

# Acknowledgement of country We acknowledge the traditional custodians of the lands on which we research and work, and we pay our respects to the Elders past, present and future. We recognise and respect their cultural heritage, beliefs and continuous relationship with the land.



### **Acknowledgements**

This report would not have been possible without the valuable contributions of our speakers, panellists, session chairs, and delegates, who generously shared their expertise, experiences, and insights throughout the 2025 Horizon Scanning Forum.

We extend our thanks to Penny Shakespeare, Deputy Secretary of the Department of Health, Disability and Ageing, for co-emceeing the Forum alongside Liz de Somer, CEO of Medicines Australia. We also extend our gratitude to Professor Dawn Craig and Dr Orin Chisholm for their insightful contributions to the event.

We are especially grateful to the patient advocates who contributed to the Forum, bringing forward the lived experience and priorities of patients. Their voices continue to remind us that patients must remain at the centre of horizon scanning and system reform.

Finally, we thank the Horizon Scanning Forum Action Group, Medicines Australia members, and the Medicines Australia team whose planning, organisation and delivery made this year's Forum a success.

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### **Foreword**

The Horizon Scanning Forum is about looking ahead – not only to the innovations that will shape the future of medicine, but also to the systems and policies that must evolve so patients can benefit from them.

Horizon scanning gives us foresight, but it is the connection to modern and adaptable regulatory and health technology assessment (HTA) reform that will turn foresight into action. A fit for purpose healthcare system with appropriate policies, processes and service delivery will ensure innovative medicines make it to the people that need them, when they need them. A recently awarded NHMRC grant to explore and build a framework for horizon scanning is only a first step and will need sustainable support if Australia is to catch up to others, where horizon scanning is a fundamental part of their system.

This year's Forum brought together government, regulators, payers, researchers, industry and patient advocacy groups to share insights and identify what must change to ensure faster and fairer access to the medicines of tomorrow. Discussions highlighted the need for regulatory and reimbursement pathways that keep pace with innovation, HTA methods that capture the true value of new therapies, and a whole-of-system approach to preparing for personalised medicine.

I extend my sincere thanks to Blair Comley PSM for his opening address, and to Penny Shakespeare, Deputy Secretary, Department of Health, Disability and Ageing, for co-emceeing the Forum. I also thank Professor Dawn Craig for her insightful keynote lecture, Dr Orin Chisholm for facilitating the panel sessions, and the many experts, patient advocates, government, regulatory and industry colleagues who contributed their time and expertise.

The 2025 Horizon Scanning Forum highlighted both the urgency and the opportunity before us. We heard of examples of innovative therapies that do not fit neatly into existing pathways. Current systems were designed for a different era and are struggling to keep pace. Reform is needed, not only to modernise regulatory and reimbursement processes, but to ensure they remain equitable, transparent and sustainable for the long term.

A clear message across the Forum was that patients must remain at the heart of this process. People are the reason we are here, and patient voices must be formally embedded into horizon scanning, therapeutic development, regulatory and health technology assessment systems. Their insights and lived experiences bring context and meaning to the data, ensuring decisions reflect what truly matters.

We also heard the importance of collaboration. Horizon scanning cannot be done in silos. Success depends on structural, system-wide cooperation. We must learn from international partners who are further along this journey, while building solutions that meet Australia's unique needs.

As we reflect on these conversations, one message is clear: horizon scanning must become a permanent, coordinated function in Australia. With strong collaboration, trust across all stakeholders, and with patients at the centre, we can build a system that not only reacts to innovation but is ready for it.

### **Summary**

Australia has entered a new era in medicine. Breakthroughs such as advanced radioligand therapies and personalised mRNA cancer vaccines are no longer distant possibilities, but already on our doorstep.

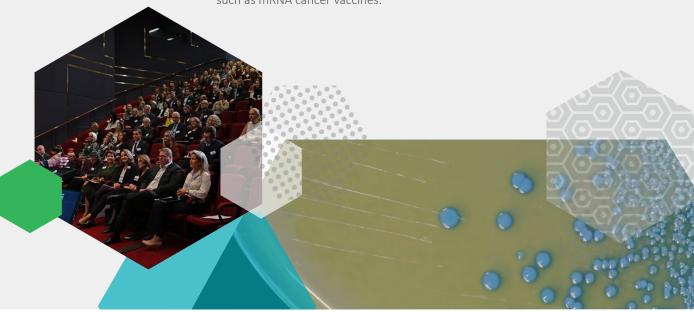
Horizon scanning gives us the ability to see these innovations coming and prepare our systems so patients can benefit in a timely and equitable way.

The 3rd annual Horizon Scanning Forum was convened by Medicines Australia under the 2022–27 Strategic Agreement with the Commonwealth. The Forum brings together leaders from government, industry, academia, regulatory bodies and patient advocacy groups to consider how horizon scanning can better prepare Australia's health system for disruptive change.

The overarching theme of this year's Forum was 'Conversation into action'. The backdrop of Parliament House elevated the prominence of this year's forum, coupled with Recommendation 47 in the HTA Review, which identified the need for a national horizon scanning function, and a recently awarded NHMRC Partnership grant to establish the Health Innovation Observatory- Australia.

The forum presented lessons learnt from an international keynote speaker who has established a national horizon scanning function in the UK, and industry-led case studies highlighted 3 themes:

- Fit for purpose regulatory and reimbursement pathways for timely patient access. Harmonising Australia's regulatory and reimbursement systems is essential to ensure patients can benefit from new therapies as soon as they are proven safe and effective.
- The importance of a values framework and methods for health technology assessment. Australia's health technology assessment (HTA) system must better capture the full value of new therapies, including impacts on carers, financial wellbeing, quality of life, and productivity, so that decisions better reflect what matters most to patients and communities.
- System preparedness for personalised therapies. We need to ensure our healthcare system, including its workforce, infrastructure, and models of care, is prepared for increasingly personalised treatments, such as mRNA cancer vaccines.



This report summarises discussions and insights from the Forum. Key takeaways include:

- Australia needs a permanent, coordinated horizon scanning capability, developed in partnership with government, industry and patients, to ensure regulatory and reimbursement systems keep pace with innovation.
- HTA reform is critical to recognise broader measures of value and to create pathways for complex and personalised therapies.
- Preparing for disruptive therapies requires
   a whole-of-system approach, addressing
   infrastructure, workforce capacity, data sharing
   and funding models.
- International collaboration offers lessons and efficiencies, but Australia must also leverage its own strengths in research, clinical trials and patient advocacy.

 Patients must remain at the centre of horizon scanning, with their perspectives embedded in a structured and transparent way.

Over 290 delegates attended the 2025 Horizon Scanning Forum, with representation across government, industry, payers, regulators, researchers and patient advocacy groups (Figure 1).

This year's Forum reinforced a clear message: science and innovation are advancing rapidly, and Australia must be prepared. By embedding horizon scanning and advancing HTA reform, Australia can create a more flexible, inclusive and future-ready health system — one that delivers faster and fairer access to the medicines of tomorrow.

### Attendance at the 2025 Horizon Scanning Forum

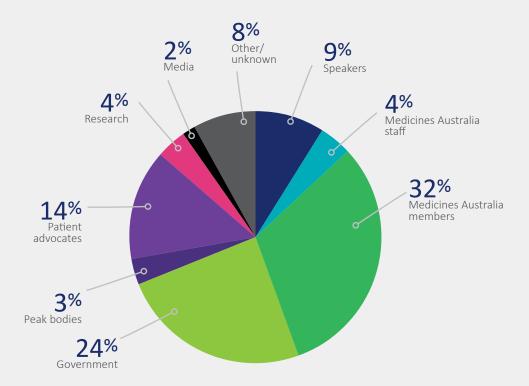


Figure 1.
Forum attendance by organisation type.

### Introduction

### Horizon Scanning – the future is now

### Key takeaways

- Horizon scanning can mean different things to different stakeholders
  across government, industry, regulators and patients. Ultimately, it is
  about anticipating new technologies and ensuring Australians have
  faster and fairer access to them.
- Innovation never stands still and neither should horizon scanning.
   The healthcare system is constantly changing, so horizon scanning must balance reactive responses with co-designed approaches that proactively anticipate unmet needs.
- Australia can learn from international models. Countries such as the UK offer valuable lessons that demonstrate the value of sustained investment, structured collaboration, and innovative approaches to strengthen system preparedness.
- The annual Medicines of Tomorrow: Horizon Scanning Forum provides a collaborative national platform. Convened by Medicines Australia with participation from the Commonwealth, the Forum brings together diverse stakeholders to share insights, align priorities and explore how horizon scanning can inform regulation and reimbursement preparedness and models of care.
- The 2025 Forum focused on moving from conversation to action. Industry-led case studies of disruptive therapies prompted discussion along 3 themes: regulatory and reimbursement pathways, values frameworks for HTA, and system readiness for personalised therapies.





Penny Shakespeare



Blair Comlev



Professor Dawn Craig



Orin Chisholm

David Pearce



Nicky Conway



Nick Henderson

Jodi Johnson-Glading

### Welcome and opening remarks

Liz de Somer, CEO, Medicines Australia

Penny Shakespeare, Deputy Secretary, Health Resourcing Group, Department of Health, Disability and Ageing

### **Opening address**

Blair Comley PSM, Secretary, Department of Health, Disability and Ageing

### **Keynote address**

Professor Dawn Craig, Director, National Institute for Health and Care Research (NIHR) Innovation Observatory at Newcastle University, UK

Panel discussion | Led by Associate Professor Orin Chisholm, University of Sydney

Professor Dawn Craig, Director, NIHR Innovation Observatory, UK

David Pearce, Managing Director, Takeda Oceania

Nicky Conway, Chair, Genetic Alliance Australia

Jodi Johnson-Glading, ACT Chief Medical Officer

Nick Henderson, First Assistant Secretary, Medicines Regulation Division, Therapeutic Goods Administration (TGA)

### What is horizon scanning?

Horizon scanning is the practice of looking ahead to anticipate innovations and system challenges before they arrive. In healthcare, these innovations may include new medicines, medical devices and technologies, diagnostic tools, and other interventions.

Horizon scanning means different things to different people, and this diversity is part of what makes it valuable. It can provide early intelligence about upcoming therapies, help healthcare systems prepare for disruptive change, and ensure that innovation is accessible and equitable across different populations.

### Horizon scanning from different perspectives

### Government

Planning workforce needs, funding and identifying where to invest and disinvest.

### Regulators

Managing the risk of emerging technologies responsibly and managing workflow while ensuring the regulatory framework remains agile and internationally aligned.

### Industry

Handling step-change innovations, capturing broader patient benefits, and shaping the system to be more predictable and sustainable.

### **Patients**

Embedding patient perspectives, recognising that many already 'do' horizon scanning informally.

In her opening remarks, CEO of Medicines Australia, Liz de Somer, emphasised that the value of horizon scanning lies in providing foresight that enables systems to prepare early, while linking that foresight to HTA reform ensures a mechanism to act on it. In this way, horizon scanning helps create a fair and fit for purpose system, positioning Australia to deliver innovations equitably and efficiently for the benefit of patients.

### Purpose of the 2025 Horizon Scanning Forum

Medicines Australia and the Commonwealth share a commitment to improving our understanding of new and emerging medicines in the development pipeline, with the goal of supporting faster and fairer access for Australians. Established under the Strategic Agreement, the Horizon Scanning Forum's purpose is to identify major therapeutic advances that may enter the Australian healthcare system in the next 2 years and understand how they may impact our resources, systems, and processes.

Preparing our healthcare system for these disruptive innovations helps ensure that Australians can access life-saving therapies as quickly and equitably as possible. By bringing together government, regulators, researchers, industry, and patient advocacy groups, the Forum provides a platform to explore the potential system-wide impacts of these innovations, from regulation and reimbursement to workforce planning and models of care. Ultimately, the Forum seeks to move Australia from a reactive position to one of preparedness, ensuring the healthcare system is ready to adapt to new technologies and deliver the best outcomes for patients.

Horizon scanning isn't just about the new 'shiny thing.' It's also about how we make sure that there is equity in access to innovation. It gives us a chance to prepare early, so that when innovations arrive, our system is prepared.

Liz de Somer, Medicines Australia



Patient voices are crucial. [...] They are why the Australian Government is committed to its National Medicines Policy, to delivering all Australians with fair, timely, reliable and affordable access to medicines and services, and making improvements for future generations.

Blair Comley PSM, Department of Health Disability and Ageing

### Forum themes

The overarching theme of the 2025 Horizon Scanning Forum was Conversation to action, reflecting the need to move beyond identifying innovations to building the structures, policies and processes required to deliver them. Discussions centred on 3 themes:

### Theme 1:

# Fit-for-purpose regulatory and reimbursement pathways for timely patient access



Harmonising Australia's regulatory and reimbursement systems is essential to ensure patients can benefit from new therapies as soon as they are proven safe and effective.

### Theme 2:

# The importance of a values framework and methods for health technology assessment



Australia's HTA system must better capture the full value of new therapies, including impacts on carers, financial wellbeing, quality of life, and productivity, so that decisions better reflect what matters most to patients and communities.

### Theme 3:

### System preparedness for personalised therapies



We need to ensure our healthcare system, including its workforce, infrastructure, and models of care, is prepared for increasingly personalised treatments, such as mRNA cancer vaccines.

Through these discussions, the Forum is helping to translate horizon scanning insights into actionable steps that will make Australia's health system more agile, equitable and ready to embrace the medicines of tomorrow.

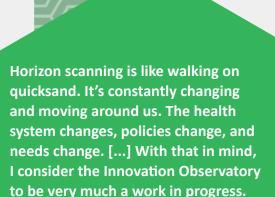
# Horizon scanning internationally

Many countries are already investing in horizon scanning to better prepare their healthcare systems for disruptive therapies. The UK offers a particularly valuable example, having established a national horizon scanning research centre, the NIHR Innovation Observatory, which has received long-term government support. Professor Dawn Craig's keynote lecture shed light on the opportunities, challenges and lessons from the UK's horizon scanning experience, and how Australia can leverage these insights as it develops its own capability.

Since the mid-1990s, UK funding for horizon scanning has steadily increased, with £27.4 million funded over the last 9 years. What started as small grants from the Department of Health and Social Care eventually grew into competitive research funding, with another £22 million awarded for 5 years, starting in 2026. This growth recognises the value that systematic horizon scanning brings to the UK health system.

In her keynote lecture, Professor Craig shared 5 key learnings from horizon scanning in the UK:

- System-wide collaboration is essential. Early efforts were siloed and fragmented, leading to duplication of efforts, missed opportunities and hindered progress. System-wide collaboration, supported by shared visions, aligned incentives, sustained leadership and adaptive systems, lays the foundations to build an effective horizon scanning function in Australia.
- Prioritisation should be guided by co-design and balance reactive and proactive approaches. The UK initially relied on a reactive, top-down approach where stakeholders put forward issues and priorities. Over time, it evolved into a proactive, bottom-up model involving patients, clinicians, and industry to identify needs and shape the pipeline earlier. Currently, about half of the UK's horizon scanning is reactive, while the other half actively 'pulls' innovation towards the health system through co-creation.
- Demand signalling connects gaps with solutions. The UK not only uses horizon scanning to spot new technologies, but also to identify unmet needs and gaps whether they are innovation, delivery or evidence gaps. Through this systematic approach, insights are then connected with the right actors who can address them, such as researchers, funders, government or industry.



And, if we're getting it right, it will

always be moving.

always be a work in progress. It will

Professor Dawn Craig,
NIHR Innovation Observatory

- Insights must be tailored to the audience.
   Different audiences need different forms of
   intelligence, from raw data to actionable insights.
   Horizon scanning should consider the data needs
   of end users and, if required, repackage outputs to
   ensure that they can support real-world decisionmaking.
- · Innovative methods keep horizon scanning adaptive and forward-looking. The NIHR Innovation Observatory has focused on making data more accessible, so stakeholders don't need to search across dozens of registries to find basic information. They developed the **Medicines Innovation Database (MInD)**, which integrates hard data, soft intelligence, and industry input to create a technology assessment pipeline that helps anticipate what could enter the health system in the short and long term. Machine learning and artificial intelligence (AI) are being used to streamline scanning and reduce resource intensity. Importantly, horizon scanning is treated as an adaptive process, with methods constantly being refined as new tools and challenges emerge.

# Horizon scanning in an Australian context

While international models such as the UK demonstrate what a mature horizon scanning system can achieve, the panel discussion highlighted what this means in an Australian context. Panellists from government, regulation, industry, academia and the patient community reflected on how horizon scanning could be applied in the Australian health system, and the opportunities and challenges ahead.

The panel discussion was centred around 5 themes: timely access, HTA reform, national coordination, global lessons, and system readiness. Key discussions from the panel are summarised below.

We want to get a wide understanding of the voices across Australia for horizon scanning, then we're going to deliver a couple of scans as proof-of-concept that we can work with Dawn's database and her team to bring these things to fruition in Australia.

Associate Professor Orin Chisholm, University of Sydney

### Panel calls to action

- **Be strategic**. Engage with the system through clear, consistent channels rather than fragmented approaches, so that efforts are aligned and effective.
- **Use a structured approach**. A national horizon scanning system must have a clear scope and allow for cross-sector collaboration between regulators, funders, researchers, industry and patients.
- **Keep patients central**. Always ground the system in what matters most to patients, ensuring their outcomes and wellbeing guide priorities.
- Lay robust foundations. Take time to understand stakeholder needs and build carefully, starting small, if necessary, so the system is sustainable in the long term.
- Drive implementation. Use horizon scanning to inform policy reform and system planning. Crosssector collaboration is vital to turn these insights into actionable policy.
- Think globally. Strengthen international collaboration through shared intelligence and early regulator-to-regulator engagement, ensuring alignment and consistency while leveraging global experience.

### **Panel cautions**

- **Avoid fragmentation**. Informal or inconsistent approaches risk missed signals and wasted effort.
- Manage expectations. Horizon scanning cannot deliver everything at once; clarity and transparency are essential.
- Balance evidence with equitable access. Patient outcomes and evidence generation are important, but should not come at the cost of timely, equitable access to new therapies.

Australia is now taking steps to build its own coordinated horizon scanning capability. Associate Professor Orin Chisholm from the University of Sydney recently secured a 3-year National Health and Medical Research Council (NHMRC) Partnership Grant to pilot a national horizon scanning approach. The project is bringing together partners, including government (Federal, State and Territory), the TGA, industry associations, Medicines Australia, patient advocacy organisations and international collaborators, such as Professor Craig.

The pilot will leverage insights from the UK's NIHR Innovation Observatory while incorporating Australian-specific data and patient insights. In its first year, the project will focus on extensive stakeholder engagement and co-creation workshops to shape what horizon scanning should deliver for Australia, with early proof-of-concept scans used to demonstrate feasibility and build the case for longer-term funding.





### Theme 1:

# Fit-for-purpose regulatory and reimbursement pathways for timely patient access

### Key takeaways

Radioligand therapies (RLTs) show great promise for advanced cancers. RLTs combine cancer-targeting molecules with radioactive isotopes to precisely destroy tumour cells while sparing healthy tissue. RLTs that target the prostate-specific membrane antigen (PSMA) offer hope for patients with advanced-stage disease, while the modular structure of RLTs enables potential applications across many tumour types.

**Current regulatory and reimbursement pathways are not fit for purpose**. Current systems are designed for community medicine, not precision medicine. RLTs highlight the limitations of Australia's existing reimbursement pathways, where the existing Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) mechanisms cannot accommodate the complexity of new precision therapies.

A clear and consistent pathway for RLT assessment needs to be established. All RLTs should undergo TGA evaluation for safety, efficacy and quality as a prerequisite to reimbursement, in line with the National Medicines Policy.

A sustainable funding mechanism is critical for equitable access. Current fragmented approaches, complex MBS funding and hospital services create gaps, inequities and uncertainty for patients. A dedicated, sustainable funding model will be essential to ensure all Australians can benefit from RLTs, regardless of where they live or how they access care.

### Industry case study

Michelle Gregory, Country Head, Public Affairs, Novartis

Sally Sara, Director of Nursing, Prostate Cancer Foundation

Deanna Mill, Advisor, **Fvohealth** 

Panel discussion Led by Liz de Somer, Medicines Australia

Rodney Hicks, Founder, Executive Chairman and Chief Medical Officer, Melbourne Theranostic Innovation Centre

Meredith Cummins, CEO, NeuroEndocrine Cancer Australia

Dylan Jones, Country Head of Value and Access, **Novartis** 

















Dylan Jones

Timely, equitable access to new medicines depends on agile regulatory and reimbursement systems that can keep pace with innovation. Many of today's therapies challenge traditional pathways and risk delays if the system cannot adapt, with patients facing the brunt of the consequences. Horizon scanning provides the foresight needed to update these processes in advance, ensuring patients benefit sooner from emerging technologies.

### **Industry case study: Radioligand** therapies and prostate cancer

Prostate cancer is the most commonly diagnosed cancer among Australian men, with more than 26,000 new cases each year. While treatment options have expanded, advanced prostate cancer remains difficult to manage, highlighting the urgent need for more effective therapies.

Radioligand therapies (RLTs) are a form of radiopharmaceutical treatment that combines cancer-targeting molecules (ligands) with radioactive isotopes. 1 When RLTs are administered, the ligands act as a homing device, guiding the radioisotope directly to cancer cells, where they emit damaging radiation to destroy cancer cells. This approach delivers radiation directly to cancer cells while sparing healthy tissue.

> What this underscores is the absolute need for horizon scanning. What we're trying to do now is fit these complex innovations into existing processes and systems. It really isn't working, and it's patients that pay the price.

> > Michelle Gregory, **Novartis**

In prostate cancer, RLTs that target a protein highly expressed on cancer cells, called prostate-specific membrane antigen (PSMA), offer new hope for patients with advanced disease.<sup>3</sup> In addition, recent advances in manufacturing have resulted in modular RLT designs that can switch out different ligands and radioisotopes to target different tumour types. This makes it possible to use the same technology to treat a wide range of cancers beyond prostate cancer.<sup>4</sup>

Globally, the pipeline for RLTs is rapidly expanding, with multiple therapies in development across different cancer types. However, despite Australia's early expertise in this field, patient access remains limited.

The current reimbursement pathway is via a complex Medicare Benefits Schedule (MBS) pathway.

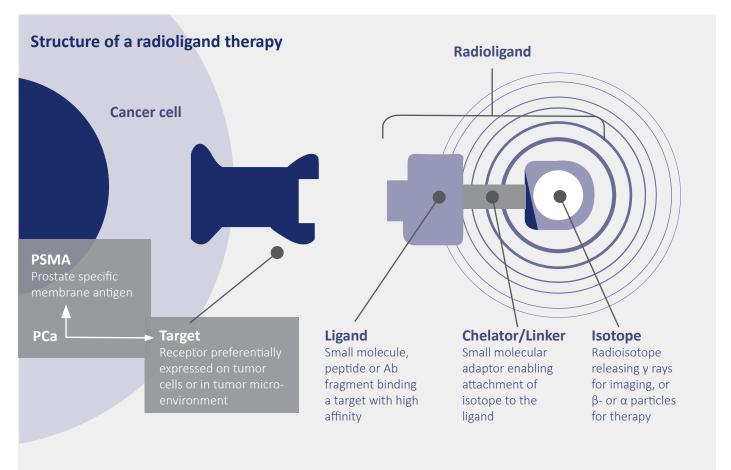
The case study highlighted a cautionary tale about relying on existing mechanisms like the MBS to fund RLTs. While the MBS has provided some interim access, it is not designed for complex, evolving treatments. This has created inequities between public and private patients, introduced uncertainty about continuity of access, and left gaps in coverage as new therapies enter

Radioligand therapy isn't on the horizon. It's here. A critical question still remains, though, and that's: how do we ensure patients can actually access these innovative therapies once they're approved?

Deanna Mill, Evohealth

the pipeline. The current model risks placing financial structures ahead of patient needs, leaving many uncertain about their access to care.

Without clear and consistent regulatory and reimbursement pathways, Australians may face delays in accessing innovative therapies like RLTs that could significantly improve their wellbeing, outcomes and quality of life.



**Figure 2.**Structure of a radioligand.<sup>2</sup> Source: Reproduced with permission from Novartis; 2025 Horizon Scanning Forum presentation.

### Why is the MBS not working?

The MBS access pathway creates challenges with equitable access to RLT.



Unpredictable cost- unclear to patient influence of service setting and classification on cost





Complex billing, multiple pathways to claim, pay full cost upfront, wait time for reimbursement



Jurisdictional policies influence access and cost

Access may depend on where you live, which system you enter (public or private) and what you can afford to pay.

**Figure 3**. The MBS access pathway creates challenges with equitable access to RLTs. Source: Reproduced with permission from Evohealth; 2025 Horizon Scanning Forum presentation.



# Challenges and opportunities to improve patient access to therapies

A panel of industry, academic, and patient advocacy representatives explored how Australia's health system can better prepare for RLTs (and other personalised treatments) to ensure patients can access innovations more quickly and equitably. The panel's discussions are summarised below.

### **Challenges**

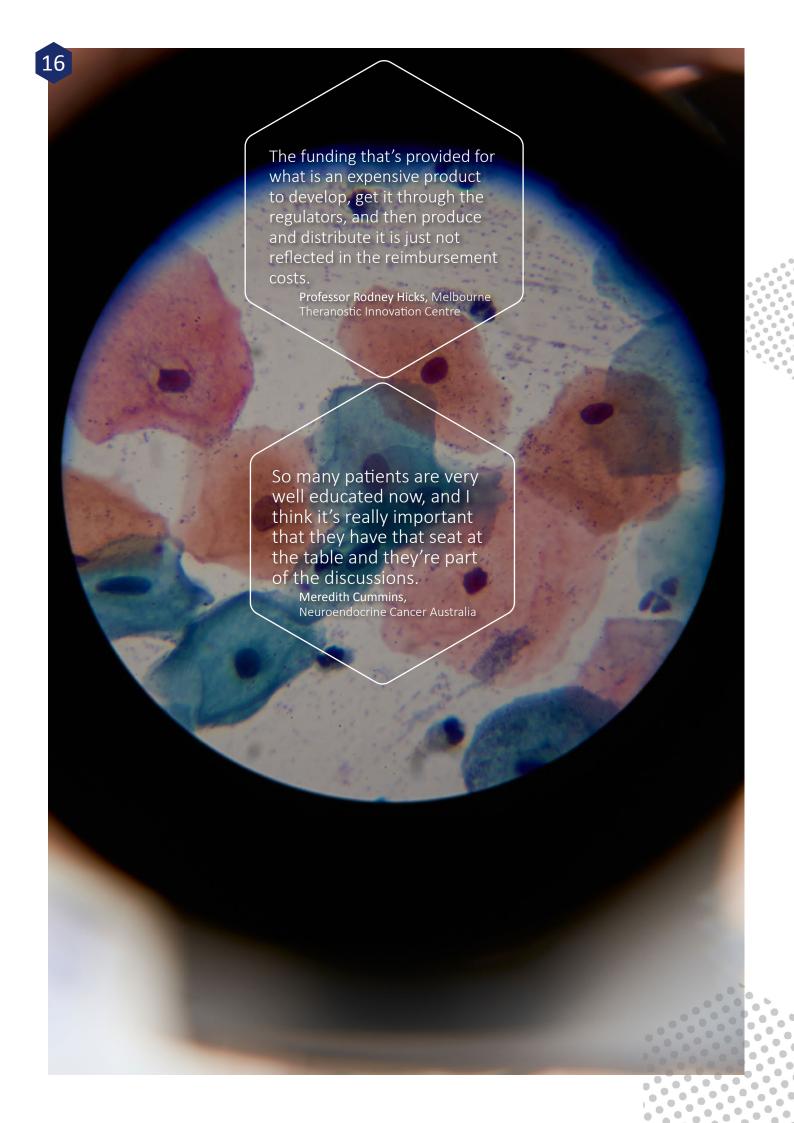
- Current systems are designed for community medicine, not precision medicine. Australia's regulatory, reimbursement and delivery pathways were largely built around standardised, community-based medicines. RLTs, by contrast, are highly personalised, requiring tailored diagnostics and complex production to account for disease heterogeneity. This mismatch creates delays and inefficiencies in bringing these innovative treatments to patients.
- Unclear funding responsibilities for manufacture vs. delivery. While the cost of producing radiopharmaceuticals might logically be covered by the PBS, the delivery of these complex therapies involves specialised equipment, facilities, and clinical teams, which are currently more aligned with MBS or state-funded hospital services. The lack of clarity over who funds which part of the RLT process creates barriers that slow patient access.
- Outdated funding models. What began as a small-scale, 'cottage industry' model of funding is no longer fit for purpose, leaving reimbursement costs out of step with the true expenses of development, production and distribution.
- Limited participation in global clinical trials.

  Too often, Australian patients miss out on early access to promising therapies because clinical trials are conducted overseas. Ensuring Australia is routinely included in international trials would reduce the burden on the healthcare system by providing access to effective therapies, rather than treatments that do not work or only treat symptoms.
- Infrastructure and workforce pressures. RLTs require specialised facilities, equipment, and staff, creating challenges in scaling up. Geographic inequities remain a risk.

• Unfair distribution of infrastructure costs
between public and private. Australia's strong mix
of public and private healthcare creates overlaps
that may unfairly distribute costs. For example,
MBS items cannot be accessed by public patients.
Only a small number of public hospitals are
able to treat private patients, with some states,
such as South Australia, disallowing the practice
entirely. As a result, only the private sector ends
up receiving the reimbursement, not the public
hospital system.

### **Opportunities**

- The National Medicines Policy should act as a North Star. The National Medicines Policy should guide all reforms, ensuring timely, safe, affordable and high-quality access to treatments.
- Leverage international approvals to expedite access. Closer collaboration with overseas regulators offers the chance to fast-track access to therapies that are already proven safe and effective in other countries.
- Enable fair access for patients with the same biomarkers. Many innovative medicines target specific receptors that may be present across multiple cancer types. Patients should have the opportunity to benefit from these therapies regardless of tumour location, ensuring equitable access based on biology rather than disease label.
- Disaggregated funding models. Separating medicine, service and infrastructure costs, rather than bundling them together, could improve transparency and sustainability in how new therapies are funded.
- Learning from international models and regulators. Other countries, such as Canada, Italy, and Belgium, provide valuable lessons in creating pathways from research to reimbursement that can help Australia implement best practices and avoid pitfalls.
- Harness emerging technologies. Rather than reinventing the wheel with each new therapy, Australia can use tools like AI to streamline evaluation and delivery to ensure the system can keep pace with innovation.
- Embedding patient voices. Patient representatives emphasised the importance of including consumers in consultations as active participants in decision-making processes, ensuring their insights and lived experiences shape assessment and access pathways.





### Theme 2:

# The importance of a values framework and methods for health technology assessment

### Key takeaways

Narcolepsy is much more than just sleepiness. It is a chronic and disabling neurological

disorder that is associated with a myriad of symptoms, including cataplexy (sudden loss of muscle tone triggered by emotion), hallucinations, and cognitive difficulties. This affects patients' overall quality of life, with far-reaching impacts on relationships and productivity.

**Australia's standard of care for narcolepsy lags behind international guidelines.** Only older treatments for narcolepsy are available in Australia, which target symptoms, rather than the underlying cause of the disease. This leaves patients without access to treatments recognised as best practice overseas.

**Effective treatments are out of reach for many patients.** Many patients face uncertainty and inequitable access to more innovative treatments due to cost barriers and lack of availability.

New therapies that target the underlying cause of narcolepsy are emerging. Innovative treatments, such as orexin agonists that directly target the underlying cause of narcolepsy, offer hope for patients beyond symptom management. Some of the newer therapies are available elsewhere but not in Australia.

**HTA reform must capture the broader value of new treatments.** Assessment processes should consider not only clinical outcomes, but also the broader benefits of treatments for patients, families and society, productivity, financial wellbeing and quality of life.



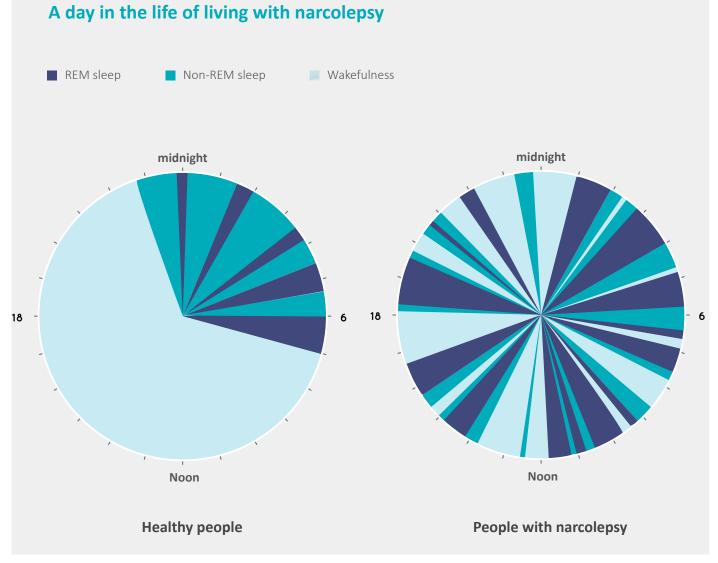
Health technology assessment (HTA) is the process used to determine the effectiveness, safety and cost-effectiveness of new medicines, devices, and health interventions, helping governments make informed decisions on which technologies should be publicly funded. Because resources are limited, HTA compares new technologies against existing treatments to determine whether they improve health outcomes and represent value for money. Traditionally, this has meant weighing clinical effectiveness and cost-effectiveness to ensure the health system delivers the greatest overall benefit within its budget.

However, as therapies advance and new innovations emerge, these traditional methods are often too narrow. A stronger values framework and updated methods are needed to capture broader benefits, such as equity of access, and societal benefits, so that decisions better reflect what matters most to patients and communities.

# Industry case study: Small molecule therapy for narcolepsy that targets the mechanism of disease

Narcolepsy is a chronic, disabling neurological disorder that disrupts the sleep—wake cycle and severely affects day-to-day functioning. Globally, it is estimated to affect around 3 million people,<sup>5</sup> with an estimated 12,000 Australians living with the condition<sup>6</sup>. Symptoms include excessive daytime sleepiness, cataplexy, hallucinations, disrupted sleep, and cognitive difficulties such as mental fog and poor concentration.<sup>7–9</sup>

including depression, anxiety, cardiovascular disease, obesity, and diabetes. The social and economic costs are considerable, with reduced productivity, increased rates of unemployment, and stigma compounding the challenges for patients.



**Figure 4**. A day in the life of living with narcolepsy. <sup>10</sup> (Abbreviations: REM: rapid eye movement; MDD: major depressive disorder). Source: Permission granted to use these images by Eleanor Wales. <sup>11</sup>

Narcolepsy type 1 is caused by a loss of orexin-producing neurons in the brain. Orexin is responsible for regulating the sleep-wake cycle. A promising new small molecule therapy, oveporexton (an orexin-2-selective agonist), has completed phase III clinical trials and directly targets the root cause of narcolepsy type  $1.^{13-15}$ 

Unlike existing treatments, which largely manage symptoms, this first-in-class therapy has the potential to transform outcomes by addressing the underlying disease mechanism. The US Food and Drug Administration (FDA) has already granted oveporexton breakthrough therapy status, recognising the urgent need to fast-track access for patients.<sup>16–21</sup>

However, in Australia, patients only have access to older therapies that treat a single symptom of narcolepsy, such as dexamfetamine, modafinil and antidepressants. <sup>22 - 23</sup> This stands in stark contrast to international best practice. <sup>24</sup> For example, sodium oxybate is a standard of care overseas for cataplexy and excessive daytime sleepiness, and is the only treatment for disrupted sleep. It has been available for over 20 years in the US and Europe but remains largely inaccessible in Australia. It is associated with large out-of-pocket costs, not subsidised and only available through the special access scheme.

Patients face what has been described as a 'postcode lottery,' where access can vary depending on financial status, state policies or individual hospital decisions.

1

The right treatment can transform lives. With timely access to effective therapies, people with narcolepsy can live safe, fulfilling and productive lives, but this remains out of reach for many Australians under current access arrangements.

2

Australia must not fall further behind. Exciting advances in narcolepsy treatment are emerging globally, yet Australians will continue to struggle without comparable options.

2

**Proposed changes offer real hope.** For patients, system changes would mean:

- timely access to evidence-based treatments that reduce functional impairment and improve quality
   of life
- certainty of access through TGA/PBS rather than reliance on the special access scheme or hospital funding
- the prospect of therapies that address the root cause of the disorder, not just its symptoms.

There's a lot of frustration in the community about why a lot of these medications aren't able to be accessed; why the person next to them can access it through their hospital system while they can't.

**Dr Aaron Schokman,** University of Sydney

Dr Aaron Schokman, a lived-experience post-doctoral researcher, explained that the current system means that sometimes patients' only treatment options are those with severe side effects, such as antidepressants that blunt emotional response. Despite strong evidence of effectiveness internationally, newer therapies that allow patients to live more functional, fulfilling lives are not subsidised in Australia and therefore remain out of reach for most. The emotional and social consequences (such as loss of relationships, employment opportunities and independence) are not captured or not adequately valued in assessments, yet are central to the patient experience. Without reform to Australia's HTA system, patients risk years of delay in accessing life-changing innovations.

# Challenges and opportunities for assessing and valuing medicines

The presentation highlighted various challenges and opportunities for HTA reform:

### **Challenges**

- Standard of care lags behind international best practice. When Australia's recognised standard of care relies on older therapies with a sparse evidence base, it is difficult to compare new treatments against older therapies, especially in rare diseases where often only placebo-controlled studies are available. This creates a barrier to access when the benchmark itself is out of step with global guidelines.
- Inappropriate or outdated comparators.

  Many conditions rely on therapies that were developed decades ago, with clinical trials using outdated endpoints that have no established relevance. Comparing new treatments against these outdated benchmarks risks producing uninformative results and undervaluing the benefits of innovation.
- Novel technologies need fit for purpose assessment. If a new therapy targets the underlying cause of disease while existing comparators only address symptoms, traditional comparison frameworks fall short.
- Failure to capture patient experience. In conditions like narcolepsy type 1, patient evidence is critical to capturing the true burden of disease. Current HTA approaches often overlook societal impacts such as lost productivity and carer burden, leading to undervaluation of therapies that could significantly improve patients' lives.

### **Opportunities**

- Value the broader benefits of innovation in HTA. The HTA process should look beyond clinical outcomes alone and capture the wider benefits that therapies bring to patients, families and society. This includes impacts on carers, financial wellbeing, quality of life and productivity. By recognising these broader dimensions of value, Australia can make more informed decisions and invest in therapies that deliver the greatest overall benefit.
- Move beyond cost minimisation to value-based assessment. Current HTA processes often emphasise cost minimisation, comparing new therapies to the cheapest available option. For conditions like narcolepsy, this fails to reflect the true value of innovation. By incorporating measures of quality of life and other outcomes, Australia can ensure that the real-world benefits of therapies are captured.

What's the burden of disease?
What's the impact on family?
What's the impact on quality of life? They're the things that need to be valued in innovation, so there are incentives for companies to bring in new medicines quickly.

Sharon Weber, Takeda







### Theme 3:

### System preparedness for personalised therapies

mRNA cancer vaccines are a breakthrough in personalised medicine. By tailoring treatment to a patient's unique genetic tumour profile, these therapies train the immune system to target cancer directly, with promising early trial results in melanoma, pancreatic, and prostate cancers.

**Australia's system is still evolving.** Current regulatory, HTA and funding models, along with genomic sequencing capacity, will need to adapt to manage therapies where every product is unique and delivery depends on rapid, large-scale tumour profiling.

**Preparing for personalised therapies demands whole-of-system change.** Success will depend on coordinated investment in infrastructure, genomics, workforce capacity, registries, and innovative funding models.

Al and global collaboration are ess enablers. Designing effective vaccines is a multivariable challenge well suited to Al, but progress will require access to large international datasets and collaboration across borders.

### **Industry case study**

Quentin Bracquart, Principal, IQVIA

### **Panel discussion**

Led by Penny Shakespeare, Deputy Secretary, Department of Health, Disability and Ageing

Quentin Bracquart, Principal, IQVIA

Dr Kaye Robertson, Acting Chief Medical Advisor, **TGA** 

Professor Matt Brown, Chief Scientific Officer, Genomics UK

Christine Cockburn, Rare Cancers Australia









Professor Matt Brown



Unlike traditional 'one-size-fits-all' treatments. personalised therapies, such as mRNA vaccines, are tailored to an individual's genetic profile. These therapies have significant potential, particularly for cancer, and offer promising outcomes for patients. However, they frequently require specialised diagnostic tools, advanced manufacturing processes, specialised clinical teams, and new models of care. Therefore, preparing for personalised therapies means more than just getting them approved. It also requires coordinated planning for infrastructure, assessment, regulation, and workforce capacity.

### Industry case study: mRNA cancer vaccines

Cancer remains one of the leading causes of death in Australia, affecting thousands of families every year. While advances in surgery, chemotherapy, and immunotherapy have improved survival rates, many cancers remain difficult to treat, particularly when tumours evolve rapidly, suppress immune responses, or when current treatments carry severe side effects.

Messenger RNA (mRNA) cancer vaccines represent a promising new approach. Unlike preventative vaccines designed with a therapeutic intent: to train a patient's immune system to recognise and destroy their own tumour cells.

The process begins by taking a sample of the tumour and performing genetic sequencing to identify unique neoantigens – specific markers on the patient's tumour that are not found anywhere else in the body. The neoantigens that trigger the highest immune response are selected as targets (sometimes with the help of AI) to encode into a custom-made vaccine. When administered, the mRNA vaccine stimulates a tumourspecific immune response to recognise and destroy cancer cells while sparing healthy tissue.

# mRNA cancer vaccines are new personalised treatments that train our body to accurately recognise and destroy cancer cells



**Tumor sample** is taken from the cancer patient



Neoantigens (tumor specific markers) in the tumor sample are **exhaustively profiled** using DNA-sequencing technology



Immunogenic neoantigens that are **specific to each patient's tumor** are carefully selected to effectively encode into a vaccine (with or without AI algorithm)



Messenger RNA vaccines stimulate a tumor-specific immune response to recognise and destroy the tumor cells (with or without additional immunotherapy)

**Figure 5**. Preparation of an mRNA vaccine. Source: Reproduced with permission from IQVIA; 2025 Horizon Scanning Forum presentation.

This technology has already shown encouraging results. In a phase II trial for melanoma, a personalised mRNA vaccine combined with pembrolizumab reduced the risk of recurrence or death by nearly 50% compared to pembrolizumab alone.<sup>25</sup> Phase I trials in pancreatic and prostate cancer have also shown promising results. Globally, more than 50 clinical trials are underway.



### **Survey insights**

77% of respondents believe personalised mRNA cancer vaccines are the most promising highly personalised treatment compared to other emerging therapies.

23 out of 30 respondents think Australia is well-positioned to attract mRNA personalised cancer vaccines clinical trials, citing a strong clinical research infrastructure, talent and capability.

Figure 6. Insights from a survey of Australian oncologists. 26

For Australia, the opportunity is clear, but so are the challenges:

- **Regulatory:** Regulatory systems are not yet adapted to handle therapies where no 2 products are the same.
- Assessment and funding: There are limitations with the existing HTA assessment and funding models for personalised treatments. These rely heavily on survival data in late-stage cancers, rather than recognising the long-term benefits of early intervention.
- Manufacturing and commercial: There are challenges related to complex manufacturing processes and commercial viability for mRNA personalised cancer vaccines.

Australia is building momentum. We have world-class researchers in mRNA. [...] We have the infrastructure, we have the talent to bring those technologies to the Australian market, but really to lead globally, we need more than momentum. We need policy reform. We need increased awareness, and we need system readiness

Quentin Bracquart, IQVIA

### **Industry case study key recommendations**

### Regulatory

- Develop standardised platform-based regulatory guidelines.
- Assess the opportunity to collaborate with other regions to harmonise the regulatory approach to mRNA personalised cancer vaccines.

# Assessment and funding

- Review Pharmaceutical Benefits Advisory
  Committee (PBAC) funding assessment to improve acceptance of surrogate endpoints, recognise longterm value of therapy with reduced base case discount rate, and plan for potential future pan-indication assessment pathways.
- Review HTA and funding models to ensure a full continuum of care is evaluated, and consider implementing a bridging funding mechanism.
- Explore innovative payment models, including early engagement with sponsors to understand end-to-end treatment cost. Factor in the entire treatment journey to develop the optimal risk-sharing agreement.

# Manufacturing and commercial

- Leverage existing investment in mRNA research and manufacturing facilities to position Australia as a global leader.
- Promote Australia as a clinical trial destination to increase early access for patients and continue building manufacturing scale.



# Challenges and opportunities for precision medicine

A panel including representatives from industry, patient advocacy groups, the TGA, and Genomics UK discussed challenges and opportunities in preparing Australia's healthcare system for the next wave of precision medicine. Key points from the panel discussion are summarised below.

### **Challenges**

- Trial eligibility and throughput are a challenge. Only a small fraction (< 10%) of screened patients qualify for vaccine trials; the logistical 'churn' to identify, profile and treat patients is substantial.
- Genomics capacity is the rate-limiter. Australia lacks a national cancer genomic medical service able to deliver large-scale sequencing and rapid turnaround. Meeting trial timelines (which are often ~31 days from consent to vaccine delivery) is currently beyond system capability.
- We need to move beyond stepwise processes to holistic system thinking. Personalised therapies rely on diagnostics, genomics, imaging, pathology, and follow-up care. Australia will need to adopt a systems approach that considers the entire continuum of care, rather than managing each element in isolation.
- Workforce capacity and genomic literacy.
  Frontline workers such as GPs and nurses are not always genomics experts, yet they are often the first point of care. Without accessible resources and training, the workforce may struggle to integrate personalised medicine into routine practice, creating barriers to timely and equitable patient care.

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### **Opportunities**

- Facilitate early, cross-system communication.

  Horizon scanning creates an opportunity for researchers, sponsors, regulators, and reimbursement bodies to engage together from the outset. Early, coordinated dialogue can build transparency around what evidence will be needed, helping stakeholders avoid the inefficiencies of a step-by-step, siloed approach.
- Advocacy organisations can play a vital role in helping patients understand and engage with new technologies. By translating complex information, addressing real versus perceived risks, and preparing patients for participation, advocacy groups can strengthen trust in new technologies like mRNA vaccines.
- Implement bridging or flexible funding mechanisms. Provide provisional or flexible funding models to enable early access while delivery models and evidence mature.
- Establish a nationally funded genomic profiling service and test directory. Delivering personalised cancer vaccines and other advanced therapies will not be possible without systematic genomic profiling. A national cancer profiling service, underpinned by an agreed national test directory, would ensure that all patients can access the genomic testing required to benefit from next-generation treatments. Progress through initiatives like Genomics Australia is encouraging.
- Harness AI and global data. Al is uniquely suited to the multi-variable challenge of designing personalised vaccines, helping identify the most effective antigen combinations and delivery methods by coupling AI with large international genomic datasets. Key opportunities include the molecular profiling of tumours and the development of globally shared public databases to better train AI algorithms.
- Capitalise on international shifts. Australia could leverage reduced US investment into mRNA vaccines, strengthening its role as a preferred destination for sponsors. This could accelerate local access for patients while building workforce capability and research capacity.
- Use registries to strengthen safety, evidence, and system learning. Personalised therapies will require ongoing evidence about long-term safety and efficacy. Well-designed registries can provide this post-market intelligence, creating an iterative feedback loop to refine clinical use and manufacturing approaches. However, there needs to be clear funding and governance.





### Where to from here?

From conversations to action

# Preparing Australia's healthcare system for the future

Australia's healthcare system has long delivered strong outcomes, but it is not yet fully equipped to keep pace with the next wave of therapies. Many emerging innovations, from radioligand therapies to mRNA cancer vaccines, challenge existing regulatory, HTA and funding pathways. Without reforms, patients may experience delays or inequitable access to treatments that could significantly improve or extend their lives.

To meet this challenge, Australia will need to develop clear, fit for purpose assessment and reimbursement pathways, invest in infrastructure, and support the workforce with the skills and tools to deliver complex therapies at scale. Embedding horizon scanning as a permanent, coordinated capability will ensure that regulators, funders, industry, clinicians and patient groups can anticipate these needs early, allowing reforms to be implemented in step with scientific progress.

# Key takeaways from the Horizon Scanning Forum

# Australia needs a permanent, coordinated horizon scanning capability.

A structured, long-term horizon scanning function is essential to prepare the health system for disruptive and emerging therapies and ensure patients benefit sooner from innovation.

## Patients must be embedded at the centre of what we do.

Horizon scanning and HTA should be grounded in the lived experiences of patients, and there needs to be formal structures that integrate patients' insights into decision-making. Advocacy groups play a vital role in translating complex science, shaping priorities, and ensuring the system reflects the needs of patients.

# Building trust through collaboration and transparency is critical.

Trust is strongest when government, industry, researchers and patients are transparent about what can and cannot be shared, acknowledge each other's expertise, and focus on shared goals. Collaboration must start early, not just at the point of crisis or decision, with clear frameworks that bring stakeholders together.

# Australia should learn from international models while leveraging local strengths.

Australia can benefit from the wealth of international experience in horizon scanning and HTA, particularly in the UK and across the Asia Pacific. At the same time, there is untapped potential in the data, research and infrastructure that already exist nationally but are not yet fully connected or leveraged. The greatest opportunity lies in combining both: drawing lessons and technical expertise from global leaders while building a fit for purpose, locally grounded system that makes the most of Australia's research assets.

We have to deliver for our patients. It's a collective responsibility to make sure the HTA recommendations are put into place and worked through in a collaborative way. It won't be easy. There's some big things to solve there, but I think if we come with the right mindset, a collaborative approach, and see what we might be able to do together, we'll be in a much better place.

Sue MacLeman, Medicines Australia

# System preparedness must go beyond medicines.

Preparing for disruptive and personalised therapies requires working holistically across the health system to align medicines with the diagnostics, genomics, imaging, data infrastructure, workforce, and models of care that enable their effective use. By thinking in systems rather than silos, Australia can ensure that innovation is translated into real-world outcomes for patients.

# HTA reform must be implemented now to prepare Australia's system for the future.

Horizon scanning can only succeed if paired with reforms to HTA that make the system more agile, equitable and responsive. Australia cannot wait for new technologies to arrive before building readiness. HTA reform must start now to prepare for the medicines of tomorrow.





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