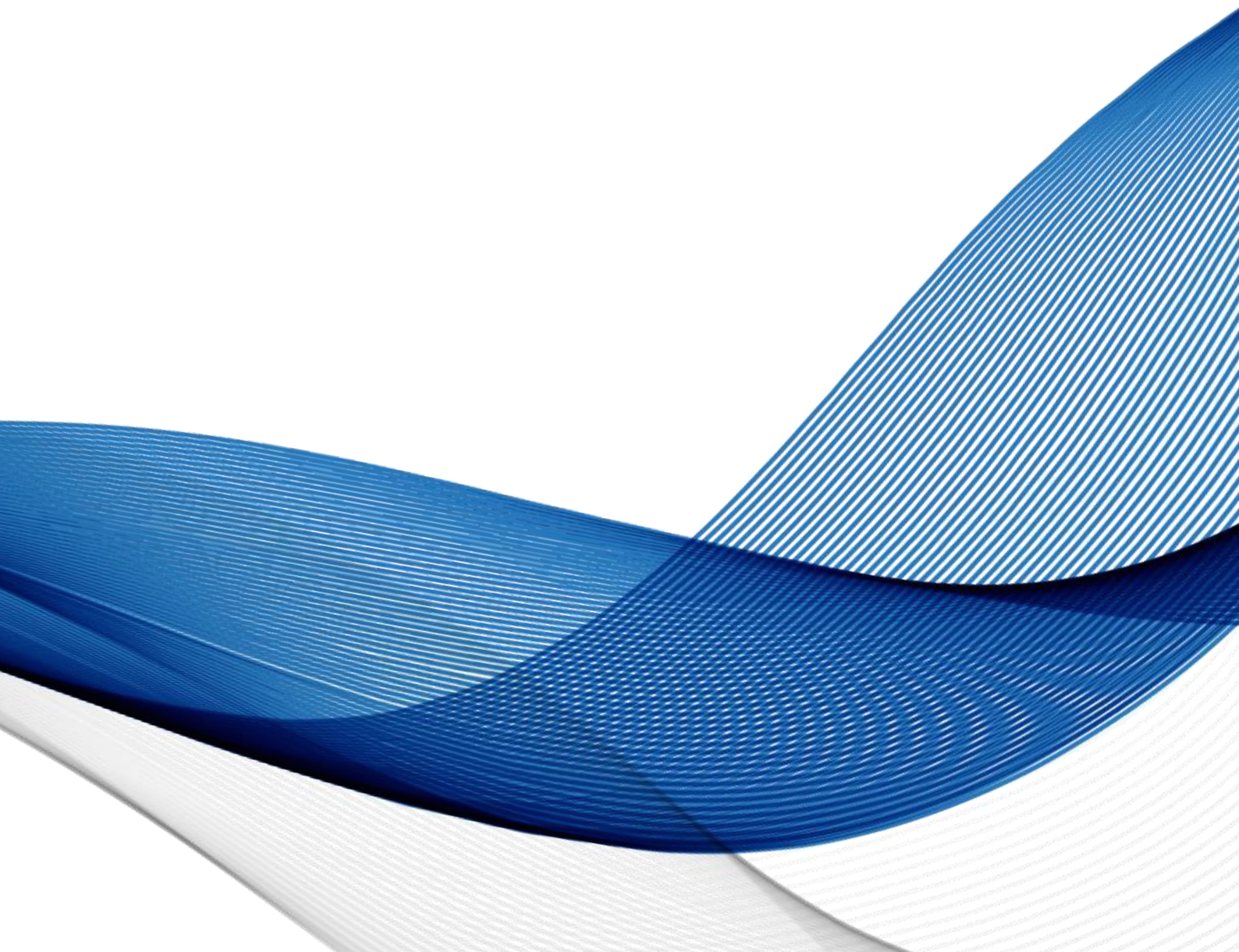
Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Lvl 12, 54 Miller St, North Sydney NSW 2060
PO Box 2016, North Sydney NSW 2059
P: (02) 9900 0600
E: mtaa@mtaa.org.au

MTAA Pre-Budget Submission FY2020/21



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 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 safe and effective use of medical technology.

Medical Technology

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

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

There are 91 ASX-listed medical technology and pharmaceutical companies in Australia, with a market capitalisation of $94 billion.

The medical technology industry in Australia is a substantial employer. In 2016, it was estimated the industry employs about 17,700 people.

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.

Summary of Policies

In recognition of the change in financial circumstances as a result of the Government's COVID-19 measures, the majority of policies in this submission seek to either provide a total saving or repurpose existing funds. MTAA is submitting 18 policies for consideration:

1. Continuation of Reimbursement while Using Telehealth
2. Continuation of Elective surgery during COVID
3. Cardiac Remote Monitoring
4. Sovereign Capability in Advanced Manufacturing
5. Private Health Insurance
6. Review of Private Health System
7. Prosthesis List
8. Reimbursement Pathways
9. Home and Community Care
10. Advanced Manufacturing
11. Research and Development
12. Clinical Trials
13. Tax Reform
14. Taxation of Intellectual Property
15. Therapeutic Goods Administrations Systems
16. PPE access for Private Hospitals
17. Digital Health
18. Artificial Intelligence

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Contents

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 modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from familiar items such as syringes and wound dressings, through to high-technology implanted devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

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 safe and effective use of medical technology.

About MedTech (In Australia)

The medical technology industry is one of the most dynamic manufacturing sectors in Australia and has the potential to provide substantial health gains and highly paid employment opportunities to Australians and add to Australia's export industry. Through innovation, this industry could expand.

Cochlear Australia and ResMed are two Australian companies that have taken medical devices to the world. The Australian Bureau of Statistics[1] (ABS) identified the industry as a growth sector, performing higher than average on indicators such as export, profitability, productivity and employment.

It is estimated that the total market for medical devices in Australia is valued at over US$4.6 billion[2]. Despite representing a small market, Australia compares favourably worldwide; according to the Worldwide Medical Device Factbook, Australia is ranked at 10th in terms of total market value.

Considering gross value-added, which is a measure of the value of industry production, there has been a steady increase in the medical technology sector. In 2016, it was calculated that the gross value added for the industry was $1.9 billion, an increase from $1.5 billion in 2013. In contrast, over the same period, the gross value added by the pharmaceutical industry has been steadily decreasing, dropping from $3.2 billion to $3 billion[3].

With continual growth and advancements in the industry, all surgical operations performed in Australia involve some form of medical technology, helping more than 2.5 million patients per year, with assistive technology providing A$3.6 to $4.5 billion annual value to the community. Globally we have seen a 25% decline in annual mortality, 25% decline in disability rates[4], 56% reduction in hospital bed days and an increase in life expectancy by 4.6 years[5], medical technology has played a central role in delivering these improvements

[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 2017 Annual Highlights. 2017
[4] Australian Bureau of Statistics, Disability, Ageing and Carers, Australia: Summary of Findings, 2015. 2015
[5] MTPConnect, MTPConnect 2017 Annual Highlights. 2017.

There are 91 ASX-listed medical technology and pharmaceutical companies in Australia, with a market capitalisation of $94 billion.

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

COVID-19 response

With Australia confirming 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 which was classified by the World Health Organization as a pandemic on 11 March 2020.

By mid-March 2020, MTAA had developed the framework for a COVID-19 Industry Working Group, involving MTAA member and non-member companies, to support the Federal Government's Taskforce and assist in securing essential supplies of ventilators, test kits, Personal Protective Equipment (PPE) and other ICU supplies required by the healthcare system to manage the pandemic.

This working group was highly successful in ensuring Australia was well placed to tackle the rising number of cases and the pandemic more broadly.

As has been shown by the re-emergence of COVID-19 in Victoria, it is unclear how long this pandemic will directly affect lives and the way people interact with the world. The MedTech industry is preparing to address the ongoing needs of the community, both in relation to the medical needs of the pandemic response, and the changes to social expectations brought on by the pandemic.

Continuation of Elective surgery during COVID

Continuity of elective surgery is not just a factor of available hospital beds and theatres but also available devices and industry reps. With the suspension of elective surgery first nationally, then in metro Victoria and most recently throughout the whole of Victoria MTAA member companies were significantly affected.

Device companies have faced significant disruption to demand, while at the same time supply chains came under significant pressure which still persists to a significant extent. MTAA and its members supported National Cabinet's tough decision to suspend elective surgery and will continue to support the Government in its COVID-19 recovery. However, whilst MTAA recognises the speed at which decisions must be made, we request governments ensure suppliers are informed of surgery planning during the pandemic for the public sector, where practical to do so, so that they can ensure supply meets the potential spike in demand.

MTAA recommends government enact procedures to ensure suppliers receive adequate warning of changes to elective surgery so that lead times may be managed.

Continuation of Reimbursement while Using Telehealth

As COVID-19 accelerated the shift to a telehealth friendly medical ecosystem, the Government acted swiftly to ensure reimbursement schemes adapted. This ensured the most at-risk Australians were able to access essential healthcare services without having to risk exposure to COVID-19 in a public setting.

Before COVID-19, virtual care attendances accounted for only 0.1% of all federally funded attendances in Australia. MTAA requests the recommendations (listed below), provided to the Australian National COVID-19 Coordination Commission by MTAA as part of the Connected Healthcare Advisory Group (CHAG) (an industry body whos aim is to "drive the implementation of an ICT enabled service delivery framework for a healthier Australia"[6]) , be accepted in full.

MTAA as part of the Connected Healthcare Advisory Group recommends:

The CHAG recommends that there be a broad-range review of existing programs with a view to expanding and standardising those programs.

- *COVID-19 Telehealth MBS consultation codes be made permanent;*
- *MBS telehealth item numbers be extended to include technology-enabled programs that help people and their healthcare teams manage health conditions for:*
  - *Hospital avoidance*
  - *Early discharge*
  - *Disease and health management*
  - *Quality of life o efficient use of community care and health resources, and*
  - *Clinical care and support*
- *MBS telehealth items numbers be extended for remote monitoring, including within aged care, retirement living, and GP clinics; and*
- *Further investment in fast-tracking the full optimisation of the EHR for all Australians.*

Longer term recommendations in the form of:

- *A review under the auspices of the COAG/National Cabinet process of MBS and State-based funding models; and*
- *A Productivity Commission (PC) review with the input and support from consumer and key stakeholder groups to investigate the benefits of, and barriers to, a nationwide ICT enabled health system.*

[6] https://www.mtaa.org.au/mtaa-forums-and-working-groups

Cardiac Remote Monitoring

The COVID-19 pandemic exemplifies why an extension of remote monitoring for privately insured patients with implanted cardiac devices is needed. Private health insurance should provide cover to patients with a high clinical need who were not provided with a remote monitoring system during hospital admission. Such a step would align with the widespread adoption of remote health services during the COVID-19 pandemic to mitigate the risk of viral transmission and protect public health.

There is a gap in coverage of privately insured patients with cardiac implantable electronic devices. Those who did not receive a monitor at the time of device implantation do not qualify to receive and the system through the Prostheses List since it is not provided in hospital. This restriction is arbitrary and exposes vulnerable patients with significant cardiac conditions to COVID-19 infection by requiring them to attend clinics more often. Extending insurance coverage to non-hospital provision of remote monitoring (RM) systems for those with a high clinical need during the pandemic is a simple, effective solution with a minimal cost impact.

MSAC and PLAC have endorsed RM as a cost-effective and clinically effective solution for patients. Uptake of RM in the private sector is now approximately 90%. Patients with older devices are likely to benefit from extending the RM system provision. The Medical Services Advisory Committee (MSAC) determined the service cost-effectivness with the cost of the remote monitoring device to be $3,000. The Government then decided to list the RM system on the prostheses list (PL) at $1960 and the benefit has since been reduced to $1450. The benefit paid for the RM system has decreased by 26% through PL cuts – which has further improved its cost-effectiveness.

MTAA recommends government require private health insurers to fund cardiac remote monitoring.

Sovereign Capability in Advanced Manufacturing

The coronavirus pandemic has exposed the gaps in Australia's manufacturing sector and laid bare the need to improve supply chain security to mitigate against future disruption, particularly with respect to items deemed to be essential items under WHO guidelines. Sovereign capability in the manufacturing of essential items can be achieved through the use of existing mechanisms for the purchase of Australian goods. An example of this would be to replenish the National Medical Stockpile with a portion of items manufactured locally. Further health system reform through the National Health Reform Agreement can also underscore the value of procurement policies to encourage local capability. This links to policies to encourage overall growth in the medical device industry and advanced manufacturing, discussed further below.

MTAA recommends government replenish and further build the National Medical Stockpile with a portion of locally manufactured essential items.

Private Health Insurance

Australia's private health insurance system is under strain. Despite government efforts to encourage more Australians to take up private health insurance, rising premiums and policy changes have driven the proportion of people with hospital coverage to 11-year lows. With only 44.6% of Australians covered by private health insurance hospital cover policies as of December 2018, and a faster decline in the participation by the young and healthy, the system is in need of reform. Unless private health insurance improves, Australia risks overburdening its public healthcare system, putting the quality of patient care at risk.

Challenges with private health insurance are not new. The 1997 Industry Commission[7] (the precursor to the Productivity Commission) noted: "We observe that large numbers of people are relinquishing private insurance, that the shrinking pool of the insured tends to be older and higher users of health services". The question for young people investigating the value of private health insurance remains the same.

If private health insurers are able to make cost savings that are reflected in a decrease in premiums this may reverse the flow of people, particularly the young, leaving private health insurance and thus stop the so-called "death spiral" currently facing the industry.

Review of Private Health System

Australia's healthcare ecosystem relies upon a balance of public and private healthcare. Beyond this, Australia's private health insurance system also relies on a balance. The young and healthy balance the cost of the old and sick through paying equal premiums. This is a simple notion that has ensured all Australians have access to a world-class health system.

Unfortunately, this system is out of balance; over the past two years approximately 127,000 young people aged 20-34 have moved off private health insurance. Compounding this is the fact they have been replaced by 107,000 more people aged between 70 and 84. APRA estimates a further 345,000 young people will drop private health insurance by 2025.

Beyond the challenges created by an exodus of young people whilst the elderly are joining, private health funds are also expected to act like other investment vehicles, turning a profit, providing perks and bonuses to executives, hospitality and security to investors, and engaging in extensive promotion. This is placing immense pressure on fund management to find savings on the other side of their business, delivering health benifits, whilst also creating further push factors for young Australians.

In 2001 HIH was placed into provisional liquidation, making it, to-date, the largest corporate collapse in Australia's history, with liquidators estimating HIH's losses totalling up to A$5.3 billion. The subsequent Royal Commission recognised APRA had not recognised the trouble the large insurer was facing until too late. In a frightening comparison, APRA has begun calling for a major independent review of private health insurance, with nothing left off the table to ensure that the entire industry and all stakeholders can work towards a solution; a solution that would secure the ongoing role of private health insurance in the Australian healthcare system. Startlingly APRA board member Geoff Summerhayes has surmised that with the challenges faced by private health "only three private health insurers will still have a sustainable business model by 2022."

[7] https://www.pc.gov.au/__data/assets/pdf_file/0006/156678/57privatehealth.pdf

The MedTech Industry stands resolutely with Government and is continuing to work with Minister Hunt to do our part. To date, we have agreed upon a deal that saves Australians $1.1 billion by reducing the cost of items on the PL. Unfortunately, despite claims from some pundits, reducing the cost of medical devices alone will not be nearly sufficient as prostheses represent a decreasing percentage of private health insurance benefits paid.

It is clear that a review of the broader private health ecosystem is needed urgently to stop and reverse what experts believe to be a death spiral.

MTAA endorses the solutions recently proposed by the AMA[8] which closely align with proposals already laid out by the 2019 report by AlphaBeta commissioned by MTAA. These include mechanisms to further incentivise the young to join and remain in private health insurance, and mandatory benefit payment targets for private health insurance.

MTAA recommends conducting an independent review into private health insurance.

Prosthesis List

Despite the claims of some, medical devices have not been a key driver of growing costs and will continue to play a minor role in the cost landscape. In fact, since enrolment in private health insurance began to persistently decline in June 2015, the Prostheses List as a percentage of hospital benefits paid has fallen from from 14.6% to 13.7%[9] in March 2020. Therefore, it cannot be the cause of the present challenges of health insurance. The MTAA's Agreement with the Government to reduce benefits on the Prostheses List is well on its way to delivering the $1.1 billion in savings outlined in the Agreement. This included a significant benefit reduction for many items on the list from 1 February 2020. No further changes are needed to deliver savings during the term of the Agreement, and the MedTech industry needs consistency from the Government through close adherence to the Agreement.

The Prosthesis List was created to ensure surgeons had the ability to choose the device that is best suited to a patient's medical need. If these protections are not provided, and choice is restricted, then both surgeons and their patients will increasingly question the value of holding private health insurance. Calls by Private Healthcare Australia and others to remove the Prostheses List risks directly undermining patient interests for the sake of profit skimming by insurers.

There is an existing process under the Agreement with the Government to deliver reforms to the Prostheses List from 2022. MTAA is committed to genuine engagement in this process.

There is still need for improvement in Prostheses List processes. Implementation of a fit-for-purpose HTA process for Prostheses List applications (i.e. for setting benefits) that recognise innovation appropriately can ensure ongoing value for money through the Prostheses List. However, the application of HTA should not undermine the intent of the Prostheses List or the value proposition of private health insurance. HTA principles used for other schemes such as the PBS and MBS need to be

8 https://ama.com.au/system/tdf/documents/FINAL%20Prescription%20for%20Private%20Health%20Insurance.pdf?file=1&type=node&id=52388

9 https://www.alphabeta.com/our-research/keeping-premiums-low-towards-a-sustainable-private-healthcare-system/

applied with caution, as there are differences in the objectives of these schemes and those of PHI, as well as prostheses and the prostheses marketplace compared to pharmaceuticals for example.

Prostheses markets frequently operate with short innovation cycles, resulting in reduced opportunities to generate extensive evidence; therefore it is important not to create hurdles that make it more difficult for innovation to be recognised. The Government should engage further on improving these processes and ensure the Department of Health is properly resourced to do so.

MTAA recommends The Agreement between the MedTech industry and Government be honoured in full.

Home and Community Care

Care in the community is a solution that not only can significantly reduce admission costs while also promoting better patient outcomes but is also scalable. Hospital in the Home (HITH) programs have been widely adopted by Australian public hospitals, as well as by health systems overseas. There are a range of conditions that may be treated from the comfort of a patient's home that present a material admission burden to the private health system.

By moving 10% of hospital admissions for conditions that are suited to home and community care programs into private patients' homes, private health insurers could save $8 million by FY2022. Transitioning some patients from the hospital to the home earlier for rehabilitation, not only has been proven to deliver better patient outcomes but will deliver savings. Transitioning 10% of relevant separations by FY2022 would save insurers $15 million. The potential for home-based rehabilitation for some categories of total knee arthroplasty (e.g. uncomplicated) instead of inpatient rehabilitation is an important example of this sort of opportunity.

MTAA recommends investigating the above budgetary measures as well as:

- *Expanding private health insurance coverage to include additional home and community based therapies in order to provide private patients with a choice of therapy that is clinically equivalent to in-centre therapies, improves the value of private health insurance, provides a better quality of life and is cost saving to the health system;*
- *Ensuring patients have access to information regarding the option of home and community based therapies and the benefits they provide;*
- *Expanding and reviewing the list of approved 'hospital substitute' treatments accessible through private healthcare to ensure that it is aligned with contemporary clinical practice in home based care; and*
- *Consider the expansion of acute and chronic home-based care alternatives as an option for treating patients in a lower risk environment during COVID-19.*

Advanced Manufacturing

With the right policy settings, Australia is positioned to emerge from COVID-19 as a leader in global MedTech manufacturing. Unlike many competitors, Australian manufacturing is seen as reliable, high-quality, and, with the recent pandemic, safe. In 2019 Australia exported $450 million worth of medical devices and diagnostic products to the US alone[10].

Cost of Energy

High energy costs are holding Australian MedTech manufacturers from reaching their potential. Without a stable energy market, industry can not fully invest in advanced manufacturing in Australia. From 2016 – 2019 the spot price of gas rose from ~$4/GJ to almost $12/GJ. This led manufacturers who were using gas-powered Tri-Gen plants (Trigeneration is where a single fuel source is used to generate electricity and thermal energy for both heating and cooling) as an alternative to applying stress to the grid to consider moving back to grid supplied power, further stressing the grids in metropolitan areas. During the COVID-19 pandemic, prices have reverted to 2016 levels, however it is likely this will rise again once global demand for gas recovers forcing manufacturers to reconsider their use of off-grid electricity.

MTAA recommends that Government develop an overarching policy encompassing electricity and gas, with an aim to provide long term certainty and lower energy costs. Australia should strongly consider increasing generation capacity to cover the shortfall and subsequent demand created through the closure of older generation facilities. In doing so, MTAA believes that no options be considered 'off the table', although factors such as price (both in development and operations), sustainability, emissions, and location need to be considered.

MTAA recommends that Government develop an all inclusive energy policy with a particular focus on the needs of manufacturing with an aim to provide long term certainty and lower energy costs.

Research and Development

For the past decade, gross R&D investment in Australia has been in decline, sitting at 1.88%, this is below the OECD average of 2.38%.

Australia is poised to be positioned as a global hub for Research and Development (R&D). The comparatively low impact of COVID-19, combined with a highly skilled and well-educated workforce means Australia has all the building blocks to be an attractive location for R&D. The growth of local R&D has a double effect on the Australian economy. Not only does it create further research leading to better health outcomes, but it also provides more high-skilled jobs. Therefore, growing R&D should form a key part of the Government's COVID-19 recovery strategy.

Currently, Australia is working well to assign early-stage R&D support, but support for innovation significantly drops off when products are reaching the commercialisation phase. Ensuring support for R&D throughout the commercialisation phase will lead to the further growth of the local industry, make Australia a more attractive location for R&D and create additional high-skilled jobs and better health outcomes for all Australians.

[10] https://www.dfat.gov.au/about-us/publications/Pages/trade-statistical-pivot-tables

A significant number of companies that are at the commercialisation stage have indicated that rather than invest in R&D through incentives and grants, as is preferable in early-stage R&D, a shift towards issuing purchase orders, by government procurement agencies for specific high-need equipment would not only provide the final funding to take research into production but also act as a show of support for Australian innovations. Since states are among the largest purchasers of medical equipment, this could potentially be considered as part of national health reform as well as industry policy. Companies at this final hurdle are not looking for the regulatory burden of additional prescriptive grant funding but rather the commercial freedom to use the same amount of money with the same freedoms afforded to any other government purchase order.

Local R&D will be significantly hampered by proposed changes to the R&D tax incentive (R&DTI). The R&DTI changes, through the intensity measure, will disincentivises large companies who will be punished for their size, suffering a reduced R&DTI. This is as a result of the proposed inclusion of expenditure on manufacturing in Australia as part of the calculation of 'size'. As such, companies will be incentivised to either reduce their manufacturing in Australia so their R&D expenditure forms a higher percentage of expense or to shift either their R&D or manufacturing activity overseas.

MTAA recommends investing in R&D as a key part of the Government's COVID-19 recovery strategy. In particular, MTAA recommends:

- *Strengthening support through the full R&D pathway from preliminary research up to and throughout the commercialisation phase;*
- *Investing in final stage R&D through purchase orders rather than grants of equal value; and*
- *Make no amendments to the R&DTI to ensure companies are not incentivised to offshore either their R&D or their manufacturing.*

Clinical Trials

Clinical trials are an integral part of the research and development of new treatments, interventions or tests, and the refinement of existing standards of care and clinical practices. As such, they are vital to the future of global healthcare.

The MedTech industry faces many obstacles in conducting clinical trials in Australia; including protracted start-up times, excessive bureaucracy which provides no extra value and inconsistent requirements across state and territory health departments. MTAA wants to ensure the benefits of modern, innovative and reliable MedTech are delivered effectively to provide better health outcomes to the Australian community.

This can be achieved through the acceleration of the Government's Clinical Trials 'One-Stop-Shop' and 'Front Door' policy initiatives, that are currently being finalised. Not only will these policies contribute to economic growth in a COVID-19 recovery environment, including by attracting overseas investment, but, more importantly, also lead to better health outcomes.

MTAA recommends the acceleration of the Government's Clinical Trials 'One-Stop-Shop' and 'Front Door' policy initiatives.

Tax Reform

Tax reform is needed if MedTech is to reach its potential in Australia. Australia's corporate tax rate, especially for large employers is disincentivising businesses to operate in Australia. Lowering Australia's corporate tax rate to closer to the OECD average of 23.59% would be a major incentive that would attract substantially attracting more investment into Australia.

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.*

.

Therapeutic Goods Administrations Systems

The TGA's IT system is based on an IBM Lotus Notes platform from 1998 and is no longer adequate to properly ensure patient safety. It is therefore critical that TGA's cash reserves are invested in TGA's digital transformation to ensure that TGA can fulfil its role, including performing activities such as:

- Applications tracking, status transparency (important for streamlining resource usage and efficiency);
- Ability to provide information in a usable format (e.g. TGA KPIs, post-market product recalls); and
- Better ability to search and link various TGA databases (ARTG, IRIS, DEAN) .

The TGA and the MedTech industry interactions using IT systems are high-frequency. Poor IT systems hamper the interactions between the MedTech industry and the TGA, creating additional regulatory

burdens, increasing cost and time, and disrupting business focus - all of which the Government is committed to alleviating. TGA also works with many other agencies and stakeholders who need to be able to access TGA systems in a timely and efficient way.

The ability to search databases with reporting capabilities is critical for enabling timely intervention in the interest of patient safety. Additionally, old IT systems are more vulnerable to cyber threats. TGA manages information about therapeutic goods that is essential for the reliable functioning of the healthcare system. This information must be accurate, reliable, and secure at all times.

TGA obtains fees from Industry as a cost-recovery administration model. As a result of recruitment restraints in past years, MTAA believes the TGA reserve funds have accumulated up to around $20 million. This is not taxpayer funds, but money accumulated from Industry fees. If these reserve funds – essentially Industry money - are released, this would be enough to fund the necessary TGA IT system upgrade as well as the future Unique Device Indentification data program. With the European Union Medical Device Regulation (EU-MDR) changes arriving, this has never been a more critical requirement.

An upgraded system would:

1. Increase patient safety with earlier and wider detection of safety signals, including links with patient implant cards and patient information leaflets;
2. Speed up robust scrutiny of innovative products, decreasing the regulatory burden and improving timely patient access to assessed technologies;
3. Avoid cybersecurity issues exposing commercial and patient privacy information; and
4. Save ongoing health system costs based on the above, as well as the extra resources currently required for this outdated IT infrastructure.

MTAA recommends TGA reserve funds be allocated towards an upgrade of IT systems and associated digital infrastructure.

PPE access for Private Hospitals

Through correspondence with the Minister for Health's office MTAA, Australian Private Hospitals Association, and Catholic Health Australia have been advised: "the [National Medical Stockpile (NMS)] will consider requests from private hospitals in an outbreak situation" under several conditions. The details of these conditions can be found in the letter signed by the Minister for Health, Ref No: MC20-018154.

MTAA recommends the Government should ensure the NMS is maintained at a capacity capable of servicing private hospitals for the event that a COVID-19 outbreak occurs in one of their facilities.

Digital Health

Digital healthcare is a growing part of the medical and health sector. It provides exciting opportunities, with timely, accurate communication that breaks physical barriers and increases the efficacy of clinical diagnostics and treatment. COVID-19 has demonstrated the critical need for healthcare apps and telehealth; further, consumers are demanding wearable devices to improve and monitor their health. These digital health tools are just a few of many, which offer ways to manage infectious disease outbreaks and reduce the burden of chronic disease.

MTAA foresees this being an area worthy of much future consideration for investment by the Commonwealth. Specifically, clearer reimbursement pathways are needed for many innovative technologies that do not meet traditional definitions.

Artificial Intelligence

Artificial intellifence (AI) is playing an increasing role in our daily lives for the past decade. In health, its use is growing rapidly, particularly in the diagnostics and devices space. In the future, MTAA foresees AI assisting human judgement, aiding clinical decision making and increasing the efficacy of care. The overall impact of this will be better health outcomes for all Australians.

The Australian Government should examine ways to take advantage of AI to improve healthcare on a holistic basis. MTAA would welcome engagement on this topic. Further Information.

MTAA represents:

- 3M Healthcare Pty Ltd
- 3DMEDiTech Pty Ltd
- 3DMorphic Pty Ltd
- Abbott (Vascular) Australasia
- Abbott Medical Australia Pty Ltd
- Alcon Laboratories (Australia) Pty Ltd
- Allergan Australia Pty Ltd
- AlphaXRT Ltd
- Analytica Pty Ltd
- APNE Surgical Pty Ltd
- Australasian Medical & Scientific Ltd
- Australian Dermatology Equipment Pty Ltd
- Avanos Medical
- Braun Australia Pty Ltd
- Bard Australia Pty Ltd
- Bausch & Lomb Pty Ltd
- Baxter Healthcare Pty Ltd
- Biocelect Pty Ltd
- Biotronik Australia Pty Ltd
- Boston Scientific Pty Ltd
- Brainlab Australia Pty Ltd
- BTC Health Pty Ltd
- ConMed Australia Pty Ltd
- Cook Australia Pty Ltd
- Corin (Australia) Pty Ltd
- Culpan Medical Australia Pty Ltd
- Device Technologies Australia Pty Ltd
- Edwards Lifesciences Pty Ltd
- Elekta Pty Ltd
- Exactech Australia Pty Ltd
- Fresenius Kabi Australia Pty Ltd
- Fresenius Medical Care Australia Pty Ltd
- Gamma Gurus
- Gel Works Pty Ltd
- Getz Healthcare Pty Ltd
- Grey Innovation
- Hemideina
- Hill-Rom Pty Ltd
- 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
- MaterialiseMaterialise Australia Pty Ltd
- Medacta Australia Pty Ltd
- MED-EL Pty Ltd
- Medical Specialties Australasia Pty Ltd
- Medigroup Australia Pty Ltd
- Medtronic Australasia Pty Ltd
- MicroPort CRM Pty Ltd
- MoInlycke Healthcare
- NeedleCalm Pty Ltd
- Nevro Medical Pty Ltd
- NL-Tec Pty Ltd
- Olympus Australia Pty Ltd
- Paragon Therapeutic Technologies
- Prism Surgical Designs Pty Ltd
- Roche Diabetes Care Australia 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
- Tomi Australia Pty Ltd
- Tunstall Australasia Pty Ltd
- Varian Medical Systems Pty Ltd
- Vision RT Australia Pty Ltd
- Vitalcare Pty Ltd
- W. L. Gore and Associates (Aust) Pty Ltd
- Wright Medical Australia
- Zimmer Biomet

Further detail of the savings listed above can be found here in the August 2019 AlphaBeta report *'Keeping Premiums Low: Towards a sustainable private healthcare system'.*

For all other information, please contact Edward Strong at estrong@mtaa.org.au or Paul Dale at pdale@mtaa.org.au