Submission to the Senate Select Committee on Women's Health

October 2026

Medical Technology Association of Australia (MTAA)

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Executive Summary

The MTAA welcomes the opportunity to make a submission to the Select Committee on Women's Health.

Closing the women's health gap presents an opportunity to improve health outcomes and strengthen Australian medical technology (MedTech) innovation. Medical technologies can support women across the life course through earlier diagnosis, effective treatment, rehabilitation and more accessible care.

MTAA proposes five complementary recommendations spanning research and evidence, regulatory prioritisation, sustainable digital health funding, commercialisation, and collaborative policy development. The table below summarises the detailed proposed government actions.

Summary of Recommendations

Recommendation	Rationale	Proposed Action	Relevant Terms of Reference
1. Prioritise medical technology research and innovation to improve women's healthcare	Gaps in research for conditions exclusive to women and sex-related differences in technology performance can limit the accuracy, safety and effectiveness of care.	Establish a long-term Women's Health Research and Translation Fund through existing NHMRC/MRFF frameworks, with a dedicated MedTech research stream supporting innovation for conditions affecting women exclusively and research into sex-related differences in medical technology performance and use, including the needs of female clinicians.	(h), (i), (j), (l), (m), (n)
2. Pilot an additional women's health eligibility criterion within the TGA medical device priority review pathway	Longstanding unmet women's health needs may not be adequately captured by the existing life-threatening or seriously debilitating condition threshold.	Consult on and pilot an alternative women's health eligibility consideration for significant longstanding unmet clinical needs, while retaining major clinical advantage or relevant IVD public-health benefit requirements and all safety and evidence standards; evaluate the time-limited pilot.	(i), (j), (k), (n), (p)
3. Improve access and affordability of women's healthcare through sustainable funding of digital medical technologies	Fragmented reimbursement can limit routine adoption of digital therapeutics and remote monitoring, including for pregnancy, postpartum care and rehabilitation.	Reform existing funding to cover technology and associated clinical services (including Medicare/bundled funding), enable proportionate HTA and provisional reimbursement with evidence generation, and coordinate Commonwealth/state/territory funding.	(c), (d), (g), (p)
4. Prioritise the commercialisation of women's health medical technologies within existing national programs	Promising innovations require capital and expertise for clinical validation, regulatory readiness, manufacturing and market entry.	Recognise women's health MedTech commercialisation within relevant existing Commonwealth programs, subject to program mandates; support development, collaboration and private co-investment, and monitor outcomes, without a new institution or dedicated funding allocation.	(p)
5. Support collaboration to advance women's health medical technology priorities	Progress across research, regulation, commercialisation, reimbursement and delivery depends on diverse stakeholders developing workable solutions together.	Formally recognise and actively engage with the multi-stakeholder Women's Health MedTech Policy Working Group facilitated by MTAA; facilitate relevant agency participation and collaborate on a focused, outcomes-oriented work program.	(g), (h), (n), (o), (p)

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About MTAA

The Medical Technology Association of Australia (MTAA) is the peak 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's membership spans Australian start-ups through to global MedTech leaders. Our members develop, manufacture and supply medical technologies 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, to high technology implantable devices such as pacemakers, defibrillators, and orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines, as well as digital health technologies such as remote monitoring devices and digital therapeutics.

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

Closing the Women's Health Gap – The Opportunity for Medical Technology

Gaps in research, diagnosis, treatment and access to appropriate care continue to limit improvements in women's health. Closing these gaps requires targeted action to ensure that healthcare responds to women's needs across the life course[1,2]. Closing the women's health gap represents a significant opportunity to improve the health and wellbeing of Australian women while delivering broader economic and societal benefits. Despite living longer than men, women spend more time in poor health. Research by the World Economic Forum and McKinsey Health Institute estimates that women globally spend approximately 25% more time in poor health than men[1].

Women's health encompasses conditions affecting women exclusively, disproportionately or differently across the whole life course, including adolescence, reproductive years, pregnancy and postpartum recovery, menopause and later life. Advances in diagnostics, medical devices, minimally invasive treatments, remote monitoring and digital health can support earlier diagnosis, more effective treatment and more equitable access to care.

The Committee's Terms of Reference highlight several areas where medical technology has a direct role. In pregnancy and postpartum care, diagnostic and monitoring technologies can support identification and management of complications, while rehabilitation technologies can assist women experiencing pelvic health conditions following childbirth. For women living with recurrent, severe or persistent pain, including endometriosis, advances in diagnostic and treatment technologies offer opportunities to improve timely diagnosis and care. Medical technologies are also integral to fertility investigations and assisted reproduction, where access, affordability and clinical effectiveness are important considerations[3].

The Committee's examination of medical device regulation, risk assessment, monitoring and reporting is particularly relevant to MTAA. The experience of transvaginal surgical mesh underscored the importance of learning from past harms and ensuring robust clinical evidence, appropriate regulatory oversight, transparent reporting and effective post-market monitoring. Comprehensive regulatory reforms were undertaken in response, including the TGA's Action Plan for Medical Devices which addressed key issues identified through the inquiry process and strengthened safeguard.

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[1] World Economic Forum and McKinsey Health Institute. Closing the Women's Health Gap: A $1 Trillion Opportunity to Improve Lives and Economies. 2024

[2] Australian Government Department of Health. National Women's Health Strategy 2020–2030. 2019

[3] Parliament of Australia. Senate Select Committee on Women's Health — Terms of Reference

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These safeguards are essential to protecting patients and maintaining confidence in device safety and effectiveness[4].

Realising the potential of medical technology to improve women's health, while ensuring its safety and effectiveness, requires coordinated action across the pathway from research and development through regulatory assessment, commercialisation, funding and clinical adoption. Building on the National Women's Health Strategy 2020–2030[2], Australia can take targeted action at each stage to support better health outcomes and more equitable access to care.

MTAA's five recommendations address these interconnected challenges by strengthening medical technology research and sex-specific evidence; piloting an additional women's health eligibility criterion within the TGA priority review pathway; improving funding for digital medical technologies; supporting commercialisation within existing national programs; and bringing stakeholders together to develop practical policy solutions.

Recommendation 1: Prioritise medical technology research and innovation to improve women's healthcare

The need for targeted medical technology research

Women and men can differ in their anatomy, physiology and the way certain diseases and health conditions present, progress and respond to treatment. These differences have important implications for medical technology research, both in developing technologies that address health conditions specific to women and in ensuring that technologies used for conditions affecting both sexes are appropriately designed and evaluated for women.

Medical technologies include diagnostic tests, medical devices and technologies used to monitor or treat health conditions. Research has an important role in advancing technologies for conditions specific to women and ensuring that technologies used for conditions affecting both sexes work appropriately for women. This research should also consider women as clinicians, including how the design and use of medical technologies can support their safety, physical needs and effective delivery of care.

MTAA identifies two distinct research priorities:

1. **Medical technology innovation for conditions that affect women exclusively:** Supporting continued innovation in diagnostic, monitoring and treatment technologies for conditions associated with female reproductive anatomy, pregnancy, childbirth and postpartum recovery to improve health outcomes and expand care options for women.
2. **Research into sex-related differences in medical technology performance and use:** Understanding how biological differences between women and men affect the accuracy, safety and effectiveness of technologies used for conditions affecting both sexes, and how technology design and use can accommodate the needs of female clinicians.

1. Medical technology innovation for conditions exclusive to women

Conditions associated with female reproductive anatomy, pregnancy and childbirth present specific healthcare challenges. Addressing unmet needs in endometriosis, postpartum recovery and female reproductive health requires continued research into technologies for earlier diagnosis, treatment and monitoring.

[4] Therapeutic Goods Administration. An Action Plan for Medical Devices. 2019

Endometriosis

Endometriosis is a chronic condition in which tissue similar to the lining of the uterus grows outside the uterus. It can cause severe pelvic pain, affect fertility and significantly disrupt education, employment and everyday activities.

The Australian Institute of Health and Welfare (AIHW) reports that approximately one in seven Australian women born between 1973 and 1978 were estimated to have been diagnosed with endometriosis by age 44–49 [5].

Although imaging and clinical diagnostic approaches have improved, diagnosing endometriosis can remain challenging, contributing to delays in women receiving appropriate care.

Examples of the research this recommendation seeks to support include the development and validation of blood-based biomarkers and advances in imaging for endometriosis. Researchers have evaluated blood-based biomarkers for their ability to detect endometriosis and investigated AI-assisted analysis of ultrasound and MRI to improve identification of endometriosis-related changes. These studies illustrate opportunities for diagnostic innovation, while also highlighting the need for further research and clinical validation to establish accuracy and clinical usefulness [6,7].

Pregnancy and postpartum healthcare

Pregnancy-related complications can have significant consequences for maternal and fetal health. Following childbirth, some women experience ongoing problems, including pelvic floor dysfunction, urinary incontinence and postnatal depression. Medical technologies and digital health interventions are already helping address some of these needs.

Australian company and MTAA member Stratos MedTech has developed PeriCoach, a pelvic floor rehabilitation device that combines a sensor with a smartphone application to guide exercises and provide feedback. It enables women to undertake guided pelvic floor training at home and monitor their progress [8].

Digital interventions also offer opportunities to support postnatal mental health. MumMoodBooster, developed by the Australian Parent-Infant Research Institute, is an online cognitive behavioural therapy program for women experiencing postnatal depression. An Australian randomised controlled trial found improvements in depressive symptoms, demonstrating the potential for evidence-based digital interventions to expand treatment options [9].

These examples illustrate how innovation can address both physical and mental health needs following childbirth. Further research is critical to ensure that Australia remains at the forefront of women's healthcare across maternal monitoring, rehabilitation and digital interventions, particularly for women requiring ongoing postpartum care.

Female fertility and assisted reproduction

Medical technologies are integral to investigating female fertility problems and delivering assisted reproductive treatments. These include diagnostic imaging, laboratory equipment and technologies used to assess embryos.

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[5] Australian Institute of Health and Welfare. Endometriosis. Updated 21 May 2025.

[6] Burghaus S, et al. Multicenter evaluation of blood-based biomarkers for the detection of endometriosis and adenomyosis: A prospective non-interventional study. International Journal of Gynecology & Obstetrics. 2024;164:305–314.

[7] Zhang Y, et al. Distilling Missing Modality Knowledge from Ultrasound for Endometriosis Diagnosis with Magnetic Resonance Images. 2023 IEEE 20th International Symposium on Biomedical Imaging (ISBI). 2023

[8] Stratos MedTech Pty Ltd. PeriCoach — Pelvic Floor Training Device. Therapeutic Goods Administration. Stratos MedTech Pty Ltd — Perineometer. ARTG 438491.

[9] Milgrom J, Danaher BG, Gemmill AW, et al. Internet Cognitive Behavioral Therapy for Women With Postnatal Depression: A Randomized Controlled Trial of MumMoodBooster. Journal of Medical Internet Research. 2016;18(3):e54.

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Research can improve the accuracy of fertility investigations and the safety and effectiveness of assisted reproductive procedures. It can also support the development of technologies that simplify treatment or improve efficiency.

While innovation alone cannot resolve the affordability of fertility treatment, better technologies may contribute to more effective and efficient care.

2. Research into sex-related differences in medical technology performance

The second priority concerns how sex-related differences affect the performance and use of medical technologies, both for patients receiving care and for clinicians using those technologies.

For women as patients, research has shown underrepresentation in some medical device clinical trials, particularly those involving certain high-risk devices. A 2024 systematic review published in JAMA Internal Medicine identified this problem [10]. Earlier research also found that medical device trials did not consistently analyse or report outcomes separately for women and men [11].

This matters because biological differences may affect how accurately a diagnostic test identifies a condition or how safely and effectively a medical device performs. Without appropriate research, these differences may go unrecognised.

Research should also consider women as users of medical technology in clinical practice, including female surgeons and other clinicians working in procedural settings. This includes examining whether surgical instruments and equipment adequately accommodate variation in hand size, grip strength and other physical characteristics among clinicians, and whether women are appropriately represented in usability studies. Research into these factors should assess implications for ergonomics, physical strain, occupational exposure and effective device use, informing improvements to existing technologies and the design of new ones.

Together, these areas of research can strengthen the evidence underpinning medical technology design and use, supporting technologies that meet the needs of both women receiving care and women delivering it.

Example 1: Cardiac troponin testing

When someone presents to hospital with a suspected heart attack, clinicians commonly use a blood test that measures cardiac troponin, a protein released when heart muscle is damaged. The result is compared against a diagnostic threshold to help identify possible heart muscle injury.

Research has identified differences in troponin concentrations between women and men, meaning that applying the same threshold to everyone may fail to identify some heart attacks in women.

A 2015 prospective study involving 1,126 patients found that using a high-sensitivity cardiac troponin test with sex-specific thresholds increased the proportion of women diagnosed with myocardial infarction from 11% to 22%, compared with an increase from 19% to 21% in men[12]. This is a practical example of how research into biological differences can improve the interpretation of an existing diagnostic technology.

The troponin example demonstrates that sex-related differences are relevant to diagnostic technologies already used in clinical care. Research into these differences can inform how existing tests are interpreted and used, helping clinicians recognise disease in women whose diagnosis might otherwise

[10] Karny Epstein N, Harpaz M, et al. Women's Representation in RCTs Evaluating FDA-Supervised Medical Devices: A Systematic Review. JAMA Internal Medicine. 2024;184(8):977–979.

[11] Nolan MR, Nguyen T-L. Analysis and Reporting of Sex Differences in Phase III Medical Device Clinical Trials—How Are We Doing? Journal of Women's Health. 2013;22(5):399–401.

[12] Shah ASV, Griffiths M, Lee KK, et al. High sensitivity cardiac troponin and the under-diagnosis of myocardial infarction in women: prospective cohort study. BMJ. 2015;350:g7873.

be missed. Addressing these evidence gaps is therefore a current clinical priority, while also providing knowledge to inform the design and evaluation of future technologies.

This is relevant to the Committee's examination of women's experiences seeking appropriate healthcare, including the systemic factors that may contribute to missed or delayed diagnoses.

Example 2: Radiation protection for female clinicians

Medical technology can also address the health needs of women delivering care. Female clinicians working in cardiac catheterisation and other fluoroscopy-guided laboratories experience occupational exposure to scatter radiation and the physical demands of wearing protective lead garments. These working conditions raise considerations for occupational health, including during pregnancy. An international survey of electrophysiology professionals identified orthopaedic injuries and pregnancy-related concerns, reinforcing the importance of considering women's needs in clinical working environments [13]. In addition, a 2023 Society for Cardiovascular Angiography & Interventions (SCAI) survey found that 28% of women respondents had been discouraged from working in the cath lab because of pregnancy or considering pregnancy, while 71% wanted the option to step away from the cath lab during pregnancy.(American College of Cardiology, 'Multisociety Statement Calls for Enhanced Radiation Protection in Cath Labs' (15 July 2026), reporting findings from the 2023 Society for Cardiovascular Angiography & Interventions survey.

Advances in medical technology are creating new ways to protect the clinicians who deliver care. Enhanced scatter radiation protection systems, such as EggNest™ designed to provide shielding around the patient and procedural table and reduce scatter reaching personnel positioned around the room illustrate how innovation can address occupational exposure, with particular relevance to female clinicians, including during pregnancy. Laboratory testing of EggNest™, reported by Wilson and colleagues, demonstrated an average 92% reduction in total-room scatter radiation compared with standard shielding, including an average 94% reduction at the nursing position across the imaging projections tested [14]. These findings demonstrate the potential of medical technology to improve protection across the procedural team.

This example demonstrates why medical technology research should consider women as clinicians as well as patients. Further research in clinical settings should evaluate radiation exposure, ergonomics and usability, including the needs of women planning pregnancy or working during pregnancy. Findings can inform improvements to existing protective technologies and the development and adoption of new approaches that support women's health and participation in the clinical workforce.

Building on Australia's existing research initiatives

Australia has already taken important steps to strengthen women's health research.The National Women's Health Strategy 2020–2030 recognises the importance of research and evidence in improving women's health outcomes [4].The National Health and Medical Research Council (NHMRC) and Medical Research Future Fund (MRFF) have introduced requirements for relevant grant opportunities opening from January 2026 to consider sex, gender and other relevant variables throughout the research process[15]. MTAA also welcomes the NHMRC's 2026 Reframing Women's Health targeted research initiative [16]. Existing MRFF initiatives, including the Medical Research Commercialisation initiative, support medical technology research and development [17].

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[13] Tamirisa KP, et al. Occupational Hazards in Cardiac Electrophysiology: Insights from an HRS Member Survey. Heart Rhythm. 2026;23(2):e307–e318.

[14] Wilson RF, et al. TCT-248 A New Device to Markedly Reduce Cardiac Cath Lab Radiation Levels. Journal of the American College of Cardiology. 2018;72(13 Suppl):B103. Conference abstract.

[15] National Health and Medical Research Council. Sex, gender, variations of sex characteristics and sexual orientation in the grant program.

[16] National Health and Medical Research Council. Targeted Call for Research: Reframing Women's Health 2026.

[17] Australian Government Department of Health, Disability and Ageing. Medical Research Commercialisation initiative.

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These initiatives provide an important foundation for improving women's health outcomes. However, addressing unmet needs in women's healthcare and closing the gap requires sustained research investment, including support for the development, clinical evaluation and translation of new medical technologies into clinical practice.

A long-term Women's Health Research and Translation Fund, established through existing NHMRC and MRFF frameworks, would build on these initiatives by providing a dedicated mechanism to support women's health research over time. The Fund should support collaboration between industry, researchers and clinicians to advance promising research through technology development, clinical trials and translation into healthcare.

Within this broader Fund, a dedicated medical technology research stream would provide a clear focus on two priorities: developing new and improved technologies for conditions exclusive to women and investigating sex-related differences in medical technology performance and use. The second priority would encompass both technologies used to diagnose and treat patients and the design, usability and protective functions of technologies used by female clinicians.

This approach would complement existing government research initiatives while providing sustained support for medical technology innovation that addresses unmet needs in women's healthcare.

Proposed government action

MTAA recommends that the Australian Government establish a long-term Women's Health Research and Translation Fund through existing NHMRC and MRFF frameworks, incorporating a dedicated medical technology research funding stream to address unmet needs in women's healthcare.

The Fund should prioritise research into conditions affecting women exclusively, disproportionately or differently, and support industry–research collaboration, technology development, clinical trials and the translation of research into clinical practice. Within this broader Fund, the dedicated medical technology research stream should focus on two priorities:

1. Medical technology innovation for conditions exclusive to women – Support research, development and clinical evaluation to advance innovation in diagnostic, monitoring and treatment technologies for conditions associated with female reproductive anatomy, pregnancy, childbirth and postpartum recovery, with the aim of improving health outcomes and expanding care options for women.
2. Research into sex-related differences in medical technology performance and use – Support research into how biological differences between women and men affect the accuracy, safety and effectiveness of medical technologies used for conditions affecting both sexes. Priority should be given to shared evidence gaps, including underlying biological differences, comparative performance across technologies and outcomes in routine clinical practice. Research should also address the design and use of medical technologies to accommodate the needs of female clinicians. Findings should inform clinical practice, improvements to existing technologies and the development of new ones.

Relevant Terms of Reference: (h), (i), (j), (l), (m), (n).

Recommendation 2: Pilot an additional women's health eligibility criterion within the TGA medical device priority review pathway

Building on Australia's established medical device regulatory framework

Safe and effective medical technologies are essential to improving women's health outcomes. Australia's regulatory framework plays a critical role in ensuring that medical devices meet appropriate standards of safety, performance and clinical evidence.

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The experience of transvaginal surgical mesh highlighted the importance of robust clinical evidence, effective post-market surveillance and transparent regulatory oversight. MTAA acknowledges the substantial reforms undertaken by the Therapeutic Goods Administration (TGA), including the reclassification of surgical mesh devices and implementation of the Action Plan for Medical Devices which strengthened safeguards and addressed key issues identified through the inquiry process.

MTAA supports maintaining rigorous regulatory standards while considering how existing pathways can better recognise significant unmet clinical needs.

Why women's health warrants specific consideration

The TGA's existing medical device priority review pathway facilitates earlier regulatory assessment of eligible technologies addressing life-threatening or seriously debilitating conditions. Applicants must also satisfy requirements relating to unmet need or improvements in safety or performance, and demonstrate a major clinical advantage or, for relevant in-vitro diagnostic (IVD) medical devices, a major public health benefit [18]. While these criteria provide an important mechanism for prioritising technologies with significant clinical benefits, they may not adequately recognise longstanding unmet needs in women's healthcare.

Historically, many conditions affecting women have received insufficient attention in medical research and technology development. Endometriosis is a clear example. Despite affecting a substantial proportion of Australian women, it has long been associated with diagnostic delays, limited treatment options and significant impacts on quality of life. These gaps have accumulated over many years, leaving considerable ground to make up in the development of effective diagnostic and treatment technologies.

The consequences extend beyond women's health. Conditions such as endometriosis can affect women's ability to participate in education, employment and everyday activities, with associated costs to individuals, employers, the healthcare system and the broader economy. Improving diagnosis and treatment therefore has the potential to deliver both health and economic benefits.

Yet conditions that cause persistent pain, reduced quality of life and substantial economic burden may not always meet the existing threshold of being life-threatening or seriously debilitating. This creates a potential gap in regulatory prioritisation, particularly for women's health technologies developed to address needs that have historically received insufficient attention.

MTAA considers that a targeted policy response is warranted to help address this historical imbalance. Introducing an additional women's health eligibility criterion would provide an opportunity for promising technologies to receive priority regulatory consideration based on demonstrated unmet clinical need and significant patient benefit, even where the condition does not meet the existing serious-condition threshold.

The proposal is not based on women's health needs being more important than those of other populations. Rather, it recognises a longstanding gap in medical technology innovation and seeks to help address that imbalance. A time-limited pilot would allow the TGA to evaluate this approach and consider whether similar provisions could benefit other populations experiencing significant unmet healthcare needs.

A targeted pilot within the existing priority review pathway

MTAA proposes that the TGA consider piloting an additional women's health eligibility criterion alongside the existing provision for life-threatening or seriously debilitating conditions.

[18] Therapeutic Goods Administration. Understanding priority applicant determination rules for medical devices including in-vitro diagnostics (IVDs).

The pilot would enable medical technologies addressing conditions affecting women exclusively, disproportionately or differently to be considered for priority review where there is evidence of a significant, longstanding unmet clinical need or historical gap in diagnostic or treatment innovation.

The purpose is to help address the cumulative effects of historical underinvestment by providing a more equitable opportunity for promising women's health technologies to progress through regulatory assessment.

Importantly, the proposal would not reduce the standards for safety, performance or clinical evidence, nor would a priority applicant determination constitute marketing authorisation or inclusion in the Australian Register of Therapeutic Goods (ARTG).

A time-limited pilot would allow the TGA to assess whether the additional criterion identifies technologies addressing significant unmet clinical needs that are not adequately captured by current eligibility requirements. Evaluation could consider application volumes, demonstrated clinical benefits, impacts on assessment capacity and whether a similar approach may be appropriate for other underserved populations.

International regulatory developments

International regulators are beginning to recognise that some populations have historically been underserved by medical technology innovation and that these disparities should be considered when determining which technologies receive priority regulatory attention.

In the United States, the Food and Drug Administration (FDA) operates a Breakthrough Devices Program, which provides an accelerated regulatory process for certain innovative medical devices. The program is intended to help promising technologies reach patients sooner, while maintaining the applicable safety and effectiveness requirements.

In 2023, the FDA updated its guidance to explicitly recognise health disparities when assessing whether a technology offers more effective diagnosis or treatment. For example, a new diagnostic device may offer particular benefits for women if existing diagnostic technologies are less accurate in women than in men. The FDA can take this difference into account when considering the device for its Breakthrough Devices Program[19].

Importantly, the FDA's approach does not create a separate women's health pathway, and devices must still meet the program's existing eligibility requirements, including addressing a life-threatening or irreversibly debilitating condition.

This provides a useful international precedent for recognising health disparities within regulatory prioritisation. MTAA's proposal would build on this principle by piloting an additional eligibility criterion for technologies addressing significant unmet women's health needs that may not be adequately recognised under Australia's existing priority review criteria.

A timely opportunity for regulatory reform

The TGA has advised MTAA that it intends to undertake a public consultation on the medical device priority review pathway in late 2026/early 2027. This provides a timely opportunity to consider whether the existing eligibility criteria should be expanded to explicitly recognise longstanding unmet women's health needs.

MTAA recommends that the consultation seek stakeholder views on piloting an additional women's health eligibility criterion, including its scope, evidentiary requirements, relationship to existing criteria and any legislative or administrative changes required for implementation.

[19] U.S. Food and Drug Administration. Breakthrough Devices Program: Guidance for Industry and FDA Staff. September 2023.

This would enable the proposal to be considered through the TGA's established consultation processes, with input from industry, clinicians, researchers and consumers, while maintaining the integrity of Australia's medical device regulatory framework.

Proposed government action

MTAA recommends that the Australian Government support the TGA in consulting on and piloting an expansion of a women's health eligibility criterion within the existing medical device priority review pathway.

The pilot should:

1. Recognise longstanding unmet women's health needs: Introduce an alternative eligibility consideration for technologies addressing conditions affecting women exclusively, disproportionately or differently, particularly where historical gaps in research and innovation have contributed to unmet clinical needs that may not be adequately captured by the existing serious-condition criterion.
2. Evaluate the effectiveness of the approach: Establish a time-limited pilot to assess whether the additional criterion helps address historical gaps in women's health innovation, its impact on regulatory assessment and its potential application to other populations experiencing significant unmet healthcare needs.

The proposed pilot should be considered through the TGA's forthcoming public consultation, including its scope, eligibility requirements, evidentiary standards and implementation.

Relevant Terms of Reference: (i), (j), (k), (n), (p).

Recommendation 3: Improve access and affordability of women's healthcare through sustainable funding of digital medical technologies

Digital medical technologies can improve access to women's healthcare

Access to appropriate women's healthcare should not depend on where a woman lives or her ability to travel repeatedly to specialist services.

Women in rural and regional communities can face significant geographical barriers to accessing healthcare, particularly specialist services. However, women in metropolitan areas may also experience barriers associated with healthcare costs, appointment availability, employment and caring responsibilities.

Digital therapeutics, connected medical devices and remote patient monitoring offer opportunities to address some of these barriers by enabling appropriate aspects of healthcare to be delivered in the home or community, while maintaining clinical oversight.

These technologies are particularly relevant to pregnancy and postpartum care, where ongoing monitoring, follow-up and rehabilitation may be required.

Example: Digital monitoring for gestational diabetes, Queensland

CSIRO's M♡THer platform, developed in collaboration with Queensland health services, demonstrates how digital technologies can support more accessible maternity care.

The platform enables women with gestational diabetes to record and share blood glucose readings and other health information with their clinical team. Clinicians can review this information remotely and provide advice or arrange further assessment when required.

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CSIRO reports that an initial feasibility study involving 40 women found the platform convenient and helpful for managing gestational diabetes. Clinicians reported improved communication and multidisciplinary coordination, with the platform enabling early intervention for some women with elevated blood glucose readings. A subsequent larger implementation study was initiated in Queensland.

This example demonstrates the potential for digitally supported maternity care to improve access to clinical monitoring and communication, particularly where frequent travel to healthcare services may be challenging[20].

Other opportunities in women's healthcare

Remote blood pressure monitoring offers a potential approach to postpartum follow-up for women who experience hypertensive disorders of pregnancy. It can enable clinical teams to review readings between appointments and identify when further assessment may be required.

Digital pelvic floor rehabilitation technologies may also support home-based exercises and rehabilitation, potentially improving access for women who face difficulties attending regular appointments.

These examples illustrate potential applications of digital medical technologies in women's healthcare. Their adoption should be supported by appropriate clinical evidence and safeguards, and they should complement rather than replace necessary face-to-face healthcare.

Realising these benefits also requires attention to digital inclusion. Funding and implementation arrangements should ensure that digitally enabled care does not disadvantage women who face barriers relating to connectivity, device access, digital literacy, disability, language or cultural safety. Appropriate onboarding, technical support and alternative non-digital pathways should remain available where required.

Existing reimbursement barriers can limit adoption

Despite the opportunities offered by digital medical technologies, Australia does not have a fit-for-purpose funding pathway for digital health technologies significantly limiting patient access to innovative medical technology and models of care.

MTAA's Digital Health: Breaking Barriers to Deliver Better Patient Outcomes (2023) report identified reimbursement barriers affecting the adoption of digital health technologies [21]. MTAA's subsequent report, Enabling Remote Care: Funding Pathways for Digital Therapeutics and Remote Patient Monitoring (2025), examined these challenges in greater detail and proposed methods to overcome them[22].

A key challenge in the reports was fragmented and inconsistent funding arrangements for digital therapeutics and remote patient monitoring. Existing mechanisms may fund aspects of healthcare delivery without adequately recognising the costs of the technology itself or the associated clinical services required for effective remote care.

For example, remote monitoring may involve a connected medical device, software, data transmission, patient onboarding, clinical review and follow-up. Without appropriate funding for these components, clinically effective technologies can face barriers to sustainable implementation.

MTAA's report also identifies limitations in Medicare funding for clinician review, nursing and allied health contributions, and software-based interventions. It also highlights challenges across public

[20] CSIRO. A digital platform for gestational diabetes support.

[21] Medical Technology Association of Australia. Digital Health: Breaking Barriers to Deliver Better Patient Outcomes. 2023.

[22] Medical Technology Association of Australia. Enabling Remote Care: Funding Pathways for Digital Therapeutics and Remote Patient Monitoring. October 2025.

hospitals, private healthcare and commissioned services, which can prevent proven technologies from progressing beyond isolated deployments.

These funding challenges can limit the ability of health services to offer digitally enabled care routinely, potentially perpetuating access barriers for women who could benefit from receiving appropriate care closer to home.

Applying MTAA's existing funding recommendations to women's healthcare

Implementing these reforms to funding arrangements, assessment pathways, and coordination across healthcare settings would create opportunities to improve access to women's healthcare, particularly in areas requiring ongoing monitoring, follow-up and rehabilitation.

As identified, pregnancy and postpartum care would be key beneficiaries of this improved accessibility. Women with gestational diabetes or hypertensive disorders of pregnancy may require frequent monitoring, while women recovering from childbirth may need ongoing access to rehabilitation and other services.

Appropriately funded digital technologies could support more flexible models of care, reduce unnecessary travel and facilitate timely clinical follow-up for all Australian women, particularly as access to maternity and specialist women's health services becomes increasingly challenging in rural, regional and remote communities, with maternity service closures occurring across parts of the country.

Rather than establishing a separate reimbursement system for women's health, MTAA recommends applying its existing digital health funding proposals, outlined in the below recommendation, to support equitable access to clinically effective technologies for women.

Proposed government action

MTAA recommends that the Australian Government reform existing funding and reimbursement arrangements for digital therapeutics and remote patient monitoring to improve equitable and affordable access to women's healthcare, regardless of geographical location.

Building on the funding framework proposed in MTAA's Enabling Remote Care: Funding Pathways for Digital Therapeutics and Remote Patient Monitoring (2025), the Government should:

1. Establish sustainable funding and reimbursement pathways for the complete digitally enabled model of care, recognizing both the digital medical technology and the associated clinical services, patient onboarding, monitoring, review and follow up required for safe and effective delivery. Funding arrangements should avoid covering the clinical service while excluding the enabling technology, or funding the technology without the capacity to use it effectively.
2. Introduce proportionate health technology assessment and provisional reimbursement pathways to support the evaluation and adoption of promising digital medical technologies, enabling further evidence generation and progression towards ongoing funding where clinical effectiveness and value for money are demonstrated. Evidence generation should include outcomes relevant to women and, where clinically appropriate, sex-disaggregated outcomes, patient-reported outcomes, access and adherence.
3. Improve coordination of funding across healthcare settings, including Commonwealth, state and territory arrangements, to enable clinically effective digital technologies to move beyond isolated pilots and become part of routine healthcare delivery.

Women's healthcare should be prioritised in implementing these reforms, particularly where clinically validated digital technologies can improve access to pregnancy and postpartum care, ongoing monitoring and rehabilitation, including for women in rural and regional communities. These reforms should build on existing health technology assessment and public funding arrangements and maintain appropriate standards for safety, clinical effectiveness and cost-effectiveness.

Relevant Terms of Reference: (c), (d), (g), (p).

Recommendation 4: Prioritise the commercialisation of women's health medical technologies within existing national programs

Bridging the gap between research and commercialisation

Australia has significant capabilities in medical research, clinical innovation and medical technology development. However, research discoveries do not automatically translate into commercially available technologies that improve patient care.

While increased investment in women's health research is essential, bringing promising medical technologies to market requires a different set of capabilities, funding mechanisms and commercial expertise.

Medical technology commercialisation involves product engineering, verification and validation, clinical evidence generation, regulatory preparation, quality management, manufacturing development and market access. Each stage requires specialised expertise and access to capital, often over extended development timelines.

Early-stage medical technology companies may face difficulties attracting private investment before they have generated sufficient clinical evidence and demonstrated commercial potential. These challenges can be particularly significant where technologies require lengthy clinical development, regulatory assessment and reimbursement processes before achieving widespread adoption. For

women's health, these barriers risk limiting the translation of promising innovations into technologies capable of addressing longstanding unmet clinical needs.

Commercialisation support should therefore prioritise medical technologies addressing significant unmet women's health needs, including conditions that affect women exclusively, disproportionately or differently across the life course. Relevant areas include endometriosis, maternal health, pelvic health and cardiovascular conditions. Research investment supports the discovery and development of new solutions, while commercialisation support helps promising technologies progress towards regulatory approval, manufacturing, market entry and ultimately patient access.

Building on existing Commonwealth investment mechanisms

Australia's existing medical technology development and commercialisation programs provide a foundation for further action. MTAA proposes building on these mechanisms through explicit prioritisation of significant unmet women's health needs, so that commercialisation support contributes to closing the women's health gap.

Relevant Commonwealth mechanisms include the Medical Research Future Fund's Medical Research Commercialisation initiative and the National Reconstruction Fund Corporation (NRFC)[23]. State-based initiatives, such as the NSW Medical Devices Fund, also support medical technology commercialisation.

The NSW Medical Devices Fund provides a relevant example of competitive government support for medical device commercialisation[24]. Its 2026 funding round identifies women's health as a priority area, demonstrating how women's health can be recognised within an existing medical technology funding program.

At the Commonwealth level, the Medical Research Commercialisation initiative supports the translation of health and medical research towards commercial outcomes. The NRFC provides investment financing for eligible projects within its legislative mandate, including the medical science sector. These programs provide a foundation for strengthening the commercialisation of women's health medical technologies without establishing a separate funding institution.

MTAA recommends that women's health medical technology commercialisation be formally recognised as a priority within relevant existing Commonwealth funding and investment programs, subject to their respective eligibility criteria, legislative mandates and investment requirements. This would help ensure that technologies addressing significant unmet women's health needs are explicitly considered within existing commercialisation and investment priorities.

Mobilising private investment and measuring outcomes

Government support for medical technology commercialisation should complement, rather than replace, private investment.

Research grants are important for generating knowledge and demonstrating scientific feasibility. However, progressing from a promising research outcome to a commercially viable medical technology may require sustained, risk-bearing capital to support product development, clinical validation, regulatory readiness, manufacturing and market entry.

Global investment evidence reinforces the need for targeted attention to women's health. The World Economic Forum's 2026 Women's Health Investment Outlook, developed with Boston Consulting Group, reports that women's health captured just 6% of private healthcare investment. Although this analysis

[23] National Reconstruction Fund Corporation. Investment guidance.

[24] NSW Government. Medical Devices Fund. Round 14, 2026.

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covers healthcare broadly rather than Australian medical technologies specifically, it highlights the limited share of private capital directed towards women's health[25].

MTAA therefore recommends using existing Commonwealth commercialisation mechanisms to strengthen investment readiness and encourage private co-investment in technologies addressing significant unmet women's health needs.

There is an opportunity to strengthen engagement with specialist medical technology investors, venture capital funds, angel investor networks and other investment partners to improve investment readiness and facilitate appropriate co-investment. Government support should help address commercialisation barriers and attract additional private investment in promising women's health medical technologies, while maintaining appropriate clinical, commercial and investment assessment standards.

Collaboration between medical technology companies, researchers, clinicians and investors is also important to ensure that innovations respond to genuine unmet clinical needs and have credible pathways to clinical use and commercial sustainability. Formally recognising women's health medical technology commercialisation as a priority should also be accompanied by proportionate monitoring of its implementation and outcomes.

Where practicable, existing Commonwealth program reporting arrangements could be used to identify investment commitments supporting women's health medical technologies, private-sector capital mobilised alongside Commonwealth support, and the progression of supported technologies through key commercialisation milestones.

This would provide greater visibility of investment in women's health medical technologies and help government assess whether existing programs are effectively supporting the translation of promising innovations into commercially viable products.

[25] World Economic Forum, in collaboration with Boston Consulting Group. Women's Health Investment Outlook: 6% of Funding for Nearly 50% of the Population – Not Just a Gap, but Untapped White Space. January 2026.

Proposed government action

MTAA recommends that the Australian Government formally recognise women's health medical technology commercialisation as a priority within relevant existing Commonwealth funding and investment programs, including the Medical Research Future Fund's Medical Research Commercialisation initiative and, where consistent with its investment mandate, the National Reconstruction Fund Corporation.
Specifically, the Government should:

1. Establish women's health MedTech commercialisation as an explicit program priority within relevant existing funding and investment mechanisms, encouraging applications from developers of technologies addressing significant unmet women's health needs.
2. Support the progression of promising women's health technologies towards commercialisation, using existing program mechanisms to facilitate product development, clinical validation, regulatory readiness, manufacturing preparation and market entry, consistent with each program's eligibility criteria and mandate.
3. Encourage private-sector investment and co-investment in commercially promising women's health medical technologies, including engagement with specialist investors, venture capital funds and angel investor networks, where appropriate and consistent with existing investment frameworks.
4. Strengthen collaboration between medical technology companies, researchers, clinicians and investors to identify unmet clinical needs, improve investment readiness and support the translation of promising technologies into commercially viable products.
5. Monitor and report on women's health MedTech commercialisation outcomes, using existing program reporting arrangements where practicable, including investment commitments, private capital mobilised and the progression of supported technologies towards market readiness.
6. Implementation should build on existing Commonwealth programs and relevant state-based experience, including the NSW Medical Devices Fund, without requiring a separate funding institution or dedicated new funding allocation.

Relevant Terms of Reference: (c), (d), (g), (p).

Recommendation 5: Support collaboration to advance women's health medical technology priorities

Bringing stakeholders together to translate policy priorities into practical action

Improving women's health through medical technology requires coordinated action across research, clinical practice, regulation, commercialisation, funding and healthcare delivery. The recommendations outlined in this submission demonstrate that these areas are interconnected, and that progress in one area may depend on addressing barriers in another.

Effective solutions require collaboration across the broader medical technology ecosystem, including government policymakers, regulators, industry, clinicians, researchers, healthcare providers, investors and consumers.

MTAA has demonstrated its convening capability through its Women's Health MedTech Summit in May 2026, which brought together diverse stakeholders to explore opportunities to improve women's health through medical technology.

Building on this collaboration, MTAA is establishing a Women's Health MedTech Policy Working Group as a multi-stakeholder forum facilitated by MTAA, with priorities and policy proposals developed collaboratively by participating stakeholders.

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The Working Group aims to bring together relevant expertise and perspectives to identify unmet women's health needs, examine barriers across the medical technology pathway and develop practical, evidence-informed policy solutions for government consideration.

The Working Group would provide a collaborative mechanism to help translate the recommendations in this submission into practical action. A focused work program could identify shared priorities, develop targeted policy proposals, facilitate engagement with relevant agencies and monitor progress towards agreed outcomes.

Formal government recognition and active participation would strengthen this collaboration, helping connect policy development with the agencies responsible for research, regulation, health technology assessment, funding and healthcare delivery.

The Working Group would complement existing government strategies and decision-making processes, including the National Women's Health Strategy 2020–2030, while respecting the independent responsibilities of participating organisations and government agencies.

By bringing stakeholders together in a shared forum, this approach would support the development of balanced, practical and implementable solutions to improve women's health outcomes through medical technology.

Proposed government action

MTAA recommends that the Australian Government formally recognise and actively engage with the Women's Health MedTech Policy Working Group as a multi-stakeholder forum facilitated by MTAA to advance women's health medical technology priorities.

Specifically, the Government should:

1. Provide formal recognition of the Working Group as a collaborative forum for identifying unmet women's health needs and developing practical medical technology policy proposals.
2. Facilitate participation by relevant government departments, regulators and agencies, according to the policy issues being considered, to support constructive engagement across research, regulation, commercialisation, reimbursement and healthcare delivery.
3. Collaborate with the Working Group on a focused, outcomes-oriented work program to identify priority policy challenges, develop practical solutions and support opportunities to progress the recommendations outlined in this submission.

This collaboration would draw on the collective expertise of participating stakeholders, with MTAA providing facilitation and coordination support, while maintaining the independent roles and decision-making responsibilities of government agencies.

Relevant Terms of Reference: (g), (h), (n), (o) and (p)

Conclusion

Closing the women's health gap requires sustained action to ensure that medical technologies respond to women's needs throughout their lives. This includes advancing innovation for conditions affecting women exclusively, strengthening evidence on sex-related differences, and addressing barriers that prevent safe and effective technologies from reaching women who need them.

MTAA's five recommendations set out practical actions across research, regulatory pathways, digital health funding, commercialisation and collaboration. Together, they seek to improve care available today while supporting future innovation, building on existing Australian institutions and programs and maintaining rigorous safety, performance and clinical evidence standards.

Success would mean women receiving timely and accurate diagnoses, having access to technologies supported by evidence relevant to them, and being able to obtain appropriate monitoring, treatment and rehabilitation regardless of where they live. It would also mean more promising women's health innovations progressing into clinical use, supported by public and private investment. Progress should be measured through improvements in diagnostic timeliness, access, patient-reported outcomes and the translation of research into care.

MTAA urges the Committee to support these recommendations and welcomes the opportunity to work with government, clinicians, researchers, consumers and industry to deliver measurable improvements in the health and wellbeing of Australian women.

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References

[1] World Economic Forum and McKinsey Health Institute. Closing the Women's Health Gap: A $1 Trillion Opportunity to Improve Lives and Economies. 2024. https://www.weforum.org/publications/closing-the-women-s-health-gap-a-1-trillion-opportunity-to-improve-lives-and-economies/

[2] Australian Government Department of Health. National Women's Health Strategy 2020–2030. 2019. https://www.health.gov.au/resources/publications/national-womens-health-strategy-2020-2030

[3] Parliament of Australia. Senate Select Committee on Women's Health — Terms of Reference. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Womens_Health

[4] Therapeutic Goods Administration. An Action Plan for Medical Devices. 2019. https://www.tga.gov.au/resources/publication/corporate-reports/action-plan-medical-devices

[5] Australian Institute of Health and Welfare. Endometriosis. Updated 21 May 2025. https://www.aihw.gov.au/reports/chronic-disease/endometriosis/contents/how-common-is-endometriosis

[6] Burghaus S, et al. Multicenter evaluation of blood-based biomarkers for the detection of endometriosis and adenomyosis: A prospective non-interventional study. International Journal of Gynecology & Obstetrics. 2024;164:305–314. https://doi.org/10.1002/ijgo.15062. This study found that none of the tested biomarkers could diagnose or rule out these conditions with high certainty.

[7] Zhang Y, et al. Distilling Missing Modality Knowledge from Ultrasound for Endometriosis Diagnosis with Magnetic Resonance Images. 2023 IEEE 20th International Symposium on Biomedical Imaging (ISBI). 2023. https://doi.org/10.1109/ISBI53787.2023.10230667. This study investigated an AI approach using ultrasound-derived information to improve MRI detection of a specific endometriosis-related change.

[8] Stratos MedTech Pty Ltd. PeriCoach — Pelvic Floor Training Device. https://stratosmedtech.com/products/ ; Therapeutic Goods Administration. Stratos MedTech Pty Ltd — Perineometer. ARTG 438491. https://www.tga.gov.au/resources/artg/438491

[9] Milgrom J, Danaher BG, Gemmill AW, et al. Internet Cognitive Behavioral Therapy for Women With Postnatal Depression: A Randomized Controlled Trial of MumMoodBooster. Journal of Medical Internet Research. 2016;18(3):e54. https://doi.org/10.2196/jmir.4993

[10] Karny Epstein N, Harpaz M, et al. Women's Representation in RCTs Evaluating FDA-Supervised Medical Devices: A Systematic Review. JAMA Internal Medicine. 2024;184(8):977–979. https://doi.org/10.1001/jamainternmed.2024.1011

[11] Nolan MR, Nguyen T-L. Analysis and Reporting of Sex Differences in Phase III Medical Device Clinical Trials—How Are We Doing? Journal of Women's Health. 2013;22(5):399–401. https://doi.org/10.1089/jwh.2013.4400

[12] Shah ASV, Griffiths M, Lee KK, et al. High sensitivity cardiac troponin and the under-diagnosis of myocardial infarction in women: prospective cohort study. BMJ. 2015;350:g7873. https://doi.org/10.1136/bmj.g7873

[13] Tamirisa KP, et al. Occupational Hazards in Cardiac Electrophysiology: Insights from an HRS Member Survey. Heart Rhythm. 2026;23(2):e307–e318. https://doi.org/10.1016/j.hrthm.2025.10.001

[14] Wilson RF, et al. TCT-248 A New Device to Markedly Reduce Cardiac Cath Lab Radiation Levels. Journal of the American College of Cardiology. 2018;72(13 Suppl):B103. Conference abstract. https://doi.org/10.1016/j.jacc.2018.08.1376

[15] National Health and Medical Research Council. Sex, gender, variations of sex characteristics and sexual orientation in the grant program. https://www.nhmrc.gov.au/research-policy/gender-equity/sex-gender-variations-sex-characteristics-and-sexual-orientation-grant-program

[16] National Health and Medical Research Council. Targeted Call for Research: Reframing Women's Health 2026. https://www.nhmrc.gov.au/funding/find-funding/targeted-call-research-reframing-womens-health-2026

[17] Australian Government Department of Health, Disability and Ageing. Medical Research Commercialisation initiative. https://www.health.gov.au/our-work/mrff-medical-research-commercialisation-initiative

[18] Therapeutic Goods Administration. Understanding priority applicant determination rules for medical devices including in-vitro diagnostics (IVDs). https://www.tga.gov.au/resources/guidance/understanding-priority-applicant-determination-rules-medical-devices-including-vitro-diagnostics-ivds

[19] U.S. Food and Drug Administration. Breakthrough Devices Program: Guidance for Industry and FDA Staff. September 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

[20] CSIRO. A digital platform for gestational diabetes support. https://www.csiro.au/en/research/health-medical/digital-platform-for-gestational-diabetes

[21] Medical Technology Association of Australia. Digital Health: Breaking Barriers to Deliver Better Patient Outcomes. 2023. https://www.mtaa.org.au/digital-health-report

[22] Medical Technology Association of Australia. Enabling Remote Care: Funding Pathways for Digital Therapeutics and Remote Patient Monitoring. October 2025. https://www.mtaa.org.au/sites/default/files/uploaded-content/website-content/healthconsult_mtaa_dtx_and_rpm_report_october_2025.pdf

[23] National Reconstruction Fund Corporation. Investment guidance. https://www.nrf.gov.au/what-we-do/investment-guidance

[24] NSW Government. Medical Devices Fund. Round 14, 2026. https://www.nsw.gov.au/grants-and-funding/medical-devices-fund

[25] World Economic Forum, in collaboration with Boston Consulting Group. Women's Health Investment Outlook: 6% of Funding for Nearly 50% of the Population – Not Just a Gap, but Untapped White Space. January 2026. https://www.weforum.org/publications/women-s-health-investment-outlook-2026/