential participants by removing the barrier of patients requiring travelling to a metropolitan centre to access a trial. In turn, access to clinical trials becomes more equitable for all Australians, which is especially important given clinical trials can be an important pathway to life saving new treatments. Regional participation in clinical tele-trials can also have the effect of ensuring regional centres are firmly included in the learning healthcare system. It would also be an easy and effective way to lift the standard of care and general health care in rural, regional and remote regions – particularly as companies, research institutes in addition to government funding would bring new health medicines, technologies and supporting infrastructure to areas that would otherwise not receive them.

[39] MTP Connect, Clinical Trials in Australia: The economic profile and competitive Advantage of the sector. June 2017
[40] Huang G et al., 2018, Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative. Contemporary Clinical Trials, Vol 66, March 2018, pp74-79

MTAA in consultation with industry partners, recommends a National Community Awareness campaign:

- *NHMRC 'Helping our Health' awareness campaign (or similar) to be strengthened and re-commenced on a more sustained or regular basis to boost numbers of patients seeking clinical trials information;*
- *That additional national patient awareness campaigns are developed, implemented and sustained.*

Decentralisation of Clinical Trials

Decentralisation of clinical trials can increase patient diversity in clinical trials, allow faster recruitment to target and ultimately accelerate the development of new treatments. Importantly, it also strengthens the healthcare service in regional areas of the country by exposing doctors and other healthcare professionals to innovations in clinical practice and treatments. Through clinical tele-trials, smaller regional hospitals and clinics can be involved in clinical trials by partnering with larger health service organisations via a hub and spoke model.

MTAA in consultation with industry partners, recommends:

- *Government invest in and develop a national standard approach; including nationally agreed systems and standard operating procedures to support and strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas. In order for the approach to satisfy the requirements of commercial clinical trials, it is further recommended that industry is consulted during the development of the model.*

Modern and Future Ready Technologies and associated practices:

The COVID-19 pandemic has seen industry pivot to ensure the continuation of clinical trials that were ongoing during 2020. Trial design, and practices and procedures that had become the norm prior to 2020 for delivering clinical trial design have come under scrutiny. Restrictions on the ability of clinical trial centres to conduct face to face patient visits coupled with sponsor staff being unable to visit centres to conduct monitoring activities has highlighted the urgent need for technology and accompanying practices to change to allow more efficient and remote ways of conducting clinical trial activities.

While industry can bring new technologies to bear, the healthcare system needs to similarly support clinical trials with remote access to Electronic Medical/Health Records at all clinical trial centres, to accept electronic signatures on clinical trial documentation, to accept e-consent technology[41] and to offer tele-health technologies as routine practice for clinical trial participants (when clinically appropriate). The increased use of these technologies can substantially reduce the workload burden on clinical trials site staff and the healthcare system. The acceptance and support of these

[41] FDA Guidance Document, December 2016, Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers)

technologies and practices are all under scrutiny by global MedTech and Pharmaceutical companies now and those countries that can undergo rapid adoption will be offered clinical trials preferentially.

MTAA in consultation with industry partners, recommends:

- *Government to move quickly to adopt and invest technologies and associated practices to ensure:*
  - *All clinical trial centres (public hospitals) to:*
    - *Utilise Electronic Medical Records for recording clinical trial source records wherever possible*
    - *Ensure Electronic Medical Records include the ability to restrict access to clinical trial participant records to facilitate remote monitoring of participant medical records*
    - *Allow for remote monitoring of clinical trial participant records by sponsors*
- *Establish national standards for the use of e-Consent in clinical trials*
- *Adopt technologies for e-signatures on clinical trial documents.*

The above response to Term of Reference 3 was written by members of the Research and Development Task Force (RDTF), which is co-sponsored by the Medical Technology Association of Australia, AusBiotech and Medicines Australia.

Term of Reference 4 Approval Processes for Novel Medical Technologies

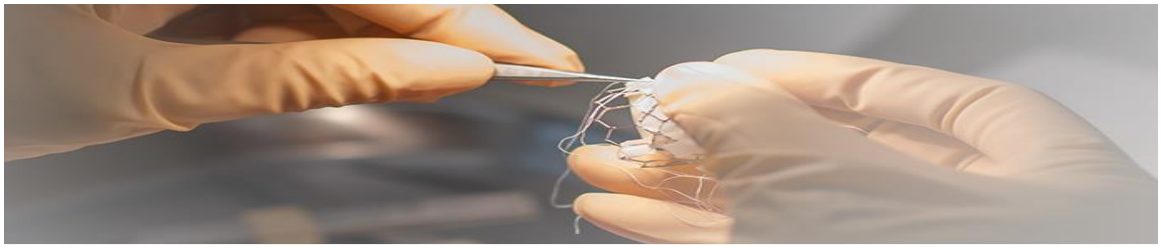
Introduction

The regulatory and reimbursement processes are critical factors determining whether Australian patients are able to get the benefits of new MedTech in a timely and affordable way. The regulatory process for medical devices and diagnostics shares some aspects with the pharmaceutical regulatory process in that both are managed centrally for the whole of Australia by the TGA. Differences in principles and approaches typically reflect differences in the technologies themselves. By contrast, reimbursement and funding for new medical devices is far more diffuse with multiple bodies and jurisdictions involved than for pharmaceuticals, which are largely funded through the PBS. As the Inquiry Terms of Reference indicate, it is very important that regulatory and reimbursement processes work together and eliminate inefficiencies and overlap as much as possible to minimise the time novel technologies will reach patients.

Regulatory Processes for Medical Devices

Since its introduction in 2018, Australian MedTech companies have used the TGA priority review for novel MedTech eight times. Of the eight applications for priority review designation that have been lodged with TGA, six received approval to use the priority review pathway. Four of the six approvals

Case study: Edwards Lifesciences use of the Priority Review Process



Established in 1958, Edwards Lifesciences is a global leader in the science of heart valves and hemodynamic monitoring. Driven by their passion to help patients, the company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring that enable them to save and enhance lives.

Edwards Lifesciences recently took advantage of the Morrison Government's regulatory review reforms for their SAPIEN 3 low-risk TGA Conformity Assessment (CA) submission, using the US FDA Pre-market Approval. Given that this was a first for Edwards Lifesciences, a pre-submission meeting with TGA's CA team was held, to discuss the requirements for using evidence and documentation issued by an overseas regulator. The meeting was lengthy, yet very informative.

A Priority Review Designation application was submitted in conjunction with the CA application which meant, once approved for priority review, the review process was reduced to six months. Given the nature of the application, ie. a Conformity Assessment, their experience during the expedited review process was very pleasant, with minimal additional requests for information from the TGA.

The process ended up being significantly less than six months. Ultimately this was a win for patients with severe symptomatic aortic stenosis who now have the full range of options of therapies.

were obtained by two MTAA members, each with two approvals. The average time for completing the assessment was up to 70 days, with one MTAA member reporting having received the approval for priority review designation within 20 working days.

To qualify for the TGA priority review, the novel technology must provide prevention, diagnosis or treatment of a life-threatening or seriously debilitating condition and address an unmet clinical need in Australian patients. In addition, the novel/breakthrough technology must offer a major clinical advantage over existing technologies or existing alternatives already included in the ARTG. For in vitro diagnostic (IVDs), the novel technology must represent a major public health benefit to qualify for the TGA priority review.[42] These criteria are similar to criteria used by other regulatory agencies such as the U.S. FDA and its Breakthrough Devices Program.[43] We hope to see increased international regulatory convergence in general, and continued alignment between the TGA priority review pathway and the U.S. FDA Breakthrough Devices Program.

Novel medical devices are subjected to the same level of regulatory scrutiny, the only difference compared to a standard review is that applications are prioritised, ie. are brought to the front of the queue and assigned a dedicated coordinating assessor to supervise timely assessment and assignment of suitable expert reviewers. The TGA priority review process is similar to the FDA breakthrough designation in the U.S. Other jurisdictions such as China have also adopted similar accelerated or priority reviews to facilitate patient access to novel medical technologies.

A further improvement to the current priority review process would be to adopt the methods TGA employed during the COVID-19 pandemic for essential medical devices, ie. combining a fast-track premarket review with a rigorous post-market oversight to ensure both fast access and patient safety.

To encourage more in the industry to take full advantage of the new TGA priority review, we would like to recommend a sustained, dedicated education and training program aimed at Australian MedTech companies developing or aiming to distribute novel/ breakthrough technologies.

Local MedTech start-ups encounter significant hurdles compared with their counterparts in U.S. and the EU, in particular in relation to:

- *Access to capital and long-term investment strategies*
- *Medical device product development skills (which are different from proof-of-concept research skills)*
- *Lack of local infrastructure and suppliers needed for MedTech development such as commercially available specialised testing services, medical-grade materials and components (most can only be outsourced from overseas)*
- *Affordable access to IEC and ISO standards that are essential in the development and testing of medical devices, and stronger alignment of Australian standards with international IEC and ISO standards*

[42] TGA Guidance Priority review designations medical devices (including IVDs) Version 1.2, August 2018: https://www.tga.gov.au/publication/priority-review-designations-medical-devices-including-ivds

[43] FDA Guidance Breakthrough Devices Program, December 2018: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Lengthy TGA Application Review Timelines for standard submissions

In 2017, the Expert Review of Medicines and Medical Devices Regulation (MMDR) made recommendations aimed at streamlining the TGA's processes for including medical devices in the ARTG in order to improve access by Australian consumers to new medical devices. The majority of applications for new medical devices involve incremental improvements to existing technologies.

The Government decided that the TGA should make greater use of marketing approvals for devices in overseas markets when the device has been approved by a third party that has been designated by an authority that is similar to the TGA, or by a comparable overseas regulator (in line with MMDR Recommendation 15, Pathways 2A & 2B).

The TGA has long accepted certification from European notified bodies as evidence of compliance with the conformity assessment procedures, and in October 2018 the TGA expanded the comparable overseas regulator bodies to include:

- Food and Drug Administration of the United States
- Health Canada
- Medical Device Single Audit Program (MDSAP) Auditing Organisation
- Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan.

The principle being, if market authorisation approval is held by one of the above comparable overseas regulators, classification rules align, and appropriate evidence is provided, the approval should be leveraged to support an abridged evaluation by TGA with reduced review timelines. In practice this is not the experience of industry. This is highlighted in the following example:

Product X (Submission name confidential), obtained FDA PMA approval and CE Design Examination in Europe. Submission dossier was provided to TGA for Conformity Assessment review on 17 June 2019 with supporting evidence of both FDA PMA and CE mark approvals for an abridged review.

Boston Scientific did not receive first round of review questions (s41JA request for additional data or to clarify information already submitted) from TGA until 2 April 2020. Following five additional rounds of review questions, conformity assessment certification was finally issued on 17 September 2020, 15 months after receipt of the submission where an abridged review should have been applied.

Per the Therapeutic Goods Act, the TGA has 255 working days to complete a conformity assessment review (applicable to high-risk devices), in comparison to FDA 180-day review, or CE mark where there is no legislated timeframe for review, however notified bodies often complete their review in less than 6 months.

TGA publish KPIs on their review timelines for conformity assessment applications which often report conformity assessment reviews being completed well within the 255 working days. This however is not reflective of the timelines experienced by industry. This is highlighted in the following example:

As per the Product X application example provided above, often an application has been under review for 9-10 months before the first round of questions (s41JA request) are issued by TGA.

When a round of questions has been issued, the 255 workday review clock is stopped. Rather than TGA issuing questions from all review sections at one time ie. clinical, engineering, biomaterials, quality, etc questions are issued individually from each section at various time points, meaning the

review clock can remained stopped for up to 6 months. The approach of how requests for additional information are made also results in the same questions being asked from different sections, therefore the sponsor having to supply the same data multiple times during the review process.

It is essential that the TGA be equipped with appropriate IT systems and staffed with sufficient human resources so that it can fulfill its mission as the national therapeutic goods regulator. Long review timelines are often caused by a lack of specialist reviewers and outdated IT systems. It is in the best interest of patients, industry and community at large to have an adequately resourced national regulator.

Per the intent of the recommendation made by the Expert Review of Medicines and Medical Devices Regulation (MMDR), TGA should look to streamline processes for including medical devices in the ARTG in order to improve access by Australian consumers to new medical devices. TGA should make greater use of the comparable overseas regulatory approvals obtained by manufacturer's and not replicate the full review process already completed by these regulators on the medical device. TGA should adopt a true abridged evaluation process to significantly reduce the review timelines.

TGA should look to improve review processes, specifically in the conformity assessment section, including the consolidation of requests for additional information (s41JA) from the various review sections, to reduce the number of stop-clocks throughout the review process and remove the duplication of requests.

Reimbursement and Funding of Medical Devices in Australia

It is an often-cited truth that the healthcare system in Australia is fragmented. Sometimes this mixed system is celebrated and sometimes it is bemoaned. Nowhere more than in reimbursement and funding of medical devices is this fragmentation more obvious. In some ways this reflects the diversity of devices themselves. In other ways, it reflects arrangements that have grown organically to solve various problems in the past as well as the public/private, federal/state split in our healthcare system.

Table 1 shows the main ways in which devices are funded and mechanisms for assessing these. This list is not exhaustive, and it would be a long list if all disease specific schemes were included. Likewise, funding mechanisms within each State and Territory for devices can vary, especially between single use implants, consumables and capital equipment.

Table 1 Medical Device Funding and Reimbursement in Australia

Scheme/program/mechanism	Devices covered	Federal or State/Territory	Public/Private/ Mixed	Payment per item or aggregated funding	Mechanism to determine reimbursement/funding
Medicare Benefits Schedule (MBS)	Diagnostics including pathology Radiation treatments	Federal	Mixed (Federal Government and insurer/OOP)	Payment per item	Medical Services Advisory Committee (MSAC) review Federal Budget decision
Prostheses List	Internal prostheses	Federal	Private (Federal Government-administered)	Payment per item	Minister's delegate in Department of Health Prostheses List Advisory Committee (PLAC) Medical Services Advisory Committee (MSAC) review
State and territory public hospitals	All devices in acute settings	State/Territory	Public	Aggregated funding	Independent Hospital Pricing Authority activity-based funding incorporating device costs State and territory funding adjustments New technology assessment processes
Department of Veterans Affairs Essential Medical Equipment	Devices for eligible veterans	Federal	Public	Payment per annum	DVA internal review on annual funding
Workers compensation	Clinically necessary devices	State/Territory and Federal	Employer-based	Conditions vary	Decisions by clinician within pre-established frameworks
Nationally Funded Centres Program (now under review)	Devices purchased by NFCs	Federal and State/Territory	Public	Aggregated funding	Purchasing decisions by NFCs
Private health insurers *ex gratia*	Devices used in hospital paid by exception	Dependent on insurer size	Private	Payment per item	Insurer review
National Disability Insurance Scheme	Various assistive technology including urinary catheters	Federal	Public	Payment per item/per person	Federal legislation, NDIS approval on some items
Disease-specific programs e.g. National Diabetes Services Scheme, My QuitBuddy app, National Bowel Screening test kits	Various from consumables, apps, screening tests to linear accelerators	Federal and State/Territory	Public	Payment per item/ aggregated funding	Various

Broadly speaking, state and territory public hospitals cover in-patient diagnostics and therapeutic devices for public patients with no out-of-pocket costs. In the community, the MBS combines typically with patient out-of-pocket costs to provide diagnostic and radiation treatment. For private hospital in-patients, the MBS combines with patient out-of-pocket costs and insurance coverage to provide therapeutic procedures. The Prostheses List provides coverage for implanted devices used during these in-hospital therapeutic procedures with no out-of-pocket costs for the implanted devices.

From the generic funding received through activity-based funding in the public sector and MBS/OOP/insurance coverage in the community and private sector, facilities purchase devices to deliver the services. This varies from large capital equipment to simple devices like basic dressings. The Prostheses List provides device-specific funding, rather than a global or general payment, as well as a guaranteed access to insured persons if they have the right insurance coverage.

In all these cases, there are two broad questions that determine the access to novel MedTech:

1. Do the funding mechanisms promote the uptake of novel MedTech and its diffusion to patients?
2. Do the decision-making processes to reimburse or purchase novel MedTech lead to appropriate patient access?

While related and to some extent overlapping, both these questions need to be considered by this Inquiry.

State and Territory Public Hospital Funding

Activity-based funding through IHPA

Under the National Health Reform Agreements allocation of funding for hospitals to each state is determined by activity-based funding. This is based on the Australian refined diagnosis-related groups (AR-DRGs) established by the Independent Hospital Pricing Authority (IHPA) based on disease and intervention classifications. Every two years IHPA collect cost data from public hospitals, updates cost weights for the AR-DRGs and determines a National Efficient Price (NEP). States and territories are then funded based on the anticipated volume of hospital or other episodes of care under each AR-DRG. States use their own efficient prices to allocate funding within their systems. Public hospitals are therefore funded based on activity, which includes the cost of the device.

This is relevant for the funding of new technology because novel devices will typically be more expensive unless they deliver short-term savings offsets directly to the hospital. If funding is based on an average, then a state or territory, or more particularly a local health district or hospital, will have to be willing to incur higher charges than they may receive in funding, particularly if the state or territory is using the same or similar DRG formula to fund its local services. This could create budget strain, and so is disincentivised. This is exacerbated because the average used is actually based on data 3 years prior.

In its Impact of New Health Technology Framework[44], IHPA claims to adjust for this in two ways. Firstly, IHPA indexes the NEP based on past expenditure growth, which is meant to capture the effects of new technology introduction. Secondly, it goes through a process of adjusting DRGs to account for new technology-based procedures if warranted based on the differences created by the

[44] Impact of New Health Technology Framework, Independent Hospital Pricing Authority. v4.3 2019, June. https://www.ihpa.gov.au/sites/default/files/publications/impact_of_new_health_technology_framework_v4.3_-_june_20192.pdf

new technology to the current DRGs. If a new AR-DRG is created, then the relevant higher cost data will be reflected in the DRGs going forward. This process by IHPA of assessing new technologies has been a set annual date up until now, although there is a proposal to enable submissions on new technology at any time. To address the criticism that allocation of new codes could also take a long time, particularly as AR-DRG updates are intended to move to a 3-year cycle, it is proposed that temporary codes can be allocated, enabling faster collection of cost data to update DRGs to reflect the technology change.

There are two major issues with this process. Firstly, as IHPA's Impact of New Health Technology Framework shows, it takes 7 years or more for cost data for the new codes to be fully incorporated into the AR-DRG. This timeline would only increase with 3-year instead of 2-year cycles leading to a decade long lag. This means that the AR-DRG system does not promote new technology, it disincentivises it, only later 'playing catch up'. Secondly, there are very few novel technologies that are allocated a new code. The process depends on organisations, including technology manufacturers, making submissions to the present annual process. These are reviewed by IHPA and its Clinical Advisory Committee (CAC) then prioritised recommendations are made to the Pricing Authority (IHPA governing body). The process takes approximately 8 months. In the experience of MTAA and its members, very few codes are created as a result of the new technology application process and many manufacturers consider the process not worth engaging with. None of the applications for new technologies in the 2019-20 round were prioritised for classification and coding.[45]

AR-DRGs are a blunt instrument at present by which to recognise and fund new technology because they are aggregated at a very high level. In the end DRGs are primarily designed to deliver a system-wide fair allocation of aggregated resources based on some defensible methodology. They are not a good vehicle for assessing and encouraging uptake of the best novel devices Australians need. The National Health Reform Agreement 2020-25 seeks to address some of these issues[46]. This will be discussed further below.

State and territory new technology processes

While the AR-DRG process allocates funding to public health services on an aggregated basis, state and territory governments can create or allow processes of assessing and purchasing new technologies within their jurisdictions. This may occur within the standard funding frameworks, or a top-up program can be instituted that facilitates uptake of the new technologies following assessment. The arrangements are often difficult to track through publicly available information. Examples of new technology programs include the NSW Framework for New Health Technologies and Specialised Services.[47] The Framework describes both a top down (NSW Ministry initiated) and bottom up (Local Health District initiated) approach to evaluating and incorporating new technology. It includes possible provision for extra centralised funding through Supra-LHD Services. While theoretically the Framework is good, the process remains largely opaque, and in practice attempts have been made by NSW Health to limit access to important new technology, as in the case of TAVI below:[48]

[45] IHPA, Assessment of new health technologies 2019-20. https://www.ihpa.gov.au/consultation/past-consultations/assessment-new-health-technologies-2019-20

[46] Department of Health, 2020–25 National Health Reform Agreement (NHRA). 2020, October. https://www.health.gov.au/initiatives-and-programs/2020-25-national-health-reform-agreement-nhra

[47] Department of Health, NSW Framework for New Health Technologies and Specialised Services. 2018, November. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_023.pdf

[48] Edwards Lifesciences data on file

Case study: Transcatheter Aortic Valve Implantation

Aortic valve replacement (AVR) is the only cure for aortic stenosis a narrowing of the aortic value in the heart. AVR can be performed either through transcatheter aortic valve implantation (TAVI), or open-heart surgery. TAVI is far less invasive than open heart surgery and may be associated with improved outcomes. It also dramatically reduces length of stay and hospital costs. According to the MBS conditions of use it can only be performed by accredited practitioners at accredited TAVI centres. Despite its advantages, TAVI is being performed at dramatically lower rates in NSW compared to other states, due to state restrictions on its use.

Another example is Queensland Health's New Technology Funding Evaluation Program which states that it provides a $5million investment to pilot new health technologies every year[49]. On the program website there are no new projects listed as having been funded since 2016-17. How the pilots are then assessed and incorporated into state-wide technology funding is not set out. However, MTAA members have reported that the pilot program can be useful to establish business cases for wider use of their technology.

As the Deeble Institute has reported[50], the approaches to incorporating new technology into public health systems across states and territories are fragmented and lacking a systemic approach. The processes also lack transparency. More broadly, as noted above, funding models do not encourage the uptake of new technology. Furthermore, there is a focus on funding by activity, not value.

This has been recognised in principle in the most recent National Health Reform Agreement 2020-25. The new addendum signed this year includes the following initiatives:

- IHPA to provide funding methodology that doesn't penalise states for undertaking trials of innovative models of care (A101)
- Developing a federated approach to health technology assessment (HTA) with a unified framework in the longer term (C7-16)
- Development of options for funding for value and outcomes (C17-22)

[49] Queensland Health, New Technology Funding Evaluation Program. 2017, November. https://www.health.qld.gov.au/improvement/make-it-happen/ntfep

[50] Flynn, A., Verhoeven, A. Measuring value in new health technology assessments: a focus on robotic surgery in public hospitals. Deeble Institute for Health Policy Research. 2020, August.https://ahha.asn.au/system/files/docs/publications/deeble_brief_no._37_-_measuring_value_in_new_health_technology_assessments.pdf

This recognition of the need for change in the 2020 Addendum is welcome. However, MTAA makes the following recommendations to this committee for action now and in implementation of the 2020 Agreement:

- *Working with the TGA and potentially other bodies, a national list of novel health technologies recently approved should be created to allow for transparent reporting on their assessment and adoption*
- *State and territory governments should be required under their reporting responsibilities for the National Health Reform Agreements to transparently outline their processes for evaluating and funding new technologies included in the novel list, what decisions have been taken and progress in uptake of the new technology*
- *Evaluation processes at state and territory level should be fit-for-purpose and not over-index long and complicated HTA if this is not needed, and should incorporate the use of pilots and local trials where further evidence is needed*
- *IHPA should demonstrate how its processes can better reflect the costs of new technology earlier in determination of the National Efficient Price, especially with a move to 3-year cycles*

Community and Private Health Funding

Outside public hospitals a substantial proportion of healthcare is funded by the MBS in combination with private individuals whether through private health insurance premiums or out-of-pocket costs. This means that device purchasing is directly affected by these funding avenues.

The Federal Government has full responsibility for the management of the relevant MBS, health insurance and Prostheses List frameworks. In determining whether procedures and associated devices are funded, the government relies on health technology assessment (HTA) methods applied by the Medical Services Advisory Committee (MSAC) and in the case of the Prostheses List, the Prostheses List Advisory Committee (PLAC) and its clinical advisory groups in addition to MSAC.

Medicare Benefits Schedule (MBS)

The MBS is a schedule of professional medical services for which the Federal Government will provide a benefit. Generally, this is 85% of the scheduled fee, unless they are bulk-billed.

The Medicare Benefits Schedule (MBS) strictly speaking is meant to only subsidise professional services provided by health care professionals. In reality, however, in most cases where it provides a fee to cover investigation interventions, such as pathology, the cost of devices used in providing that intervention are *de facto* included. If they are not covered, or inadequately covered, the clinic or hospital will be forced to either charge patient co-payments or wear the cost, particularly if an insurer requires no extra patient charges for hospital admissions.

An example of this is Magnetic Resonance Imaging (MRI) scanning. These are covered by MBS item numbers 63001-63523. MRIs are typically done in the community setting. They are not eligible for health insurance cover. The typical MBS fee scales of $330 to $492.80 for MRIs, depending on body location, are not intended to cover the time of the radiologist and other staff alone, but some portion of the cost of the MRI machine itself. Costs of the diagnostic imaging clinic, including the capital equipment and consumables not covered by these fees (which incorporates 15% patient out-of-pocket cost unless bulk billed), would need to be recovered by additional patient out-of-pocket costs. A different example where this does not apply is for coronary pressure wires in the case study below:

Case study: Coronary pressure wires used in fractional flow reserve

Coronary pressure wires are used in fractional flow reserve (FFR) during coronary angiography (detecting blockages of blood flows using x-ray) to determine whether revascularisation (procedures to open up the blood flow) is necessary or management with medicine is sufficient. In other words, it is used to avoid unnecessary procedures. It is done in hospital typically when a patient has had a cardiac event.

Item 38241 on the MBS schedule pays a fee for USE OF A CORONARY PRESSURE WIRE during selective coronary angiography to measure fractional flow reserve (FFR) and coronary flow reserve (CFR)[1] [emphasis in original]. But it does not cover the cost of pressure wire to perform the procedure, despite the whole procedure being recommended by MSAC as cost-effective. The Report from the Cardiac Services Clinical Committee of the Federal Government's Medicare Benefits Schedule Review Taskforce recommended the use of fractional flow reserve but noted it was limited due to the pressure wires not being listed on the Prostheses List (see further explanation of the Prostheses List below).

The Cardiac Society of Australia and New Zealand in its submission to the Cardiac Services Clinical Committee[1] that: 'CSANZ recommends that 'the Committee provide a strong recommendation to DoHA supporting funding of the pressure wire device on the [Prostheses List]'. This has still not happened. Recent correspondence from the Department of Health stated that pressure wires are not eligible for listing on the Prostheses List since they are investigative not therapeutic and makes the claim that private health insurers already routinely cover these in case payments.

MTAA notes in response that Part C of the Prostheses List can be used to list devices that are investigational and that cardiologists and hospitals regularly report that payment for pressure wires is restricted by insurers. This is consistent with the report of the Government-appointed Cardiac Services Clinical Committee that 'the FFR wire is not available on the Prostheses List and therefore the procedure is costly to perform' and therefore was a reason for their reluctance to list it as routine with coronary angiography, despite its value.

This case study illustrates how funding of valuable new technology can fall through the cracks, particularly if it does not neatly fit into a funding bucket.

The process for determining whether a service is covered on the MBS involves a review by MSAC to determine whether the service is cost-effective according to HTA principles. If it received a positive recommendation, the Government, usually following consultation with professional societies and other stakeholders, will pass the changes as a budget measure in the Budget or MYEFO. These two steps combined can be very lengthy and proposed additions to MBS items number can sometimes disappear from public view altogether for months, or even years, behind the veil of 'Budget-in-

confidence', even though it may have received a positive HTA recommendation. This will be discussed further below, as this can impact the uptake of novel health technology.

When a new technology also requires a new medical service, since it is not covered by the current MBS items, MSAC will be required to evaluate both the technology and the service together and make a recommendation. For therapeutic interventions, the technology will generally have to be listed on the Prostheses List to be accessible to private patients. As noted above, the cost of the technology in investigational interventions is typically wrapped into the MBS fee and supplemented with patient out-of-pocket payments in many cases.

Prostheses List

The Prostheses List is a list of medical devices for which insurers are required to pay a benefit when a member has the relevant coverage. This requirement is set out in the *Private Health Insurance Act 2007*. For instance, if a member of a health fund has hospital orthopaedic cover and requires a hip replacement, their health fund would be required to pay the benefit for any artificial hip on the Prostheses List. There are no patient co-payments on the Prostheses List unlike most other areas of private health insurance or indeed health care in the community generally as funded by the MBS.

The Prostheses List ensures that surgeons can choose the best available prostheses for privately insured patients from a clinically assessed range of options without the decision being restricted by health funds or the hospital administrators.

The List is an essential part of the private health insurance offering, enabling members to receive the best quality health care as determined by their doctor. Demand for prostheses has been growing due to population ageing, chronic health conditions and the introduction of new technology.

There are approximately 11,000 items on the Prostheses List. The List is divided into Parts A, B and C.

Part A covers devices that are used as part of hospital or hospital substitute treatment where a Medicare benefit must be paid to the doctor for the procedure performed. The device must be surgically implanted in the body or enable another device to be implanted or allow an implant to continue to function after surgery[51].

Devices on Part A also must be approved for use by the Therapeutic Goods Administration and assessed for effectiveness and cost against other products by the Prostheses List Advisory Committee (PLAC) before they can be listed.

Part A is divided into 13 major categories according to the broad conditions they address, and is further divided into sub-categories, groups and sub-groups. Each prosthesis has its own billing code with a benefit that must be paid for the device.

Part B covers products that are derived from human tissue for treatment of a condition. Part C covers specific groups of medical devices which don't meet the criteria of Part A but which the Minister for Health considers suitable for benefit payments by private health insurers.

Contrary to popular belief, external prostheses, such as artificial limbs, or prostheses used for cosmetic rather than reconstructive purposes, are not eligible for reimbursement according to

[51] Prostheses List Guide February 2017 Revision 3 https://www1.health.gov.au/internet/main/publishing.nsf/Content/02D01D760C5386E9CA2581670024F1A2/$File/Prostheses-List-Guide-Feb-2020.pdf p.13

Prostheses List criteria. In the case of external prostheses, these are generally fitted and paid for by state and territory hospitals. Cosmetic prostheses are an out-of-pocket cost to the consumer.

The Prostheses List is now updated 3 times a year on 1 March, 1 July and 1 November. It is published as the Private Health Insurance (Prostheses) Rules and notification of the list is provided through Private Health Insurance Circulars issued by the Department of Health.

HTA processes – MSAC and PLAC

Patient access to novel technologies in the private and community sector hinge strongly on the methods and performance of these two HTA evaluation bodies managed by the Department of Health. Unlike the TGA, their role is to determine whether technologies are worth paying for and make a recommendation to the Government. Increasingly MSAC's role has been growing beyond MBS recommendations to cover referrals from PLAC for more novel technology, blood products, hybrid technologies (such as CAR T-cell therapy) and screening programs (i.e. nearly everything except biopharmaceuticals and vaccines). MSAC doesn't just review sponsor applications but also take referrals from the Minister for Health or bodies such as the Australian Health Minister's Advisory Council (AHMAC). MSAC and PLAC receive support from secretariats within the Department of Health.

If MSAC and PLAC are to deliver enabling access to novel technologies that address unmet clinical need, they need to have:

- Timely and efficient processes
- Clear guidance and engagement with sponsors
- Relevant understanding and expertise
- Evaluative approaches appropriate to the technology
- Recommendations supported by timely government action

While the committees and their secretariats make laudable efforts to achieve these goals, there is evidence that they can fall short, which presents challenges for enabling access to novel technologies.

MSAC Access Challenges

The MSAC Process Framework[52] separates the overall process into four main stages:

1. Pre-assessment triage
2. PICO confirmation
3. Application assessment
4. Appraisal by MSAC

A fifth and critical stage could be added: how a positive recommendation is acted upon by government.

Timing of the whole process depends on whether the applicant develops the submission to be reviewed (Applicant Developed Assessment Report or ADAR), the Department develops the report to be assessed (Department Contracted Assessment Report or DCAR) or if it is an Integrated Co-dependent Submission involving both a drug and a device technology, usually investigational.

[52] MSAC Reform Implementation, process Framework. 2016, March. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/FFDFEFDA8B25248FCA25801000123AD3/$File/Final%20Process%20Framework.pdf

As the medical device industry typically goes through the ADAR process, the following will largely be confined to that process. Comments about the integration of MSAC and PLAC will be made further below.

Timeliness

Industry's experience is that the entire process for undergoing MSAC review and getting access following this review is very lengthy, frequently 2 years or more. The Department advises the industry that the core process for an ADAR is only 24 weeks, because it is optional for sponsors to use the PICO process, which defines the Population Intervention Comparator and Outcome (PICO) being assessed. The PICO confirmation process is 22 weeks and the time between the PICO recommendation and the MSAC process adds another 8 weeks. Contrary to the Department's statement, industry sponsors have felt obliged or strongly advised to go through the PICO process by the MSAC Secretariat. In fact, the MSAC Guidelines now under review consistently refer to a PICO Confirmation as a given in any ADAR. Altogether the process from PICO submission to MSAC decision is 54 weeks. Following this, the sponsor has to wait several weeks to receive a draft Public Summary Document outlining the reasons for the decision before the Public Summary Document is released approximately 8 weeks after the decision. Therefore, including the PICO, the full process time is approximately 60 weeks assuming there is no need for resubmission. This excludes pre-submission discussions.

Even more importantly, after a positive recommendation the time for the Government to act on the decision is indefinite. Unlike Pharmaceutical Benefits Scheme (PBS) listings which, as of this October Budget, now have their own allocated funding in the Budget and can be announced at any time, MBS listings can disappear into the Budget process for a long period, are only announced at the Budget or MYEFO and still require a financial offset from within the Health portfolio.

Therefore, even a submission for a new MedTech with a professional service that doesn't go through resubmissions, the length of time can be 2 years or more before a result is implemented. Resubmissions are frequent and only add to the length of time. Similarly, PLAC processes are added onto the MSAC process. This will be discussed below.

Overall, even excluding the PICO process, the length of time for implementation and access can be significant and unknown. In the case of the pressure wires described in the case study earlier, regulated access was never provided.

Below represents a further case study highlighting the delays that can occur through MSAC:

Case study: Left Atrial Appendage Closure in Non-valvular Atrial Fibrillation

In January 2013, Boston Scientific initiated an MSAC application to obtain a new MBS item for transcatheter insertion of a left atrial appendage closure (LAAC) device for patients with non-valvular atrial fibrillation (NVAF) and a high risk of stroke. In July 2016, after a resubmission by Boston Scientific and Abbott Medical, MSAC supported listing for a subset of patients – those with NVAF at moderate to high risk of stroke and lifelong contraindications to both oral anticoagulation therapy (OAT) and dual antiplatelet therapy (DAPT). The associated MedTech was subsequently listed on the Prostheses List in August 2017, more than a year after MSAC's recommendation.

Australian clinical expert advice is that the definitions of absolute contraindication in the current MBS item for LAAC (38276) has resulted in some patients, who despite having an absolute contraindication, cannot access LAAC because of not meeting one of the three criteria listed. These patients remain untreated and at risk of stroke. Boston Scientific and Abbott have submitted a third application to MSAC to extend access to LAAC to high risk patients that need an alternative treatment option, and MSAC will make a recommendation in April 2021 with implementation potentially 12+ months thereafter.

The therapy will be approaching a decade of consideration by the MSAC, for regulatory approved products in the target population, while these patients have remained with a high unmet clinical need for stroke prevention during this time.

Clear guidance and engagement with sponsors

Pre-submission meetings for MSAC are possible but not openly advertised on the MSAC website as they are for the Pharmaceutical Benefits Advisory Scheme (PBAC) process. In fact, a number of our members were not even aware that they were possible when MTAA raised this. This opportunity should be clearly spelled out including the ability to bring subject matter experts into the discussion.

Furthermore, unlike major submissions for the PBAC, there is no opportunity for sponsors or their invited experts to address the MSAC meeting, which is needed to enable good decision making.

Relevant understanding and expertise

MSAC consists of many high-quality experts from a range of fields, including health economics. However, it must cover a wide spectrum of technologies and disease states. As highlighted under Term of Reference 1, the types of medical devices that will need to be evaluated in the future will be diverse. Of particular note is the central role of information and digital technology in many of these future devices. MSAC appointees already have limited knowledge of bioengineering in comparison to genetics or immunology for example. The growth of digital health will likely require the addition of expertise in this area as well. Heavy reliance on TGA will be important in the future but this should be augmented with other expertise within MSAC and, potentially, the secretariat, in order for medical devices to be properly assessed.

Even with the spread of expertise within MSAC, specialised knowledge in a particular procedure or device can be lacking. For instance, an interventional cardiologist may not be experienced as electrophysiologist and have no direct experience in the use of technologies for these purposes, even though broadly they are in the same specialty. This direct experience is even more important

with medical devices than biopharmaceuticals, because the clinician is often physically manipulating the device in question and the interrelationship between device and user is much closer.

Furthermore, the quality of contracted assessments by evaluators that are provided to the Economic Sub-Committee (ESC) and MSAC remain variable, sometimes showing clear lack of understanding of the device and evidence. This can also come back to the issue that most expertise in the health economics field is in biopharmaceuticals, not devices, so this becomes the lens through which everything is viewed.

Evaluative approaches appropriate to the technology

MSAC applies methods of health technology assessment (HTA) to evaluate novel medical technologies. While the methodologies can be complex, the basic principle is relatively straightforward. The evaluation looks at the evidence for the intervention's safety and effectiveness relative to what it would replace in practice. These benefits are then modelled out with costs to determine the incremental cost for the health gain, allowing a decision on whether the technology is cost-effective.

However good this approach sounds in theory, in practice sponsors of new technology can encounter many challenges. The biggest challenge is the expected evidence levels that are applied to new technologies. HTA methodology was essentially developed for the pharmaceutical industry. However, pharmaceuticals typically lend themselves to the development of much more data than do medical devices. Below are some of the key differences between medical and pharmaceutical industries that can impact on ability and relevance of large data generation.

Broad generalisations of differences between medical and pharmaceutical technologies

	Medical	Pharmaceutical
Cost of production	Ongoing manufacturing costs	Often low once on market
Direct doctor involvement in development	High	Low
Ongoing direct support by company once on market	High	Low
Size of market	Usually small	Often huge
Alteration to product once on the market	Continues evolving during trials and post-market	Does not continue evolving post-market
Typical size of company	Small	Large
Evidence required	Not established	Level I*
Effect on patient	Usually physical	Chemical action
Importance of therapy administration skills (eg, surgeon)	High	Low
Usual development pathway	Invention of new medical device	Discovery of new chemical entities

* Evidence obtained from a systematic review of all relevant randomised controlled trials (National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: NHMRC, 1999). ◆

*O'Malley SP Issues facing the Australian Health Technology Assessment Review of MedTech funding MJA • Volume 193 Number 1 • 5 July 2010

Further the following are addition reasons why medical device companies may not be able to develop the same level of randomised controlled clinical trial data that is common in pharmaceuticals, and remains preferred or even demanded by MSAC:

- Device performance is dependent on operator skill
- Blinded trials often not practicable
- Short life cycles/incremental improvements narrow evidence window
- Low volume in some cases reduces quantity of evidence

There are some medical devices that do not face all these challenges. Conversely, pharmaceuticals for rare diseases or used in small sub-populations may face some but not all of the challenges described above.

While MSAC reaches for technical perfection in data requirements, it results in frequent recycling of submissions, and delays to patient access.

Furthermore, the new wave of novel devices that are yet to come will stress this pharmaceutical evidence paradigm even further. For instance, digital technology undergoes constant upgrading. It will be very difficult to generate new clinical data for every innovation cycle. Under the MSAC approach of 'beyond reasonable doubt' evidence levels, this technology will simply be blocked from patient access on the grounds that it is not 'cost-effective'. To push the legal analogy further, the assessment of evidence will need to be closer to a 'balance of probabilities' test, with the potential to develop follow up information with the use of registries. Different types of evidence will also need to be taken more seriously, including observational data from the 'real world'.

One additional point of relevance is that MSAC and HTA committees generally need to avoid repeating evaluations already undertaken by the TGA. While the comparative safety of a device is relevant to HTA, whether the product is sufficiently *safe* has already been established by the TGA. Nonetheless, this question can sometimes be revisited at MSAC.

MTAA acknowledges that in the most recent draft version of the MSAC guidelines under consultation, there was recognition of the need for approaches for digital technology. However, this was primarily raised in the context of tests, not therapeutic devices.

Evaluation processes do not sufficiently account for patient input and preference. The MSAC application form allows for nomination of patient representatives to provide input to the process, but it is unclear how this is used, and often it appears that decisions are taken by MSAC without reference to their input. Overall, there seems to be process and methodological issues with how patient perspectives of either a qualitative or quantitative nature are incorporated into the evaluation. In the most recent MSAC guidelines for consultation, reference is made to the possible importance of personal utility for investigational interventions (diagnostic tests) but not for therapeutic interventions.[53]

Recommendations supported by timely government action

An MSAC recommendation remains just that until it is implemented by the government. This could be in the form of new MBS items, listing on the Prostheses List or some other measure. As already referenced above, this process can be lengthy and lack transparency, or may not even be followed through at all, particularly if private health insurers claim they already cover it, as happened with the coronary pressure wires example or more recently with cardiac ablation catheters (see example below).

[53] MSAC, Consultation on the Medical Services Advisory Committee (MSAC) Revised Draft Guidelines. 2020, October. https://consultations.health.gov.au/technology-assessment-access-division/msac-guidelines-review-consultation/

Recommendations:

- *If sponsors do not need to go through the PASC process, this should be clearly laid out in the MSAC Framework, Guidelines and website documentation*
- *Pre-submission meetings should be a clearly laid out opportunity prior to MSAC meetings. This will be particularly important for novel technologies where pathways may not be so clear and different approaches may be needed*
- *Sponsors and invited experts should be able to appear at MSAC hearings to clarify aspects of the technology and the submission and consideration should be given to having a clinical expert in the technology and a patient who has/had the condition to attending the full deliberation by MSAC to provide input*
- *The Government should strengthen the knowledge base on MSAC and HTA evaluators of bioengineering and digital technology and ensure relevant TGA experts in these areas are fully engaged in decision making*
- *The Department should hold an open workshop on the incorporation of patient input and preference into MSAC evaluations with a commitment to implement aligned recommendations*
- *Rather than simply revising guidelines and adhering to established HTA methods derived from the pharmaceutical industry, the Department and MSAC should fully engage with the device industry in a solution oriented discussion about the appropriate level of evidence that should be generated and expected for medical devices, including novel devices across the spectrum of technologies that exist and will come to market*
- *The Government should commit to a similar model for MSAC-recommended procedures and devices as exists for the PBS – committed funding with no offset required within the health portfolio and stronger commitments to timelines for post-MSAC review and implementation, transparent reporting on the status of MSAC recommendations*

If COAG under the National Health Reform Agreement begins to rely even more heavily on MSAC for national HTA recommendations in the public sector as well, its performance in appropriately assessing novel devices will be even more critical.

PLAC and Prostheses List Access Challenges

Many of the challenges described above with MSAC also apply to, or are exacerbated by, challenges with the PLAC and Prostheses List process. Typically, PLAC alone will not review the most novel technologies. Nonetheless, it can review improvements that are significant to patients and may reflect a cumulative series of innovations that have more momentous patient benefits over time.

Timeliness

Firstly, PLAC and MSAC processes do not synchronise well, and this can lead to unnecessary delays.

In the case that a novel medical device already has an MBS number for the procedure in which it would be used, the sponsor would typically be encouraged to make an application to PLAC. Prostheses List process follows a cycle of approximately 13-18 weeks in length from submission cut-off to PLAC meeting. In a typical PLAC cycle where there was a positive recommendation, this would result in a listing approximately 25 weeks after application cut-off. However, if PLAC made a decision to refer the device to evaluation by MSAC as has happened on a number of occasions, the MSAC 24-week ADAR process would be overlaid on top of the PLAC process. Then, following the MSAC decision, it would be referred back to PLAC for approval and potential subsequent listing discussions with the Department which may or may not be concluded by the listing date following the PLAC

meeting. In other words, the device would have gone through two disjointed processes resulting in significant delay, assuming a positive recommendation. Unfortunately, this does not provide a process that would be receptive to the novel technology that this Inquiry is intending to encourage.

Some of these elements can be seen in the case study below for cardiac ablation catheters:

Case study: Cardiac ablation catheters

Cardiac arrhythmia is a problem with the rate or rhythm of the heartbeat. It is a serious condition with the potential to lead to heart failure, stroke or sudden cardiac arrest. There are different sub-types of arrhythmia including atrial fibrillation, ventricle arrhythmias and super ventricular arrhythmias. Ablation to scar or destroy the heart muscle tissue that is causing the arrhythmia is a well-accepted treatment for arrhythmia. MBS items have existed to fund the professional services for the ablation since 1998 and the recent MBS review of cardiac items left them unchanged on the basis that they are now considered first line treatment for arrhythmias.

However, a longstanding issue is that the cardiac ablation catheters used to perform these procedures were not explicitly funded. Due to the fact that they are not implanted, they were not considered to qualify for Part A of the Prostheses List. They could be included on Part C of the Prostheses List only at the Minister's discretion, since this does not have formal criteria other than the basic legislative requirements for listing an item for use in private health insurance. Private health insurers claimed that they were routinely funding them through ex-gratia payments (payments made as an exception to the policy following application by the clinician), but there was strong anecdotal evidence that this was patchy at best and either patients were forced into the public system or the hospital had to cover the cost since in most cases contracts with insurers prevented them from charging patients out-of-pocket.

This issue was explicitly recognised by the Minister for Health during negotiations with MTAA over the Prostheses List in 2017. As a result the Agreement included a commitment by the Government to: 'Reviewing, through the PLAC, ways of listing new targeted medical devices on the Prostheses List that do not meet the current criteria for listing, but are safe, clinically effective and cost effective to support private health insurance reimbursement for a wider range of medical devices taking into account overall costs associated with the listing. These include, but are not limited to, cardiac ablation catheters for atrial fibrillation.'

As a consequence of this, a process was commenced in late 2018 that ultimately resulted in the listing of cardiac ablation catheters and related technology on Part C of the Prostheses List on 1 March 2019 for atrial fibrillation, but not for other arrhythmias, which had not been considered explicitly in the process. This was very welcome and the Minister is to be congratulated on the outcome.

However, shortly after this hospitals and clinicians reported that a number of insurers had stopped ex-gratia funding for arrhythmias other than atrial fibrillation, seemingly on the basis that because they were listed on the Prostheses List for that indication, they didn't need to fund them for anything else, despite the clinical guidelines supporting their use.

This turn of events was raised with the Department by private hospital, the device industry, and patient and clinical groups in May 2019. After several discussions with the Department, the Department advised in August that an MSAC submission would need to be made but following the PLAC timelines. Owing to the fact that sponsors were not in a position to make an application by the next cut-off date of September 2019, the application to MSAC was provided by the following PLAC cut-off date of January 2020 as requested, one month earlier than the lodgement deadline for the next eligible MSAC meeting. The application then followed the standard MSAC course.

Following the MSAC meeting MTAA and the sponsors were advised that the technologies would still need to go through another full round of PLAC review and that, if recommended, the earliest listing date would be 1 March, a full two years after the issue of non-coverage by insurers was first triggered and 8 months after the MSAC decision. While MTAA can't share more details in this submission as some information is not public, this case illustrates how the lack of coordination between PLAC and MSAC processes can cause significant and unnecessary delays in ensuring important technology that makes a significant clinical difference in an area of high need can be accessed by patients. It also illustrates clearly the problem of access falling through the cracks in different funding mechanisms and relying on insurer ex-gratia payments as a consistent source of coverage for private patients.

Overall, there is a great lack of clarity about when a submission to PLAC would be referred to MSAC for consideration. The new Prostheses List Guide due out early this year may assist with this, but sponsor confusion remains. MTAA submits that the Department and PLAC should not be too quick to refer applications to MSAC especially where the financial risk is small.

Secondly, if a sponsor's device is referred for a focused HTA review that is handled within the PLAC process, assuming a positive recommendation the process would take approximately 30 weeks from cut-off to the second PLAC meeting for final decision. This is around 6 weeks longer than a full MSAC process for a less expansive evaluation. MTAA sincerely welcomes the focused HTA pathway as an attempt to find better evaluation processes that are 'fit-for-purpose' but the lack of upfront triage makes the process longer than it needs to be.

Clear guidance and engagement with sponsors

It is not practical for the Department to meet with sponsors of any application to the Prostheses List as the volume is high. However, where there are applications for higher benefits, and a more detailed HTA is almost certain, a pre-meeting with the Department would enable sponsors to be better prepared and more likely to provide the information need for the assessment. This kind of request for higher benefits will usually be for improved technology.

While the feedback to sponsors from Clinical Advisory Groups (CAGs) and the PLAC have been improving overall, the level and variability of feedback remains concerning and needs improvement if sponsors are to be better placed to provide quality responses.

Relevant understanding and expertise

PLAC and its CAG groups do have a wide range of expertise, although the pool of clinical advisors has been significantly reduced by tighter Conflict of Interest rule applications by the Department, which in MTAA's view have been more stringent than reasonably needed. Nonetheless, unlike MSAC, it does include bioengineering expertise. Digital technology expertise could be added. The Department should take the opportunity to routinely include specific TGA expertise in decisions on technologies that are not are not standard listings.

The issue of patient input described above with MSAC also applies to PLAC in the case of improved technologies. While there are patient representatives that sit on PLAC, they often do not have specific experience with the disease in question. Given that the Prostheses List is for privately insured members of the public who invest their own money into their healthcare, it seems particularly pertinent that the perspectives of patients are strongly taken into account where appropriate, and there is an avenue to do this. At present, none exists.

Evaluative approaches appropriate to the technology

The issues raised under this heading related to MSAC equally apply here. As stated, the new focused HTA pathway is welcome as an initiative to moderate the evaluation to the level of clinical and financial risk. However, experience to date is that very few of these evaluations are leading to a positive recommendation, even for applications submitted by companies with greater resources to develop a robust submission. This suggests that the process continues to be more onerous than is warranted.

A particular issue that continually arises in the assessment of devices by CAGs and the PLAC is attempts to repeat evaluations of safety that have already been conducted by the TGA. Clinical experts in the CAGs and PLAC sometimes seem to have limited confidence in the TGA's evaluation, although the TGA are best placed to make this assessment. It is an unnecessary and inconsistent overlap to duplicate this process. It is legitimate for CAGs and PLAC to evaluate comparative safety in the context of overall cost and effectiveness, but the assessments at times move beyond this.

Recommendations supported by timely government action

In the case of the PLAC process, recommendations by PLAC are generally implemented quite efficiently by the Department, except as noted where MSAC becomes involved.

Recommendations:

- *Pre-submission meetings should be available for sponsors making applications for higher benefits on the PL, which are likely to be the applications for novel or improved technology*
- *Significantly improved triage of applications for novel or improved technology should occur so that the need for MSAC review or focused HTA can be identified early, duplication avoided, and timelines reduced*
- *The Department should manage the process to minimise any additional processing time for Prostheses Listing following positive PLAC recommendation for a technology*
- *The Government should strengthen the capability of PLAC and the CAGs in digital technologies, including through the use of TGA expertise*
- *The open workshop and recommendations for incorporating patient input described above should be modified and implemented to scale for PLAC consideration in evaluations where technology improvements or different approaches are being discussed*
- *Further guidance should be developed in conjunction with the TGA for CAGs and PLAC to avoid overlap in assessment between regulatory approval and Prostheses List assessments*
- *As for MSAC, rather than simply revising guidelines and adhering to established HTA methods derived from the pharmaceutical industry, the Department and PLAC should fully engage with the device industry in a solution oriented discussion about the appropriate level of evidence that should be generated and expected for medical devices, including novel devices across the spectrum of technologies that exist and will come to market*

Summary of HTA Processes

The focus of this section has been on areas of improvement in the MSAC and PLAC processes and government follow up to better enable novel technology to be made accessible to patients in Australia. The system has many successes, but it also has some challenges that need to be addressed. The approach to assessment of devices taken by the Department has often been one of expecting sponsors to prove their case without much dialogue. This sometimes leads to poor outcomes, especially when the HTA model developed in pharmaceuticals is routinely applied. Ultimately, the Government need to take a proactive, solution-oriented approach to listing novel technologies, so that patients do not miss out.

Prostheses Reform and its implications for access to novel technology

The Agreement between the Government and MTAA concludes on 31 January 2022. Under the Agreement, medical device companies delivered $1.1 billion in savings to the Prostheses List. The Agreement included recognition of the need for further Prostheses List reform, something that MTAA has willingly engaged in. However, there are proposals being put by private health insurers that rather than facilitating access to the best technologies will likely dampen their uptake, or result in market failure in the form of out-of-pocket costs to consumers. The proposals include paying for devices through a DRG (activity-based funding) system rather than the Prostheses List. This would abolish the Prostheses List as a consumer protection for patients. The TAVI case study in NSW above illustrates how funding technology through activity-based funding without consumer protections can lead to very uneven access, even in the public system which in principle must take final responsibility for ensuring access to interventions regardless of status. The private system is potentially even more open to restriction of access without the protection provided by the Prostheses List.

Private health insurers as an industry have a poor record of paying for novel health technology unless they are forced to. This is true even if there is an HTA or clinical guideline recommendation to use it. In the cardiac space alone, we have seen this in the last couple of years in the case of:

- Pressure wires for fractional flow reserve (case study above)
- Cardiac ablation catheters for arrhythmia (case study above)
- Cardiac remote monitoring for patients with legacy pacemakers and implants

It is critical for patients in the private sector where 70% of all elective procedures take place that the Prostheses List reforms demonstrably enhance and do not limit access to novel technologies. This includes enhancing the assessment pathways and ensuring they are more fit-for-purpose.

MTAA will be providing recommendations for PL reform and will provide further information in coming months.

Critical to any Prostheses List reform is that devices that are single-use and patient specific, but not implantable and so not eligible for the Prostheses List Part A, are able to be appropriately covered for private health insurance patients. As in the case for cardiac ablation catheters cited above, at the moment these are listed on the Prostheses List Part C by exception.

Recommendation:

The Inquiry consider and recommend funding approaches to ensure all technologies, including non-implantable single-use devices, are made available to private patients if found to be cost effective.

Table of recommendations:

Term of Reference 1 - What is the next wave of medical device technologies?	*MTAA recommends the government re-establish an effective horizon scanning process which includes an assessment of the key enablers to uptake for each technology*
Term of Reference 2 - Incentives for new medical technologies for unmet needs	• *Health procurement agencies to consider policies to selectively purchase some essential devices from local companies based on an equitable process to grow local capability where strong global supply chains do not meet local needs* • *A cross-portfolio review to consider the types of core expertise required to advance high quality R&D in medical devices, such as regulatory capability, and action ways to fill these both through visas and local skill development* • *Lead a discussion with the investment community on why Australian fundholders are reluctant to invest in MedTech but consistently prefer lower technology industries and promote change in investment patterns* • *Provide tax credits for commercialisation advice to start-ups that allow them to choose their own consultants but increase affordability* • *Actively audit technology needs in hospitals as reported by clinicians and staff and provide these lists to Australian companies* • *Reset government grant programs for the MedTech sector to more explicitly support commercialisation by start-ups*
	<u>Taxation of Intellectual Property</u> *MTAA recommends the Government to investigate international solutions such as the UK's Patent Box, Ireland's Knowledge Development Box, or section 238 of the French General Tax Code. By significantly reducing the marginal tax rate for income earned on locally developed and beneficially owned IP, these policies incentivise companies to:* • *Keep IP onshore;* • *Expand local manufacturing of the IP; and* • *Pay the taxable portion of the related review back to the country that invested in their initial R&D.*

	• *Further incentivise cross-institution and cross state border collaboration through linkage grants and incentives for flagship programs, similar to the Australian Cardiovascular Alliance* • *Actively co-locate science parks next to major hospitals and incentivise engagement between industry, researchers and clinicians* • *Have a full time internal government capability undertaking 'no fault' and confidential reviews of the results of past grants and incentives for MedTech and related research on a case by case basis to build a systematic body of information for government policy action and for education of researchers, investors and companies engaged in the sector*

Term of Reference 3 - Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies	***National Harmonisation of Ethics Review***
	MTAA in consultation with industry partners, recommends that:
	• *Public health policies are updated to provide that the following are mutually accepted by all States, Territories and Universities participating in the clinical trial;*
	  ○ *All nationally NHMRC accredited ethics committees can review and approve clinical trials at all public hospitals, private hospitals and trial centres, and universities.*
	  ○ *That the approval granted by a nationally NHMRC accredited ethics committee will be mutually accepted by all clinical trial centres without exception and without additional written agreements being required.*
	• *That the Australian Commission on Safety and Quality in Healthcare be tasked to facilitate processes on a national basis to address the items referred to in this recommendation.*

	A National Platform for Ethics and Governance Submissions *MTAA in consultation with industry partners, recommends that:* • *HREC and SSA submissions are harmonised into one Australian online platform, and that these are reviewed in parallel by HRECs and Research Governance offices. Further, that the development of this platform is within the purview of the Australian Commission On Safety And Quality In Health Care (ACSQH).*
	Recruitment of Clinical Trial Participants *MTAA in consultation with industry partners, recommends a National Community Awareness campaign:* • *NHMRC 'Helping our Health' awareness campaign (or similar) to be strengthened and re-commenced on a more sustained or regular basis to boost numbers of patients seeking clinical trials information;* • *That additional national patient awareness campaigns are developed, implemented and sustained.*
	Decentralisation of Clinical Trials *MTAA in consultation with industry partners, recommends:* • *Government invest in and develop a national standard approach; including nationally agreed systems and standard operating procedures to support and strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas. In order for the approach to satisfy the requirements of commercial clinical*

	trials, it is further recommended that industry is consulted during the development of the model.

	Modern and Future Ready Technologies and associated practices
	
	MTAA in consultation with industry partners, recommends:
	
	• *Government to move quickly to adopt and invest technologies and associated practices to ensure:*
	  ○ *All clinical trial centres (public hospitals) to:*
	  ▪ *Utilise Electronic Medical Records for recording clinical trial source records wherever possible*
	  ▪ *Ensure Electronic Medical Records include the ability to restrict access to clinical trial participant records to facilitate remote monitoring of participant medical records*
	  ▪ *Allow for remote monitoring of clinical trial participant records by sponsors*
	• *Establish national standards for the use of e-Consent in clinical trials*
	• *Adopt technologies for e-signatures on clinical trial documents.*

Term of Reference 4 - Approval Processes for Novel Medical Technologies	**Regulatory Processes for Medical Devices** *To encourage more in the industry to take full advantage of the new TGA priority review, we would like to recommend a sustained, dedicated education and training program aimed at Australian MedTech companies developing or aiming to distribute novel/ breakthrough technologies.* *Local MedTech start-ups encounter significant hurdles compared with their counterparts in U.S. and the EU, in particular in relation to:* • *Access to capital and long-term investment strategies* • *Medical device product development skills (which are different from proof-of-concept research skills)* • *Lack of local infrastructure and suppliers needed for MedTech development such as commercially available specialised testing services, medical-grade materials and components (most can only be outsourced from overseas)* • *Affordable access to IEC and ISO standards that are essential in the development and testing of medical devices, and stronger alignment of Australian standards with international IEC and ISO standards*

	Lengthy TGA Application Review Timelines for standard submissions *It is essential that the TGA be equipped with appropriate IT systems and staffed with sufficient human resources so that it can fulfill its mission as the national therapeutic goods regulator. Long review timelines are often caused by a lack of specialist reviewers and outdated IT systems. It is in the best interest of patients, industry and community at large to have an adequately resourced national regulator.* *Per the intent of the recommendation made by the Expert Review of Medicines and Medical Devices Regulation (MMDR), TGA should look to streamline processes for including medical devices in the ARTG in order to improve access by Australian consumers to new medical devices. TGA should make greater use of the comparable overseas regulatory approvals obtained by manufacturer's and not replicate the full review process already completed by these regulators on the medical device. TGA should adopt a true abridged evaluation process to significantly reduce the review timelines.* *TGA should look to improve review processes, specifically in the conformity assessment section, including the consolidation of requests for additional information (s41JA) from the various review sections, to reduce the number of stop-clocks throughout the review process and remove the duplication of requests.*
	State and territory new technology processes *This recognition of the need for change in the 2020 Addendum is welcome. However, MTAA makes the following recommendations to this committee for action now and in implementation of the 2020 Agreement:* • *Working with the TGA and potentially other bodies, a national list of novel health technologies recently approved should be created to allow for transparent reporting on their assessment and adoption* • *State and territory governments should be required under their reporting responsibilities for the National Health Reform Agreements to transparently outline their processes for evaluating and funding new technologies included in the novel list, what decisions have been taken and progress in uptake of the new technology* • *Evaluation processes at state and territory level should be fit-for-purpose and not overindex long and complicated HTA if this is not needed, and should incorporate the use of pilots and local trials where further evidence is needed* *IHPA should demonstrate how its processes can better reflect the costs of new technology earlier in determination of the National Efficient Price, especially with a move to 3-year cycles.*
	HTA processes – MSAC and PLAC • *If sponsors do not need to go through the PASC process, this should be clearly laid out in the MSAC Framework, Guidelines and website documentation* • *Pre-submission meetings should be a clearly laid out opportunity prior to MSAC meetings. This will be particularly important for novel technologies where pathways may not be so clear and different approaches may be needed*

	• *Sponsors and invited experts should be able to appear at MSAC hearings to clarify aspects of the technology and the submission and consideration should be given to having a clinical expert in the technology and a patient who has/had the condition to attending the full deliberation by MSAC to provide input* • *The Government should strengthen the knowledge base on MSAC and HTA evaluators of bioengineering and digital technology and ensure relevant TGA experts in these areas are fully engaged in decision making* • *The Department should hold an open workshop on the incorporation of patient input and preference into MSAC evaluations with a commitment to implement aligned recommendations* • *Rather than simply revising guidelines and adhering to established HTA methods derived from the pharmaceutical industry, the Department and MSAC should fully engage with the device industry in a solution oriented discussion about the appropriate level of evidence that should be generated and expected for medical devices, including novel devices across the spectrum of technologies that exist and will come to market* • *The Government should commit to a similar model for MSAC-recommended procedures and devices as exists for the PBS – committed funding with no offset required within the health portfolio and stronger commitments to timelines for post-MSAC review and implementation, transparent reporting on the status of MSAC recommendations*
	PLAC and Prostheses List Access Challenges • *Pre-submission meetings should be available for sponsors making applications for higher benefits on the PL, which are likely to be the applications for novel or improved technology* • *Significantly improved triage of applications for novel or improved technology should occur so that the need for MSAC review or focused HTA can be identified early, duplication avoided, and timelines reduced* • *The Department should manage the process to minimise any additional processing time for Prostheses Listing following positive PLAC recommendation for a technology* • *The Government should strengthen the capability of PLAC and the CAGs in digital technologies, including through the use of TGA expertise* • *The open workshop and recommendations for incorporating patient input described above should be modified and implemented to scale for PLAC consideration in evaluations where technology improvements or different approaches are being discussed* • *Further guidance should be developed in conjunction with the TGA for CAGs and PLAC to avoid overlap in assessment between regulatory approval and Prostheses List assessments* • *As for MSAC, rather than simply revising guidelines and adhering to established HTA methods derived from the pharmaceutical industry, the Department and PLAC should fully engage with the device industry in a solution oriented discussion about the appropriate level of evidence that should be generated and expected for medical devices, including novel devices across the spectrum of technologies that exist and will come to market*

	The Inquiry consider and recommend funding approaches to ensure all technologies, including non-implantable single-use devices, are made available to private patients if found to be cost effective.