MTAA's submission to the Deregulation Taskforce 26/03/2021

Medical Technology Association of Australia

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

MTAA members provide all of Australia's healthcare professionals with essential product information, continuing education and training to ensure safety and to optimise the effective use of medical technology. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

Medical Technology

The medical technology (MedTech) industry is one of the most advanced and dynamic manufacturing sectors in Australia and has the potential to provide substantial health gains and highly skilled employment opportunities for Australians and add to Australia's export industry.

It is estimated that the total market for medical devices in Australia was valued at US$4.9 billion

There are 135 ASX-listed MedTech and pharmaceutical companies in Australia, with a market capitalisation of $179 billion.

The MedTech industry in Australia is a substantial employer. In 2014, it was estimated that the industry (including digital health) employs about 19,000 people.

It is also estimated that the total market for medical devices in Australia is valued at over US$4.9 billion, with a compound annual growth rate of 1.4% since 2014. Despite representing a small market, Australia ranks as a prominent developer of MedTech worldwide. From the smallest sutures and neurosurgical coils to the largest linear accelerators, MedTech provides the platform from which healthcare is delivered. Without MedTech, healthcare cannot be delivered.

Summary of Regulatory Burdens

The Medical Devices Industry in Australia is regulated by three main bodies and several smaller or boutique entities. The three primary regulators are The Therapeutic Goods Administration (TGA), The Medical Services Advisory Committee (MSAC), and the Prostheses List Advisory Committee (PLAC). For a medical device to be available to Australian patients it must always be approved by the TGA, for it to be reimbursed by Government it may need to pass through the MSAC process and always needs to pass through multiple state and territory approval processes. To be reimbursed by private health insurers it (or the procedure) must have passed through all three regulators. MTAA strongly supports the regulatory process in its aim to ensure every medical device in Australia meets the high efficacy and safety standards to which we are accustomed, however, we cannot support regulation that overlaps other regulation or unnecessarily slows access to new medical devices.

About MTAA

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

MTAA represents manufacturers and suppliers of medical technology (MedTech) used in the diagnosis, prevention, treatment and management of disease and disability. The MedTech industry is diverse, with medical products ranging from frequently used items such as syringes and wound dressings through to high technology implantable devices such as pacemakers, defibrillators, bone and joint replacements, and other prostheses. MedTech includes hospital and diagnostic imaging equipment used in all settings, from the smallest rural clinic to the largest multi-site hospital, e.g., ultrasound and magnetic resonance imaging (MRI) equipment.

MTAA members develop and distribute the majority of all medical products used in the diagnosis and treatment of every disease and disability that Australians experience. Our member companies play a vital role in educating healthcare professionals with essential information, training and support to ensure safe, innovative and efficacious use of MedTech.

About MedTech In Australia

The MedTech industry is one of the most dynamic advanced manufacturing sectors in Australia and has sustained its potential to provide substantial health gains and high-level employment opportunities to Australians and grow Australia's export of technology. Through innovation, this industry will continue to expand and share its discoveries with the world.

For example, Prism Surgical, Cochlear Australia and ResMed are three Australian companies that have exported Australian innovation in medical devices to the world and continue to do so. The Australian Bureau of Statistics[1] (ABS) identified the industry as a growth industry, performing higher than average on indicators such as export, productivity and employment.

More than 3,000,000 medical devices were used in 2019.

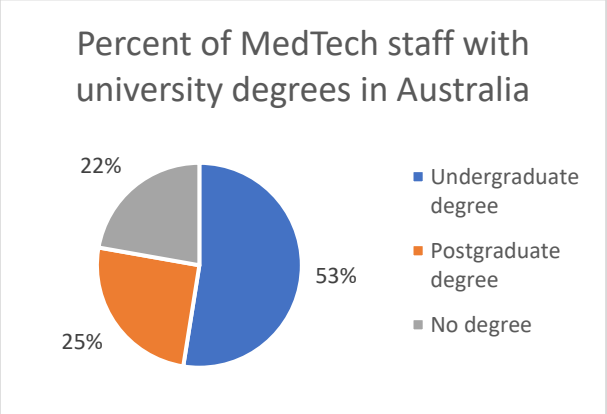
It is estimated that the total market for medical devices in Australia is valued at over US$4.9 billion[2]. Despite representing a small market, Australia compares favourably worldwide; according to the Worldwide Medical Device Factbook, Australia is ranked at 13th in terms of total market value.

Considering gross-value-added, which is a measure of the value of industry production, there have been steady increases for both the MedTech and the pharmaceutical sector. In 2019, it was calculated that the gross value added for the entire industry was $5.2 billion, an increase from $4.9 billion in 2016.[3]

[1] Australian Bureau of Statistics, Characteristics of Businesses in Selected Growth Sectors, Australia, 2013–2014. 2015, Australian Bureau of Statistics: Canberra.
[2] https://www.statista.com/statistics/716902/medical-equipment-market-size-in-australia/
[3] MTPConnect, MTPConnect 2020 Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan. 2020.

With continual growth and advancements in the industry, all surgical operations and clinical procedures performed in Australia involve some form of MedTech, whether it is patient consumables or diagnostic machinery. Over 2.5 million patient per year are served with assistive technology that provides A$3.6 to $4.5 billion annual value to the community. As a result, globally we have seen a 30% decline in annual mortality in the last 20 years, an 18.7% decline in disability rates in the last 15 years, and a 56% reduction in hospital bed days and an increase in life expectancy by 4.1 years. MedTech has been a key partner in these achievements. Currently, there are 135 ASX-listed MedTech and pharmaceutical companies in Australia, with a market capitalisation of $179 billion.

The MedTech industry in Australia is a substantial employer. In 2014, it was estimated the industry employs approximately 19,000 people, excluding those working in digital health. Overall, 78% of all MedTech employees have graduated with a university degree, demonstrating the highly educated nature of the workforce. Of these employees, 52% earned an undergraduate degree, and a further 25% completed a postgraduate degree.[4]



The MedTech Industry's COVID-19 response

Australia confirmed its first case of the Coronavirus (COVID-19) on 25 January 2020, it wasn't long before COVID-19, emerged as an international public health emergency and it was classified by the World Health Organization as a pandemic on 11 March 2020.

Within days of the WHO's designation, MTAA had provided a framework for a COVID-19 Industry Working Group. This Group included both MTAA members and non-member companies, who worked together to support the Federal Government's Taskforce and assist in securing essential supplies of ventilators, test kits, Personal Protective Equipment (PPE) and other Intensive Care Unit supplies required by the healthcare system to move swiftly to manage the Pandemic effectively.

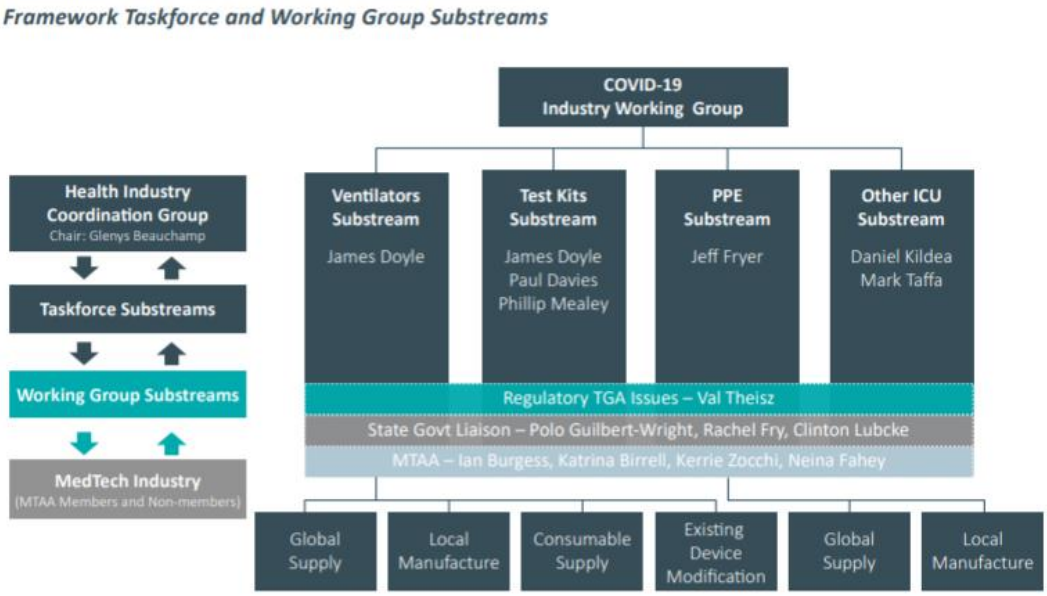
The MedTech industry was quickly tasked by the Federal Government with supplying 7,500 ventilators. It was modelled that at the Pandemic's potential peak, Australia would require these to manage the 7,500 people needing mechanical ventilation at that time. MTAA member companies answered the call. This included a consortium of leading MedTech companies including Grey Innovation from Victoria who began the local manufacturing of ventilators.

MedTech's efforts extended well beyond ventilators with MTAA members such as Abbott providing six COVID-19 tests included in the Australian Register of Therapeutic Goods (ARTG) and Hologic providing two. These companies are leading the charge in the development, manufacturing, and distribution of COVID-19 testing kits with Abbott's broad range of tests providing further opportunities for testing during the vaccination stage.

Further to this, local businesses who had previously never ventured into the health sector stepped up and became MedTech manufacturers. Distilleries such as Archie Rose Distilling Co in Sydney and Prohibition Liquor Co in South Australia switched from bottling gin to bottling hand sanitiser.

[4] [4] Deloitte, Medical technology industry workforce and skills review. 2015.

Existing local MedTech manufacturers had to increase production rates dramatically. Non-MTAA member Med-Con from rural Victoria used to produce 2 million facemasks each year. With the onset of the pandemic, the Australian Army stepped up to assist on the production line allowing Med-Con to produce 2 million face masks each week, 52 times their usual production rates.



MTAA member Stryker moved quickly to support Australia's need for additional ICU beds designing and producing rapid response ICU beds. Fortunately, the high numbers of hospitalisations that forced other jurisdictions to erect and use field hospitals and pop-up ICUs were mostly avoided in Australia.

Not all MedTech companies were able to ramp up production with many companies catastrophically affected by the national elective surgery suspension and subsequent state and regional suspensions. Companies who were exclusively focused on surgical procedures saw revenue drop to zero overnight.

All companies faced dramatic shifts to freight movements and costs. Overnight, airfreight services were cut, and companies had to adapt quickly. With 90% of Australia's exports usually shipped as additional cargo in passenger aircraft, our export capacity promptly fell, and prices rose by greater than 500%.

Throughout the Pandemic, the MedTech industry has adapted to change, absorbed additional costs, opened new production lines and shifted existing production capacity, joined forces with other companies, industries, and governments, and developed new procedures to keep Australians healthy. All of this occurred whilst the MedTech industry did its best to continue to support patients and the broader health sector. MedTech in theatre technicians spent countless cumulative days in quarantines, sometimes just to assist a single patient. Importers met demand and ensured Australia was supplied, even with immense costs that were not passed on.

Despite vaccination programs being underway, the vast majority of Australians are yet to receive their vaccination and as has been shown by the re-emergence of COVID-19 in Victoria, New South Wales, and South Australia, it is unclear how long this Pandemic will directly affect lives and the way people interact with the world. The MedTech industry is prepared to address the ongoing medical needs of the community as we continue our pandemic response. In June of 2020 after extensive work in ensuring Australia was pandemic ready MTAA, in collaboration with MTPConnect published a report

"Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19" This report goes into detail in regards to the COVID-19 industry working groups and it's sub-streams, including regulatory issues.

Medical Technology and Medical Device Regulators

Therapeutic Goods Administration (TGA)

As part of the Department of Health, the TGA safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods such as medical devices. The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of devices. The TGA regulates medical devices through: pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

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.

Medical Services Advisory Committee (MSAC)

The Medical Services Advisory Committee (MSAC) is an independent non-statutory committee established by the Australian Government in 1998. It has two sub-committees, the PICO Advisory Sub-committee (PASC) and the Economic Sub-committee (ESC).

MSAC appraises new medical services proposed for public funding using Health Technology Assessment (HTA) and provides advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence. Amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other programs (for example, blood products and blood-related products; or screening programs) are also considered by MSAC. Almost every medical procedure or medical service uses some form of medical device, such as a MRI, pathology test, or even a tongue depressant. MSAC is also sometimes tasked by the Department specifically to review one or more prostheses for addition or amendment to the Prostheses List. Consequently, MSAC's decisions greatly affect access to medical devices.

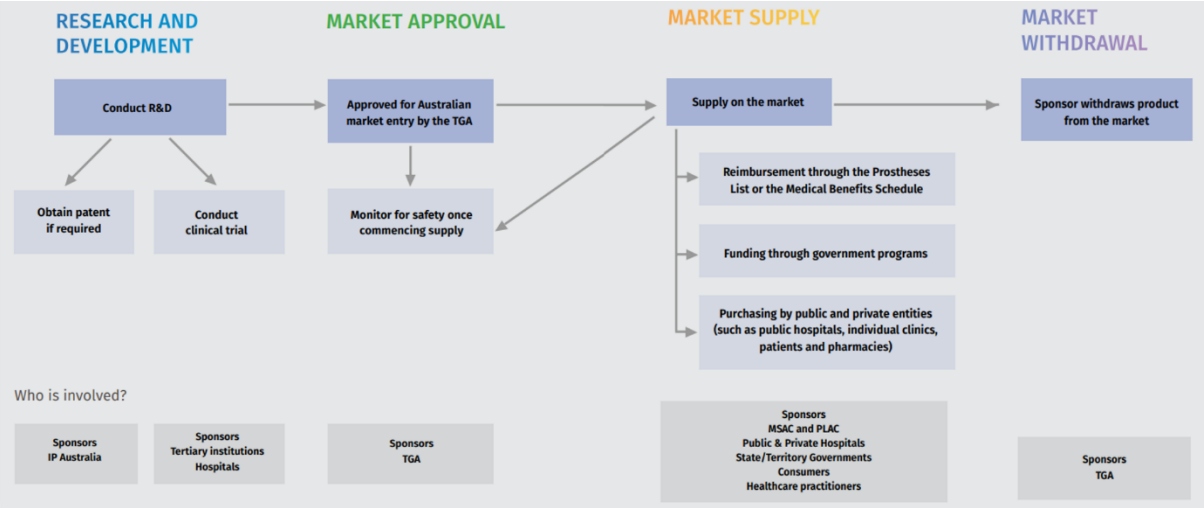
Prostheses List Advisory Committee (PLAC)

The Prostheses List (PL) is a list of implantable medical devices which insurers are required to fund should a patient require them for hospital treatment and have the requisite cover. These devices include orthopedics such as knees and hips, cardiac devices such as pacemakers and implantable cardioverter defibrillators, ophthalmic lenses for permanently correcting vision, and a broad array of other lifesaving medical products. The Prostheses List Advisory Committee (PLAC) is responsible for advising which of these medical devices may be listed on the Prostheses List and the benefit levels payable by private health insurers for these devices. Clinical Advisory Groups (CAGs) advise the PLAC on these decisions. The Minister's delegate in the Department of Health is responsible for the final decision on listing.

The life of a medical device comprises the stages involving activities leading up to and including marketing approval by the TGA and the stages once marketing approval has been obtained and the product is being supplied on the market. The key steps a devices lifecycle include:

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

A visual representation of this process has been included in the following page.



Prostheses List Reform

Currently the Prostheses List, administered by the Department of Health with the advice of the PLAC, is due for reform. It is not 'broken' as some have argued, but rather there is significant scope for the PL to be further optimised. At present, the PL does deliver on its core function: patients are able to access the very best medical devices for their specific diagnosis and clinicians are able to prescribe the device that they, in their expert opinion, believe will best treat a patient's condition. Any reform to the PL must not affect these primary outcomes but rather amend the listing and reimbursement processes to achieve efficiencies and positive secondary outcomes. MTAA has recently put together a comprehensive submission that seeks to strip red tape, drive efficiencies through competitive market forces and provide long term stability to clinicians and patients. This submission is available via our website.

There is an alternative option being proposed by some private health insurers which utilises Diagnosis Related Groups (DRGs), a method of average payments across broad diagnosis groups. Under this proposal insurers would shift their financial risk onto patients, clinicians, and health care providers (HCPs) whilst relying on another regulator, the Independent Hospital Pricing Authority to set benefits. MTAA, along with the Australian Medical Association, the Australian Private Hospitals Association, and the Consumer Health Forum have all voiced strong opposition to the use of DRGs as they either totally erode the primary objectives of the PL or place them at extreme risk.

This reform has, in part, been brought about due to Australian Prudential Regulation Authority's (APRA) very real concerns about the long-term viability of many private health insurers. Each year, insurers petition the Minister for Health for the ability to increase their premiums, and whilst the Minister has constrained this to the smallest increase in 20 years this is still a questionably large increase. Insurers claim that this increase is needed due to the rising cost of the PL however, the cost of the Prostheses List has increased by significantly less than premiums, over the same period, insurers have increased their internal management expenses by 4.4% almost double their increase in premiums. It is clear this is unsustainable, and shaving a few percentage points off the PL when the PL accounts for less than 10% of insurers total benefit costs will not provide savings in the order of magnitude required for insurers to achieve sustainability.

Regulation Challenges

Federal Challenges

PLAC and MSAC Challenges

Patient access to medical 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, whether by the Commonwealth or by private health insurers for eligible policies, 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, as well as 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 sitting within the Office of Health Technology Assessment branch.

If MSAC and PLAC are to deliver enabling access to medical 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 medical technology.

MSAC Access Challenges

The MSAC Process Framework[5] 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.

[5] MSAC Process Framework Version 1 March 2016
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-process-framework

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.

MSAC 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 approximately 8 weeks after the decision before the Public Summary Document is released and next steps can occur. 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 medical device to be used 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 some technologies recommended as cost-effective by MSAC, regulated access is never provided because they don't meet current Prostheses List criteria.

Some of these elements can be seen in the case study for Left Atrial Appendage Closure in Non-valvular Atrial Fibrillation– Appendix 1.

Many of the challenges that apply to MSAC also apply to, or are exacerbated by, challenges with the PLAC and Prostheses List process. Typically, PLAC alone will not review entirely novel medical 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.

PLAC Timeliness

Firstly, PLAC and MSAC processes do not synchronise well, and this can lead to unnecessary delays. In the case that a medical device already has a Medicare Benefits Schedule (MBS) number for the procedure in which it would be used, the sponsor would typically be encouraged to make an application to PLAC. The 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 delays, assuming a positive recommendation. Unfortunately, this does not provide a process that would be receptive to companies attempting to introduce new and advanced medical devices for Australian patients.

Some of these elements can be seen in the case study for cardiac ablation catheters – Appendix 2.

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 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 Health Technology Assessment (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 instituted by the Department 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. Furthermore, while there have been reforms recently, the timeliness and quality of feedback to sponsors about CAG and PLAC decisions need to be improved to ensure sponsors don't need to miss a whole cycle to address a particular issue.

Overlap of TGA and PLAC

While TGA is a highly respected international regulator that assesses safety and efficacy of devices, there are a number of instances where the PLAC and its CAGs revisit efficacy and safety issues that are not in their remit and not relevant to the assessment of relative cost and effectiveness, which is their role in advising on additions or changes to the Prostheses List. While attempts have been made to address this, the problem is still ongoing, and duplicates effort and resources, including sponsor time.

Interjurisdictional Overlap

In regulators ever vigilant bit to ensure community safety there are often instances of interjurisdictional overlap, points in which state and territory governments take on equivalent or identical functions to the Federal Government. A case study regarding this can be seen in Appendix 3. Other examples include procurement processes in state and territory governments, which frequently ask for detailed information on device compliance with standards when these are already covered by the TGA listing for the device.

If this submission has raised any questions for you or you would like to organise a briefing, please contact MTAA's Public Affairs and Communications Coordinator - Edward Strong at estrong@mtaa.org.au or Director of Policy - Paul Dale at pdale@mtaa.org.au

Appendix 1 – 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.

Appendix 2 – 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 subtypes 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. Following requests from MTAA, the catheters' listing expanded to include ventricular tachycardia on 1 November 2020. The full listing for all arrythmias was finalised on 1 March 2021.

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.

Appendix 3 – Case Study: Health Purchasing Victoria

Health Purchasing Victoria require companies hold registration with GS1 Australia's platforms Recall Health and the National Product Catalogue (NPC).

This results in the payment of multiple fees including ongoing annual fees to GS1 as a condition for participation in public hospitals tenders. This is a duplication as the TGA already has requirements and databases for product recall and product information.

The cost, time and effort that sponsors spend to meet the duplicative requirements at state level erode the financial profitability and competitiveness of Australian medical device companies.

Appendix 4 – MTAA Members

MTAA Members

- 61medical Pty Ltd
- 3D-Matrix Medical Technology Pty Ltd
- 3DMEDiTech
- 3DMorphic Pty Ltd
- 3M Australia Pty Ltd
- Abbott [Vascular] Australasia
- Abbott Medical Australia Pty Ltd
- Alcon Laboratories (Australia) Pty Ltd
- Allergan Australia Pty Ltd
- AlphaXRT
- Amplifon Australia
- Analytica Ltd
- APNE Surgical Pty Ltd
- Atomo Diagnostics Ltd
- Australasian Medical & Scientific Ltd
- Australian Dermatology Equipment
- Avanos Medical Australia Pty Ltd
- B Braun Australia Pty Ltd
- Bard Australia Pty Ltd
- Bausch & Lomb (Australia) Pty Limited
- Baxter Healthcare Pty Ltd
- Biocelect Pty Ltd
- Biotronik Australia Pty Ltd
- Boston Scientific Pty Ltd
- Brainlab Australia Pty Ltd
- BTC Health (BTC Specialty Health Pty Ltd)
- Cardinal Health Australia 503 Pty Ltd
- ConMed Australia
- Cook Australia Pty Ltd
- Corin (Australia) Pty Ltd
- Cortical Dynamics Limited
- Culpan Medical Australia Pty Ltd
- Device Technologies Australia Pty Ltd
- Edwards Lifesciences Pty Ltd
- Elekta Pty Ltd
- Exactech Australia
- Fresenius Kabi Australia Pty Ltd
- Fresenius Medical Care Australia Pty Ltd
- Gamma Gurus
- Gel Works Pty Ltd
- Getz Healthcare Pty Ltd
- Grey Innovation
- Hemideina
- Hologic (Australia) Pty Ltd
- Horten Medical
- Johnson & Johnson Medical Pty Ltd
- KLS Martin Australia Pty Ltd
- Laminar Air Flow Pty Ltd
- LifeHealthcare Pty Ltd
- LivaNova Australia Pty Ltd
- Materialise Australia Pty Ltd
- Medacta Australia Pty Ltd
- MED-EL Implant Systems Australasia Pty Ltd
- Medical Specialties Australia Pty Ltd
- Medigroup Australia Pty Ltd
- Medi Press
- Medtronic Australasia Pty Ltd
- MicroPort CRM Pty Ltd
- Molnlycke Healthcare
- NeedleCalm Pty Ltd
- Nevro Medical Pty Ltd
- NL-Tec Pty Ltd
- Olympus Australia Pty Ltd
- Palette Life Sciences Australia
- Paragon Therapeutic Technologies
- Prism Surgical Designs Pty Ltd
- Roche Diabetes Care Australia Pty Ltd
- Singular Health PTY LTD
- Smith & Nephew Pty Ltd
- Smiths Medical Australasia Pty Ltd
- Spectrum Surgical Pty Ltd
- Stryker Australia Pty Ltd
- Teleflex Medical Australia Pty Ltd
- Terumo Australia Pty Ltd
- Tunstall Australasia Pty Ltd
- Varian Medical Systems Australasia Pty Ltd
- Vitalcare Pty Limited
- W. L. Gore and Associates (Aust) Pty Ltd
- Wright Medical Australia
- Zimmer Biomet