# STRENGTHENING HEALTH SYSTEM SUSTAINABILITY AND INNOVATION

2025 PRE-BUDGET SUBMISSION

Medical Technology Association of Australia (MTAA)

31 January 2025

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# About MTAA

## Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology (MedTech) 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 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 digital health products and services.

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 MedTech. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

## About MedTech in Australia

The MedTech industry is one of the most dynamic advanced manufacturing sectors in Australia and provides substantial health improvements and high-level employment opportunities to Australians and grows Australia's technology exports. Through innovation, this industry will continue to expand and share its discoveries with the world.

Over 2.5 million patients per year are served with lifesaving and improving medical technologies.

MedTech not only saves lives but – as demonstrated in the treatment and management of type 1 diabetes by insulin pumps and continuous glucose monitoring – its use can also significantly improve patients' quality of life.

**SAVING LIVES THROUGH EARLIER DIAGNOSIS**

**>500,000**

Every day, more than **HALF A MILLION** pathology and diagnostic services are delivered to detect and diagnose disease and chronic illness, including cancer, stroke, diabetes and CVD.[1]

MedTech plays a crucial role in treating the top five most burdensome disease groups which account for close to two-thirds of the Australia's disease burden.[i] This shows MedTech's significant contribution to not only making Australians healthier, but also to decreasing stress on the wider health system.

The MedTech industry contributes significantly to the broader Australian economy, adding $5.4 billion to Australia's GDP and supporting over 17,000 direct and 51,000 total jobs.

**51k** **SUPPORTING AUSTRALIAN JOBS:**
**MEDTECH EMPLOYS AN ESTIMATED 17,000 PEOPLE IN AUSTRALIA** and a further 34,000 people through jobs that support and supply the industry.

Australian MedTech exports $1.95 billion overseas, contributes to over 4,000 manufacturing jobs, and has been experiencing revenue and employment growth, which is projected to continue.[ii]

Despite representing a relatively small market globally, Australia ranks as a prominent developer of MedTech worldwide and, according to the Worldwide Medical Device Factbook, is 13th in terms of total market value. From the smallest sutures and neurosurgical coils to the largest linear accelerators, MedTech provides the platform from which healthcare is delivered.

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## Executive Summary and Key Recommendations

MTAA's pre-Budget submission outlines a series of initiatives that, if introduced, would lead to improved patient outcomes and greater opportunities for Australia's MedTech industry to support patients both in Australia and around the world. MTAA invites government to consider the below summarised key recommendations which are further detailed in the body of this submission.

### High Priority Recommendations:

| | |
|---|---|
| Key Recommendation 1 | Guarantee patient access and clinical choice via retention of a price-stable Prescribed List (PL) that facilitates the entry of new technology. |
| Key Recommendation 2 | Develop a digital health reimbursement scheme. |
| Key Recommendation 3 | Establish a Department of Health and Aged Care MedTech Service Charter, covering TGA, MSAC and MDHTAC. |

### Additional Recommendations:

| | |
|---|---|
| Key Recommendation 4 | Establish a Centre for Precision Medicine and Rare Diseases. |
| Key Recommendation 5 | Make Australia a destination for global clinical trials. |
| Key Recommendation 6 | Strengthen support for Australian MedTech start-ups and small businesses. |
| Key Recommendation 7 | Elevate patient input in health technology assessments (HTA). |
| Key Recommendation 8 | Expand domestic manufacturing and digital health infrastructure. |

MTAA thanks the Government for the opportunity to contribute to the 2025-26 Budget and looks forward to further collaboration regarding MTAA's key recommendations.

# High Priority – Key Recommendation 1 – Guarantee Patient Access and Clinical Choice by Retaining Price-Stable PL That Facilitates the Entry of New Technology

## Problem

The Prescribed List of Medical Devices and Human Tissue Products (PL) is still the only feasible mechanism to guarantee patient access and clinical choice of life-changing and life-saving medical technologies for privately insured policy holders in Australia.

Further major ad hoc change to the PL risks reducing access to innovative technologies and undermining affordability in the private health sector. Patients may lose timely access to life-saving devices, and industry sustainability is at stake.

## Recommendation

1. Maintain price and policy stability and clinical choice by preserving a transparent and robust PL framework.
2. Ensure continued funding for essential devices, such as cardiac implantable devices, to safeguard patient outcomes.
3. $2.1 million p.a. ongoing funding to support management of the Prescribed List (as stated in Budget 2021-22) recognising that the PL benefits a wide set of stakeholders beyond industry.

## Impact

Protects patient access to advanced medical devices, ensures clinical best practices, supports the sustainability of private healthcare and encourages entry of new technology to Australia.

# High Priority – Key Recommendation 2 - Develop a Digital Health Reimbursement Scheme

## Problem

Australia lacks a formal reimbursement pathway for digital health technologies, such as digital therapeutics, remote patient monitoring, wearables, AI-driven diagnostic tools and some forms of telemedicine.

Digital technologies are underused in Australian healthcare because the already stressed budgets of primary care practices, public and private hospitals, and aged care facilities cannot justify the investment without some form of federal or state subsidy for that investment.

These innovations can dramatically improve patient outcomes, reduce the burden on healthcare infrastructure, improve workforce productivity, and address access issues in rural and underserved areas. However, Australia's current healthcare reimbursement system is ill-equipped to handle the complexity and rapid evolution of these technologies.

## Recommendation

1. Allocate $20 million over four years to scope and establish a comprehensive Digital Health Reimbursement Scheme.
2. Conduct targeted consultations to ensure alignment with global best practices and address the unique needs of Australia's healthcare system.
3. Ensure the reimbursement scheme includes:
    o **Fair Valuation of Digital Health Solutions:** Many digital health technologies offer long-term cost savings, but their upfront costs can be high. A reimbursement model should factor in these savings over time and provide adequate compensation to technology developers and providers.
    o **Adoption of New Metrics:** Traditional reimbursement models are based on face-to-face interactions and physical treatments. Digital health requires the adoption of new metrics for evaluating effectiveness, such as patient engagement, adherence to digital therapeutic protocols, and remote monitoring outcomes. As digital technologies are scalable (i.e., face lower costs for servicing additional patients over time) the investment case is stronger than for many current services or technologies.
    o **Support for Small Innovators:** Many digital health solutions are developed by Australian start-ups or smaller companies calibrated to work in a local context. A reimbursement process

should include mechanisms to help local innovators navigate the complex healthcare system and access funding opportunities for piloting and scaling their technologies.

## Impact

Accelerates the adoption of digital health innovations, enhances care delivery, and positions Australia as a leader in digital health. Improving patient outcomes and reducing costs by increasing the availability of relevant information, allowing better diagnosis, treatment and care.

## High Priority – Key Recommendation 3 - Establish a Department of Health and Aged Care MedTech Service Charter Covering TGA, MSAC and MDHTAC

### Problem

Operational inefficiencies delay the introduction of innovative medical technologies, limiting patient access and stalling industry growth.

The Department of Finance's Regulatory Policy, Practice and Performance Framework implementing the *Public Governance, Performance and Accountability Act of 2013* sets out the expectation that "*regulatory processes are timely and transparent and that customer expectations are managed through service charters*". To date, no Department of Health and Aged Care regulatory process involving private sector stakeholders appears to be managed through a Service Charter.

A Service Charter would address several key issues:

1. **Clear Timelines and Expectations:** The MedTech industry often faces unexplained delays in regulatory or reimbursement approval, which can hinder the introduction of new technologies for the benefit of Australian patients and the productivity of the health care system. The charter would establish specific timelines for each stage of the approval process, helping companies plan more effectively, reducing delays in getting devices to market, and creating accountability for regulator behaviour.

2. **Transparent Communication:** The charter would include provisions for regular updates and communication between the Department and industry stakeholders. This would foster a more collaborative approach to engagement under cost-recovered processes, ensuring that issues are addressed promptly, and that regulatory changes or requirements are communicated clearly and well in advance.

3. **Accountability and Support:** By establishing service standards, the charter would ensure that the Department is held accountable for meeting the needs of the health care system through timely availability of new technologies, particularly in areas like the MBS reimbursement processes, device listing on the PL, and regulatory compliance. It would also outline pathways for industry to raise concerns and receive support when facing challenges with the system.

### Recommendation

1. Create a MedTech Service Charter to:

  o Streamline timelines and establish clear service standards and accountability for regulatory processes.

  o Enhance transparency, collaboration and between industry and government agencies.

### Impact

Reduces delays, improves patient access to innovations, and fosters stronger partnerships between stakeholders.

# Key Recommendation 4 – Establish a Centre for Precision Medicine and Rare Diseases

## Problem

Australians with rare diseases face long delays in accessing novel therapies, partly due to limited evaluation capacity within government agencies.

The House of Representatives Standing Committee in Health, Aged Care and Sport's Inquiry into approval processes for new drugs and novel medical technologies in Australia recommended the creation of a Centre for Precision Medicine and Rare Diseases.

This recommendation was made to overcome the Department of Health and Aged Care's gap in capacity and expertise, causing delays in patient access to new drugs and novel medical technologies, including for rare diseases.

The Federal Government has accepted this recommendation in principle; suggesting this proposal requires detailed scoping. This work has yet to begin and is critical to ensuring Australians receive the innovations they need when and where they need them.

## Recommendation

Fund a Centre for Precision Medicine and Rare Diseases to ensure the Australian Government has the expertise and capacity required to provide timely access to novel MedTech and medicines.

The Centre would include a comprehensive horizon scanning unit for new medicines and novel medical technologies to anticipate potential barriers ahead of time and provide regular advice to government on the effectiveness of Australia's Health Technology Assessment (HTA) pathways and areas for further reform.

## Impact

Improves outcomes for patients with rare conditions and fosters advanced research and innovation in Australia.

## Key Recommendation 5 – Make Australia a Destination for Global Clinical Trials

### Problem

Infrastructure limitations and regulatory hurdles reduce Australia's competitiveness in attracting clinical trials in a globally competitive market.

Decisions on where to invest in clinical trials hinges on factors such as regulation, start-up times, researcher capabilities, tax incentives and quality assurance. As The New Frontier Report noted, "*Investment capital is mobile and will move to the country best able to meet the research needs in the time available.*"[iii]

### Recommendation

Invest in clinical trial infrastructure to remove the barriers that limit clinical trial investment, including:

- Increasing capacity for Australian hospitals to conduct clinical trials incorporating recruiting and training of staff and acquiring the required technology.
- Investment in technological platforms, infrastructure, education, and training to enable multi-centre trials to become more common in Australia.
- Enhance the attractiveness of existing Research and Development (R&D) Tax Offset through increasing the offset rate for focused clinical trials activities to attract activity across pre-clinical and later stage validation studies.

### Impact

Positions Australia as a destination for clinical trials.

In addition to encouraging medical advances, clinical trials:

- Increase clinician experience with innovations and enhance the translation of evidence into local practice.
- Increase patient access to innovative MedTech and medicines.
- Deliver huge economic benefits, with active clinical trial investment estimated to be worth over $1.1 billion to the Australian economy in 2019.[iv]

## Key Recommendation 6 – Strengthen support for Australian MedTech start-ups and small businesses.

### Problem

Small MedTech companies face barriers to innovation and market entry, limiting their contribution to the healthcare ecosystem.

The MedTech industry is growing, employing thousands of workers around Australia and contributing billions to the economy. However, we can better capture the value of the MedTech industry by supporting a strong innovation ecosystem and support these companies to innovate.

Currently, the Australian Innovation Statistics (AIS) shows small firms consistently have the lowest prevalence of innovation-active firms, growing from 30.5% in 2010–11 to 39.7% in 2022–23. Yet, while there has been growth over the last decade, there has been a decline in the last five years.[v]

### Recommendation

1. Identify key regulatory, reimbursement, market access and procurement barriers and introduce targeted incentives to overcome these challenges and support to encourage innovation and development within Australian start-ups and SMEs.
2. Enhance existing Southeast Asian export market development support programs for local innovations through funding focused clinician fellowships in Australian teaching hospitals.
3. Link information systems to better focus innovation initiatives and concepts on specific high profile (cost/volume) indications.

### Impact

Drives Australia's priorities in innovation, improvements in patient outcomes, and enhances benefits to the economy.

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# Key Recommendation 7 – Elevate Patient Input in Health Technology Assessments (HTA)

## Problem

Over the past few years, the Health Technology Assessments (HTA) processes for medicines and devices have endeavoured to involve and include the opinions of patients, carers, family members and patient groups to ensure that their points of view are taken into account. There is now an increased realisation and appreciation that, beyond the scientific, public health and economic factors, the impact on those living with certain health conditions should be factored into any HTA.

The importance of including the patient voice in the assessment of health technology and devices is crucial. Whether it be via the Therapeutic Goods Administration (TGA) and their granting of market authorisation or, in the case of services and devices, The Medical Services Advisory Committee (MSAC) and the Medical Devices and Human Tissue Advisory Committee (MDHTAC) who decide on matters related to public funding and the Prescribed List, there are several opportunities for patient voices to be heard.

However, many of these opportunities are often too complicated for patients and their representatives to navigate. More work needs to be done to encourage patients and those around them to participate in the HTA process, and this is particularly important in relation to medical technology. Making the participation process more open, transparent, simple, and inclusive will help people to submit their opinions and for their voices to be heard. This not only makes inputting into the processes easier but also increases the value of their views in the decision-making process. Moreover, providing support for patients who might well be unfamiliar with the HTA process or even the technology or device itself will facilitate their inclusion and make the patients more knowledgeable and engaged.

## Recommendation

Implement the recommendations described in the Conversations for Change report from the Department for Health and Aged Care entitled 'Improving Consumer Engagement in Health Technology Assessment' as well as the 'Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment – A Report of Recommendations' from the Co-design Working Group for the HTA Enhanced Consumer Engagement Process, and ensure they are applied specifically to the assessment of medical technology, devices and services.

## Impact

Making the participation process more open, transparent, simple, and inclusive will help people to submit their opinions and for their voices to be heard. This not only makes inputting into the processes easier but also increases the value of their views in the decision-making process. Moreover, providing support for patients who might well be unfamiliar with the HTA process or even the technology or device itself will facilitate their inclusion and make the patients more knowledgeable and engaged.

## Key Recommendation 8 – Expand Domestic Manufacturing and Digital Health Infrastructure

### Problem

A high dependence on imported medical technologies threatens Australia's health security and supply chain resilience if future supply disruptions occur. This means reduced patient access across the Australian health system to critical life-saving medical technologies.

### Recommendation

1. Further Government progress implementing initiatives that will bolster Australia's local manufacturing capabilities and subsequently its supply chain resilience. These include further investment in MedTech projects through the Industry Growth Program and National Reconstruction Fund to ensure and maintain MedTech manufacturing security. Further reforms to stimulate local manufacturing include proactive reimbursement and preferential procurement initiatives.

2. Leverage the investment track record of the Medical Research Future Fund (MRFF) to analyse and communicate MedTech asset class returns to educate and attract private investors as part of reforming sophisticated investor frameworks.

3. Leverage aggregate health care incidence trend data to inform focused research translation and innovation commercialisation.

### Impact

Strengthens national resilience, creates high-quality jobs, and ensures continuity of care during global supply chain disruptions.

By selectively investing in local manufacturing of key MedTech technologies here at home that are of national importance to have adequate domestic supply, Australia is better prepared to avoid certain geopolitical, trade, global health and supply-side disturbances that might affect product and service delivery.

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## Investment and Economic Impact

The recommended reforms and investments are projected to:

1. Enhance healthcare system efficiency and generate savings for health budgets across Australia.

2. Generate high-value employment opportunities in R&D, manufacturing and supply chain which are areas of national importance to protect critical supply chains.

3. Support Australia's GDP growth through increased MedTech exports and innovation.

4. Maintain Australia's standing globally in delivering in a health system that is high quality and upholds equitable access to healthcare

5. Bolster other government initiatives such as the Federal Government's National One Stop Shop.

6. Provide funding support to analysis and communication of medical technology investment returns and trends based on the MRFF's track record.

## Conclusion

MTAA's 2025 Pre-Budget Submission provides a roadmap to strengthen Australia's healthcare system through strategic investments and reforms. We look forward to working with the government to achieve these shared goals.

## Endnotes:

i Australian Burden of Disease Study 2022: https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2022/contents/about
ii The Value of MedTech Report 2023: https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/the_value_of_medtech_report.pdf pg. 68.
iii House of Representatives Standing Committee on Health, Aged Care and Sport. The New Frontier - Delivering better health for all Australians. Accessed at The New Frontier - Delivering better health for all Australians [Jan 2025], page 241.
iv House of Representatives Standing Committee on Health, Aged Care and Sport. The New Frontier - Delivering better health for all Australians. Accessed at The New Frontier - Delivering better health for all Australians [Dec 2024].
v Office of the Chief Economist. Australian Innovation Statistics 2024 Accessed at www.industry.gov.au/publications/australian-innovation-statistics#:~:text=The%20Australian%20Innovation%20Statistics%20(AIS,of%20the%20Australian%20innovation%20system [Dec 2024]