



Horizon Scanning

Strengthening Australia's approach
to horizon scanning for new
therapies



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Executive Summary

Horizon scanning is a process or system which seeks to systematically identify and assess the potential impact of new and emerging health technologies on patients and other healthcare system stakeholders. This facilitates proactive planning for the arrival of new health technologies. BMS convened the Shaping Healthcare Together Roundtable, under the Broadening the Evidence project, online with representatives of 25 Australian patient advocacy organisations in October 2021. The roundtable explored horizon scanning activities and opportunities in the Australian healthcare system.

This report presents the findings of the roundtable, combined with desk research and interviews with a range of international experts involved in horizon scanning processes. It makes recommendations for an efficient, effective and inclusive horizon scanning process for the Australian healthcare system.

The healthcare landscape is rapidly evolving as disruptive technologies shape the way we diagnose, treat and manage diseases. Such technologies include precision medicines, immunotherapies, potentially curative cell and gene therapies and digital therapeutics. These developments not only challenge clinical approaches to disease management, but also the traditional pathways of therapeutic development, from the clinical trial stage through regulatory approval to health technology assessment (HTA), and reimbursement. New technologies may offer significant value to patients, but also have resourcing impacts that must be managed within the healthcare system and budgets.

These increasing complexities create a need to proactively identify the clinical trials and innovative therapies that may come to Australia and the potential implications for patients and the healthcare system. Patients may have opportunities to participate in clinical trials, to provide inputs into regulatory and reimbursement processes, and may benefit from greater awareness of new treatment options. Government, healthcare providers and stakeholders in the healthcare system must plan for potential changes to clinical practice and resourcing requirements. This is critical for maintaining an efficient, equitable and sustainable healthcare system.

Given the range of potential uses for the information gathered through horizon scanning, it may be conducted and assisted by a broad range of stakeholders including government, payers, healthcare providers, industry, not-for-profit and patient advocacy organisations. Internationally, approaches to horizon scanning vary in scope, purpose and methodologies, and there is significant duplication of effort.

Australia does not currently have a formalised, comprehensive horizon scanning program. An annual horizon scanning forum will begin in 2022 under the Strategic Agreement between the Commonwealth Government and Medicines Australia (1). This is an important step; however other opportunities for key stakeholders to contribute to the strengthening of horizon scanning in Australia exist. These could include:

There are a number of opportunities for various stakeholders to contribute to the strengthening of horizon scanning in Australia. These could include:



Patient advocacy and non-government organisations

Consolidating and coordinating work that is already undertaken by many patient advocacy organisations and participating in broader efforts, such as the annual horizon scanning forum.



The Medicines Industry

Leveraging the planned 2022 horizon scanning forum and ensuring collaboration with relevant stakeholders including patient advocacy organisations, clinicians, researchers and



Government

Establishing a formalised, government driven horizon scanning process which builds on the activities already undertaken and which captures input from a broad range of stakeholders.

Key Findings

Horizon scanning activities are already being undertaken informally by stakeholders across the healthcare ecosystem in Australia, including by patient advocacy organisations, which forms a strong foundation to build upon for the future.

Internationally, horizon scanning is highly fragmented and there is significant variation in the approaches taken by different jurisdictions and organisations. This is inefficient and leads to significant duplication of effort, particularly where public information regarding the design, progress and results of global clinical trials is the main data source.

Formalised horizon scanning processes have historically been designed primarily to inform payers, regulators and healthcare providers; yet, some institutions recognise that a broader range of stakeholders have the potential to effectively contribute to, and benefit from, this information and analysis. For example, England's National Institute of Health Research Innovation Observatory (NIHRIO) and National Institute for Health and Care Excellence (NICE) have established procedures to strengthen patient involvement and consultation in horizon scanning.

For patients and caregivers, awareness and understanding of potential future product launches would enable better preparation and therefore more thorough and impactful contribution to HTA and reimbursement processes. Information gathered through horizon scanning may also be utilised to raise awareness about clinical trials in Australia.

Vision for horizon scanning in Australia

Australia should aim for a gold standard approach to horizon scanning for new health technologies. Key components of this system should include:

- › Broad scope that includes medicines, vaccines, devices, diagnostics and cell and gene therapies that are in development. Inclusion (filtering) criteria should be agreed by stakeholders and subject to regular review to keep pace with technological advances. This may include, for example, technologies that are expected to address areas of high unmet need, and that may present complexities in evaluation and/or implementation.
- › Commonwealth Government driven and funded process, conducted via an independent third party, with the appropriate expertise to effectively identify and impartially document relevant products and technologies and apply filtering criteria.
- › Process conducted in consultation with a broad range of relevant stakeholders from throughout the health ecosystem, including government, payers, patients and patient advocacy organisations, clinicians, industry and researchers.
- › Support healthcare system capabilities and preparedness for new therapies and technologies. This should include alignment with relevant steps in the path to market for medicines in Australia such as regulatory (TGA) and reimbursement (PBAC/MSAC) processes.
- › Ensure appropriate outputs of the horizon scanning research are developed to support dissemination amongst a broad range of relevant stakeholders. This may require outputs that are tailored to the needs of different stakeholders. For example, reports and online resources

Recommendations

The following recommendations are proposed to lead progress towards the *vision for horizon scanning in Australia*:

Inclusion of key stakeholders, including patient advocacy organisations, in the upcoming, inaugural Medicines Australia – Department of Health horizon scanning forum. This may include:

- Information sharing or sessions/workshops with relevant stakeholders
- Consultation with stakeholders regarding their needs and expectations of horizon scanning
- Alignment on the scope and purpose of horizon scanning
- Potential role of patient advocacy groups in horizon scanning, such as advising on areas of unmet need
- Potential roles of other stakeholders, such as clinicians and researchers, in the horizon scanning process,
- Format of publicly available outputs and analyses that would provide useful information to stakeholders

This educational experience should be repeated as horizon scanning becomes more established and there is increasing awareness and understanding of horizon scanning amongst key stakeholders.

Mapping of horizon scanning activities already being undertaken by stakeholders, including patient advocacy organisations, in Australia. This would serve to articulate the rationale and benefits of gathering specific information for different stakeholders, as well as address any duplicated effort. This could be incorporated into the consultation process outlined under recommendation 1.

Appointment of an independent third party to research and develop a public report that draws on a broad range of sources including literature, company press releases, clinical trial readouts etc. This should inform the annual horizon scanning forum and be broad in scope (noting that the forum will focus on disruptive technologies). The scope should be informed by consultation with a broad range of relevant stakeholders and be reconfirmed each year in the lead up to the forum.

Exploration of potential opportunities to leverage horizon scanning that is conducted in other countries and organisations with a similar purpose, where this draws on publicly available information and hence may be expected to generate similar reports.

Provision of a single source of easy to access and interpret information for Australian patients and other healthcare system stakeholders regarding both clinical trials and emerging health technologies – for example, via a searchable online database such as the Medicines Australia clinical trial portal. The database should be updated regularly, with relevant notifications given to the stakeholders.

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Shaping Healthcare Together and Broadening the Evidence

Shaping Healthcare Together is an annual roundtable series that is convened by BMS Australia, together with patient advocacy groups. The October 2021 Roundtable focused on horizon scanning in Australia. BMS partnered with strategic consultancy, Biointelect, to conduct research into the horizon scanning landscape locally and internationally. This research helped to inform the roundtable discussion.

Following broad community consultation in 2019, BMS launched the Broadening the Evidence report which outlined nine key recommendations for enhancing patient engagement in the Australian HTA process. Recommendation 9 was to improve horizon scanning to facilitate understanding of pipelines and associated impacts on the healthcare system for patient advocates.

BMS Australia is committed to initiatives that support the role of consumers, as exemplified through these recent initiatives under the umbrella of the Broadening the Evidence project.







Introduction to horizon scanning

Both within Australia and internationally, the healthcare landscape is rapidly evolving in response to innovations in the way we diagnose, treat and manage disease (2) (3) (4). The evolution of precision medicine and genomics has revolutionised the clinical management of various cancers. For example, molecular profiling is now an important consideration in the treatment and management of non-small cell lung cancer (NSCLC) – creating opportunities to utilise targeted therapies and personalised treatment approaches (5). Meanwhile, innovative immunotherapies have significantly increased the survival rates for certain cancer types by utilising a patient’s own immune system to fight the cancer (6). CAR-T cell therapies and gene therapies with curative potential have created significant disruption, not only to the way we treat certain conditions, but also to the healthcare services responsible for delivering them (3).

These developments are continuing to challenge, not only the way different diseases are treated, but also traditional pathways for therapeutic development, regulatory process, HTA, reimbursement processes and delivery. For example, potentially curative cell and gene therapies may necessitate innovative approaches to HTA in order to account for uncertainty in terms of long-term clinical benefit (7). Novel delivery models may also be required to effectively bring these products to patients (4). Compounding these challenges, innovative technologies are often associated with significant additional costs and budget impact (8) (9).

Appropriate and timely access to new technologies is a key factor in an efficient, equitable and sustainable healthcare system. There is a need for stakeholders throughout the healthcare ecosystem to understand which potentially disruptive therapies or technologies in development are on the cusp of reaching the market such that they can prepare accordingly.

What is horizon scanning?

Horizon scanning refers to the process of systematically identifying and evaluating new or emerging health technologies in order to identify their potential impact on healthcare systems and stakeholders, or to expedite access to these technologies (10). It is often undertaken to help policymakers, payers and healthcare providers prepare for disruptive, emerging technologies (10). The horizon scanning process may seek to answer questions such as:

- In 5 years' time, will this condition continue to be treated in hospital or at the family doctor?
- When can we expect new treatments for this disease, and will they change the way it is managed?
- Do we need to plan for expanding our services in the future because of rising caseloads?
- Do we think that better diagnostics will come soon that allow for earlier detection?

Horizon scanning is all in the name: keeping an eye on the future for upcoming change. Understanding future medicines, devices and diagnostics helps shape policy, regulation, approvals and stimulate research activity. NIHRIO (11).

Most horizon scanning processes follow a similar series of steps (10) (12):



The horizon scanning process varies between countries, jurisdictions and institutions in accordance with the priorities and objectives of the relevant stakeholders involved in the process. Key variables include (10) (12):

Scope

- The scope determines the type of technologies captured in the horizon scanning process. In some countries, like Canada, the scope includes medical devices and health technologies, whereas the NICE horizon scanning process in the UK also includes pharmaceuticals and cell and gene therapy products.

Purpose

- The aim of the horizon scanning process will shape the information captured and the way this is subsequently utilised. For example, HTA bodies might undertake horizon scanning to predict the impact of new technologies on relevant healthcare expenditure, while patient advocacy organisations may undertake horizon scanning to help inform their patients of potential treatment options or clinical trials.

Timeframe or time horizon

- A short-term (up to 5 years) or a long term (> 5 years) approach can be taken to horizon scanning. The timeframe will dictate which technologies are captured for consideration, and their degree of maturity during evaluation.

Intended audience or target end-users

- The outputs of horizon scanning can be utilised by a broad range of stakeholders. The intended end-user typically dictates the type of information captured and how this is subsequently disseminated.

The benefits of horizon scanning

Horizon scanning has the potential to improve forward planning and preparation for new health technologies for a broad range of stakeholders, which, in turn, can support accelerated patient access.

Government- or payer-driven horizon scanning processes have been established within the context of HTA processes to proactively identify upcoming therapies for assessment and to understand their potential budgetary impact. Horizon scanning is, however, conducted by a broad range of stakeholders with varying objectives, and may therefore be associated with a range of benefits for different stakeholders as outlined in Table 1.

Table 1: Overview of how different stakeholders stand to benefit from horizon scanning

Healthcare stakeholder	Potential benefits of horizon scanning
Governments and ministries of health	Help support the effective and appropriate establishment of priorities and budgets – thereby ensuring the healthcare system is appropriately resourced for the future.
Hospitals and healthcare systems	Facilitates the proactive identification of services and facilities that will meet the future needs of patients.
Payers and HTA	Ability to plan for upcoming assessments of new medicines and potential budget impact for those reimbursed.
Advocates and patient groups	To understand the future needs of their community and facilitate access to clinical studies or new treatments / models of care.

International examples of horizon scanning

There are many examples of horizon scanning processes across the globe, ranging from less formal or ad hoc scanning of the landscape, through to more formalised, well established, processes which directly impact access to new technologies or therapies.

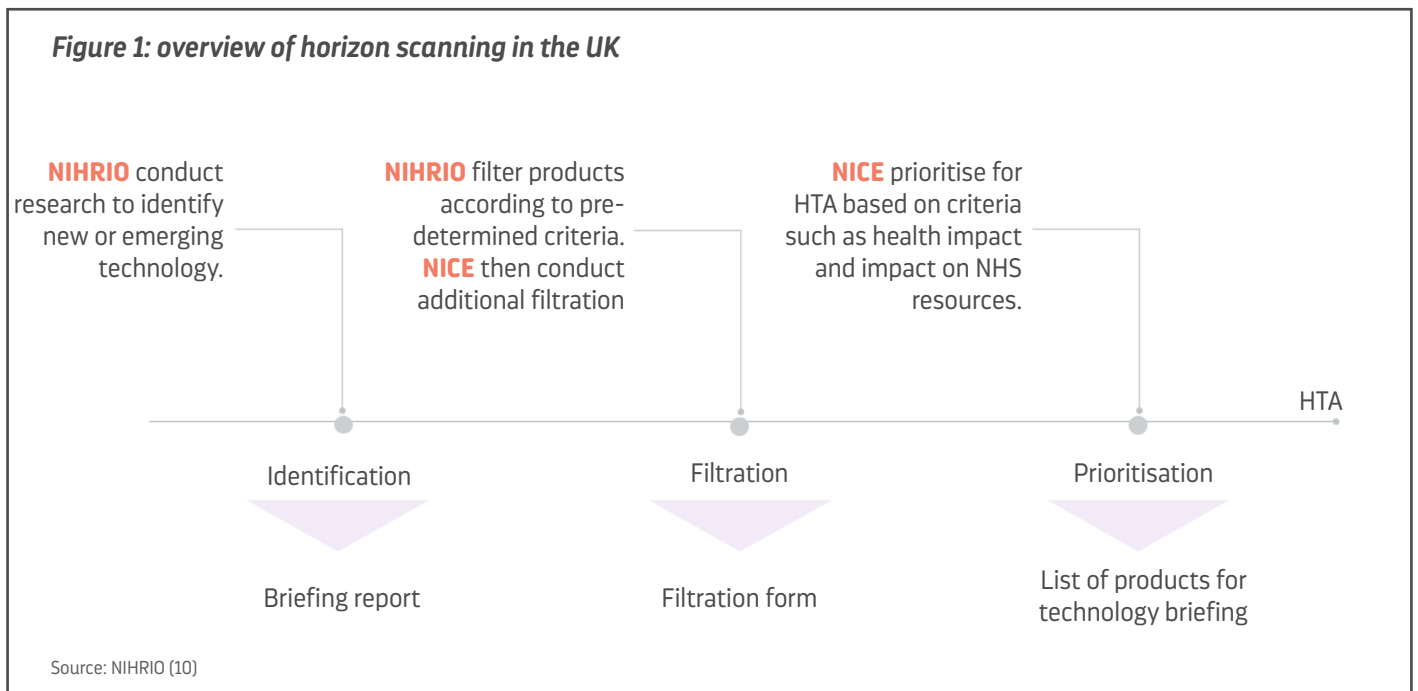
Horizon scanning in the UK

In England, horizon scanning is considered the first step in the “technology appraisal” (HTA) process for new therapeutic products and is described as Industry’s gateway to NICE (11). The NIHRIO is an independent body based at Newcastle University that is contracted to conduct horizon scanning and gather information on emerging health technologies that are expected to have a significant impact for patients or healthcare services

(11). Information is collected from a range of sources including from industry (via the PharmaScan database and other interactions with companies), data systems which scan for open and confidential data sources, trial registries, scientific literature and regulatory agencies (10).

Horizon scanning has two main roles:

- For NICE, “to identify, filter, monitor and produce technology briefings for all innovative technologies that meet the NICE criteria and are within 5 years of an estimated UK license date”. NICE then undertakes additional filtration and subsequent prioritisation for HTA based on criteria such as significance of health benefit, variation in use and added value.
- For NHS England’s Accelerated Access Collaborative, to conduct proactive scanning and produce bespoke reports about new technologies that are being considered for investment and adoption (11).



Patient involvement in the horizon scanning process

The NIHRIO and NICE are actively seeking to strengthen patient input within the horizon scanning process and have implemented the following initiatives (11):

- A patient and public involvement arm throughout the HTA process (NICE)
- Input sought from patients and patient advocacy groups to help the NIHRIO understand patient and carer perspectives to support priority setting
- Knowledge exchange workshops with patients and caregivers to help inform them of the research landscape
- The development of reports and outputs that are suitable for dissemination amongst patients
- Partnership with Valuing Our Intellectual Capacity and Experience (VOICE)

The NIHRIO have also implemented the Imagine Series – a series of workshops conducted with stakeholders including patients, caregivers, clinicians and healthcare providers. These workshops are typically targeted

with a focus on a specific disease or therapeutic area. Participants are presented with an overview of the landscape of new technologies in development, along with any relevant evidence, from which the goal is to identify potential gaps in research and the evidence base (11). The outputs are subsequently utilised by NIHRIO to shape their horizon scanning research.

In the UK, horizon scanning has been in place for over 20 years (10) but primarily as a means of informing payers and healthcare providers of upcoming technologies. As a result, relevant outputs such as the NIHRIO's reports, have been developed with these end-users in mind. Though publicly available, it is recognised that reports may not be easily accessible to patients or the public, as they discuss and analyse complex clinical trial information. NIHRIO and NICE increasingly recognise that a broader range of stakeholders, including patients and members of the general public, have the potential to meaningfully contribute to the horizon scanning process, and utilise the outputs to inform their activities. This has led to the establishment of various initiatives, such as those described above, which seek to better incorporate patients into the process.

Horizon scanning by PCORI in the US

The Patient-Centred Outcomes Research Institute (PCORI), in the US also conducts horizon scanning. Unlike the UK system which is strongly tied to the HTA process, PCORI's horizon scanning system has been designed primarily to inform patients and caregivers of therapeutic advancements (13).

PCORI conduct horizon scanning in a number of targeted focus areas including Alzheimer's disease and dementia, cancer, cardiovascular disease, COVID-19, mental and behavioural health and rare diseases (13). The results are captured in a horizon scanning database as well as a series of reports that are publicly available online (13).

Figure 2: PCORI horizon scanning



Source: PCORI (13)

Shortfalls of existing horizon scanning

Though horizon scanning has the potential to positively shape the healthcare landscape and patients' access to innovative therapies, existing processes and systems are associated with a number of limitations. Of particular concern is the highly fragmented nature horizon scanning, both at a local and international level. At present, there are many systems in place, all with various goals and different approaches to horizon scanning. This results in significant duplication of effort and poor utilisation of limited resources – with many organisations conducting their own horizon scanning without interacting with others undertaking the same work.

This could be better addressed with a higher level of collaboration and transparency between those who are already conducting horizon scanning.

Key Takeaways



Horizon scanning involves the proactive identification and assessment of innovative health technologies to understand the potential impacts on patients and the broader healthcare system.



Horizon scanning may be undertaken by a broad range of stakeholders from across the healthcare ecosystem, and there are currently a range of different organisations conducting horizon scanning around the world.



Each organisation conducting horizon scanning must prioritise its efforts for maximum impact, by defining objectives, scope, time horizon and target audience – this may include focusing on areas of high unmet need and potential for high impact on patients or the healthcare system, or by focusing on specific conditions, therapeutic areas or technology types.



The role of patients and patient advocacy organisations in horizon scanning is evolving and there are international examples of reports that are produced with the objective of informing patients (PCORI, US) and processes that incorporate inputs from patients and other stakeholders (NIHRIO, UK)



Highly fragmented horizon scanning at a global level results in inefficiencies and creates challenges for stakeholders in interpreting reports produced by different organisations with different scopes, purposes and methodologies.







Horizon scanning in Australia

In Australia there is no “formal” horizon scanning process for new health technologies that is comparable to the process conducted by NIHRIO and NICE in the UK. In 2003, the Australian and New Zealand Horizon Scanning Network (ANZHSN) was established under the MSAC, with the subcommittee HealthPACT responsible for its operation (14). This has subsequently been discontinued.

HealthPACT’s horizon scanning was designed to provide advance notice of significant new and emerging technologies to health departments in Australia and New Zealand and to exchange information on and evaluate the potential impact of emerging technologies on their respective health systems.

The insights captured during this process were primarily used to inform financial planning and decisions amongst state governments and healthcare providers like public hospitals (10). The effectiveness of HealthPACT’s horizon scanning has previously been called into question, with a review conducted by O’Malley et al. suggesting that the process had minimal impact when it came to proactively identifying technologies that would be required to undergo MSAC evaluation (14).

HealthPACT sat within the Council of Australian Governments (COAG) framework which was replaced in 2020 by the National Cabinet. As part of this process, a review into all COAG former councils and forums was announced. It remains unclear what impact this will have on HealthPACT and the future of its horizon scanning process (15).

The Strategic agreement between Medicines Australia and the Commonwealth Government

In 2021, Medicines Australia and the Commonwealth Government announced a 5-year Strategic Agreement, which includes a commitment to an annual horizon scanning forum (1). The aim of this process will be :

- To identify major therapeutic advances anticipated to enter the regulatory and reimbursement process within the following 18-24 months and which have the potential to disrupt existing treatment paradigms or healthcare systems.
- To ensure that the Commonwealth understands the potential financial, resourcing and system implications of these products.

Ultimately, this process aims to cultivate a greater understanding of new and emerging medicines and technologies with a view to accelerating access to these for Australian patients (1). This horizon scanning process remains in its infancy and the scope and outputs are yet to be fully defined; however, the intent is to focus on medicines/therapeutics and be targeted to those that are likely to be disruptive.

This implies that the intention is related to HTA and, potentially, implementation planning. There should be opportunities to broaden this scope to address the needs of other stakeholders.

Horizon scanning insights from Australian patient advocacy organisations

Horizon scanning within a therapeutic area is already an important component of the work conducted by some patient advocacy organisations. It allows organisations to understand potential opportunities for, and the needs of, their communities. It can also help to empower patients with the knowledge and language relevant to their ongoing care such that they can actively participate in their own healthcare.

In 2021, BMS Australia conducted its annual Shaping Healthcare Together Roundtable, with a focus on horizon scanning. The roundtable included representatives from 25 patient advocacy organisations to discuss their perspectives and experiences with horizon scanning in Australia.

The roundtable revealed that Australian patient advocacy organisations gather information from a broad range of sources to conduct their own horizon scanning, most notably healthcare practitioners (HCPs) and HCP organisations, as well as scientific advisory boards. Other sources of information include medical journals, conferences, other patient advocacy groups and government sources.

The pharmaceutical industry was also widely seen as a good source of information, but concerns were raised regarding the inconsistent interpretation of the Medicines Australia Code of Conduct by different companies. For example, where some interpret the code as permitting the sharing of medical information with patient

advocacy organisations, others view such groups as “consumers” and, as such, are restricted in what they can share. These inconsistencies resulted in varying levels of information that was provided and when information was provided.

- Despite the widespread recognition of the importance of horizon scanning amongst patient advocacy organisations, a number of barriers to these activities were also identified. These included:
- Finding and interpreting existing information sources
- Lack of Australian-specific publicly available data
- Capacity and resourcing to conduct horizon scanning activities
- Lack of a centralised body or hub to support of host horizon scanning in Australia and subsequent fragmentation of activities

Case study: Introduction of CAR-T cell therapies in Australia

The consequences of inadequate forward planning are illustrated by Australia’s experience with the arrival of the first CAR-T cell therapies (CAR-T), which challenged the existing HTA and reimbursement pathways. CAR-T cannot be clearly classified as a medicine, a device or a service, but rather as a combination of all of these (16).

Patient access to Australia’s first CAR-T (tisagenlecleucel), for acute lymphoblastic leukaemia, was delayed for a number of reasons including (17):

- › Need to develop new arrangements for shared funding responsibilities (between the Commonwealth and state/territory governments) and associated contracting
- › Need to ensure healthcare system preparedness for implementation, including the
- › Establishment of appropriate delivery model, development of quality management and increased workforce capacity.

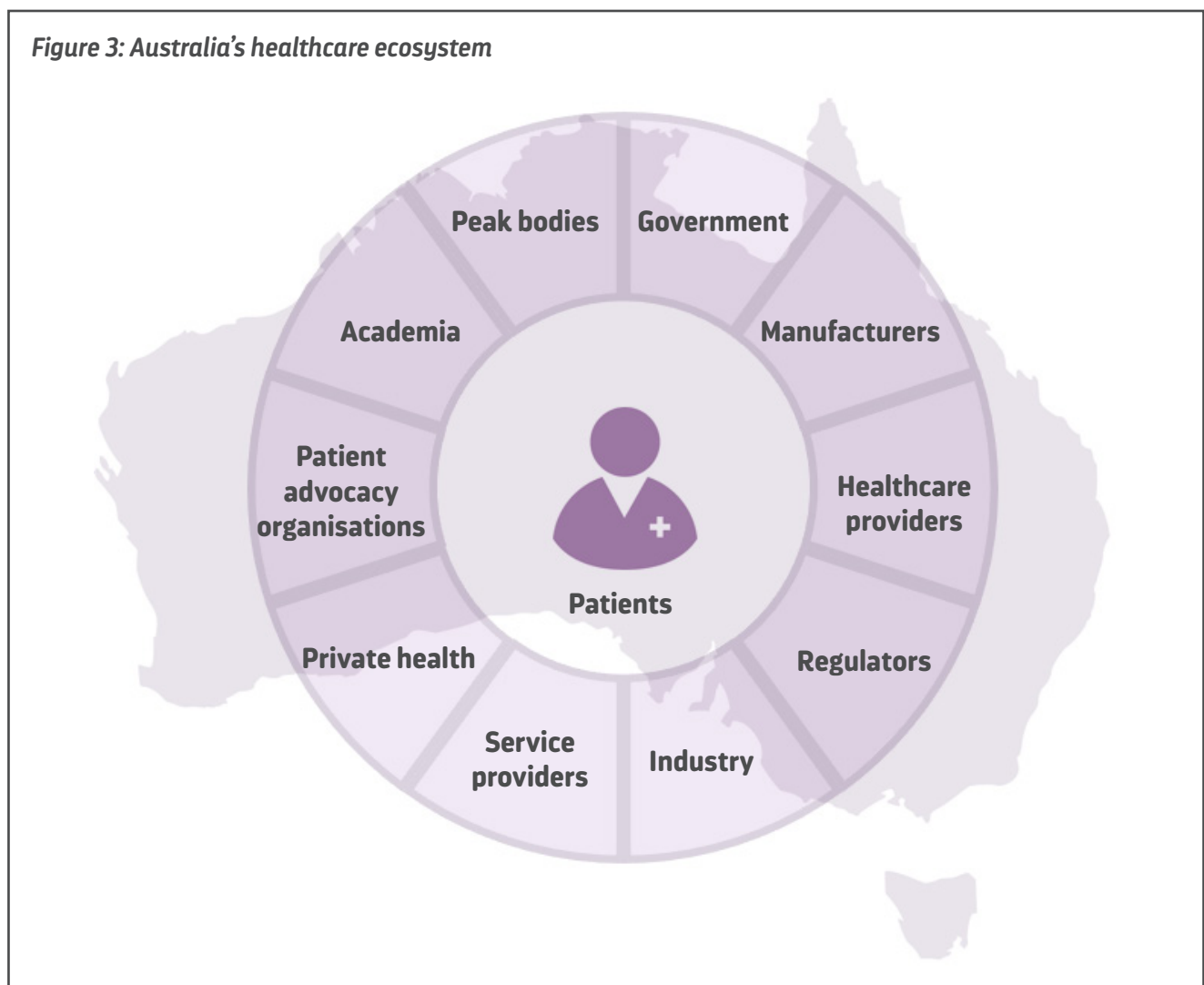
These barriers ultimately delayed access to CAR-T for Australian patients with life-threatening conditions, whose only alternative was to travel overseas to access therapy at a cost of over \$500,000 (21).

In 2020, MSAC made a positive recommendation for the funding of a second CAR-T (axicabtagene ciloleucel). Uncertainty in the clinical data available at the time of HTA, coupled with concerns over potential budget impact, contributed to restrictions on patient access, conditions on funding criteria and the requirement for a re-review after two years (23).

Strengthening horizon scanning in Australia

The Australian healthcare ecosystem

Australia's healthcare ecosystem is diverse and consists of a broad range of stakeholders who contribute in varying ways to the lifecycle of a therapy, from discovery through to use in the clinic. Effective horizon scanning has the potential to benefit a broad range of stakeholders despite each having different objectives. It is therefore important to consider horizon scanning within the context of Australia's broader healthcare ecosystem.



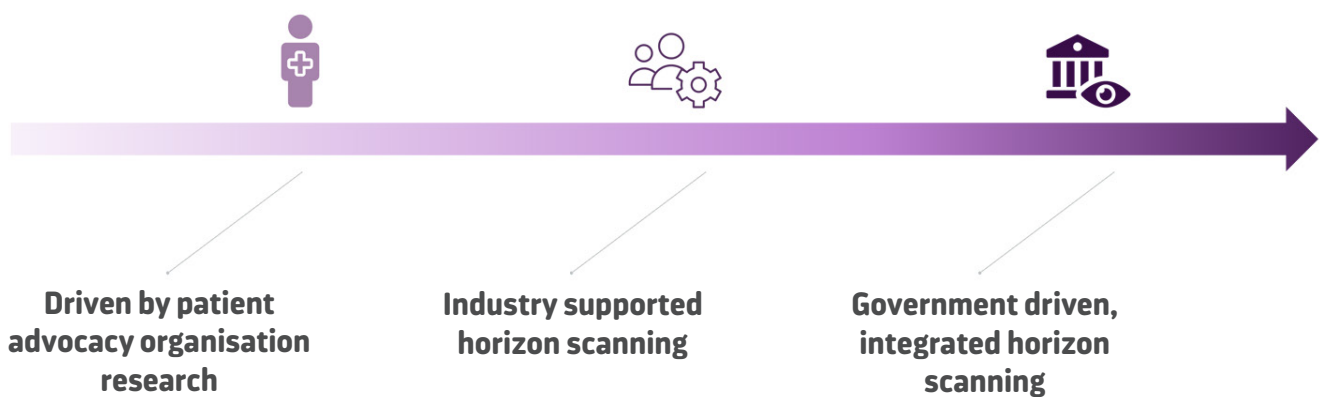
The ways in which various stakeholders can both contribute to, and benefit from, effective horizon scanning are outlined in Table 2 below.

Table 2: Overview of horizon scanning opportunities for different stakeholders

Stakeholder	Opportunity to contribute to horizon scanning	Opportunity to benefit from horizon scanning
Patients and patient advocacy organisations	<ul style="list-style-type: none"> ▪ Providing valuable insight into unmet need and important clinical and non-clinical outcomes 	<ul style="list-style-type: none"> ▪ Empowered with knowledge of future treatment options, including access to clinical trials, as well as enabling better preparation to contribute to HTA processes.
Government and Payers	<ul style="list-style-type: none"> ▪ Insight into reimbursement landscape and HTA process / considerations ▪ Technology evaluations ▪ Insight into existing treatment / hospital landscape 	<ul style="list-style-type: none"> ▪ Effective and appropriate allocation of resources ▪ Proactive establishment of appropriate pathways to support introduction of innovative therapies
Healthcare providers	<ul style="list-style-type: none"> ▪ Insight into existing treatment / hospital landscape ▪ Technology evaluations 	<ul style="list-style-type: none"> ▪ Effective and appropriate allocation of resources ▪ Proactive establishment of appropriate pathways to support introduction of innovative therapies
Industry	<ul style="list-style-type: none"> ▪ Insight into pipeline and upcoming therapies 	<ul style="list-style-type: none"> ▪ Improved understanding of patient needs and future treatment pathways ▪ Efficient navigation of path to market – accelerating time to patient access.
Clinicians	<ul style="list-style-type: none"> ▪ Insight into existing clinical practice and unmet need 	<ul style="list-style-type: none"> ▪ Empowered with knowledge of potential clinical trials and treatment options
Researchers	<ul style="list-style-type: none"> ▪ Insight into research landscape and opportunities 	<ul style="list-style-type: none"> ▪ Ability to shape research priorities to meet areas of unmet need

Opportunities for horizon scanning in Australia

As outlined throughout the report, there are many different approaches which could be considered in order to strengthen horizon scanning in Australia. These can be considered across a spectrum, ranging from more informal stakeholder initiatives through to formalised, government-driven processes. While roundtable participants agreed that a systematic and fully integrated system may be considered the optimal solution, there are also opportunities to strengthen and consolidate much of the work that is already underway throughout the ecosystem.



Opportunities for patient advocacy and non-government organisations

Australian patient advocacy organisations are already conducting horizon scanning activities, although the scope, purpose and level of sophistication varies between different organisations based on their capabilities and resourcing. A coordinated and centralised horizon scanning process would level the playing field across organisations and enable research and analysis conducted by other organisations to be consolidated.

The existing work undertaken by patient advocacy organisations could be strengthened by:

- Mapping existing activities and work underway throughout the landscape. This would provide a picture of what is already happening and create an opportunity to address duplication of effort through consolidation where possible.
- Highlighting potential benefits, with a view to encouraging patient advocacy organisations that are not currently involved in horizon scanning to participate.
- Identifying synergies and opportunities for collaboration across relevant organisations, both locally and internationally.
- Contributing to broader horizon scanning efforts in Australia, such as the annual horizon scanning forum.

Opportunities for the Medicines Industry

Horizon scanning supported by the medicines industry could be utilised as a potential ‘interim’ approach to government driven, integrated horizon scanning which is likely to take time to evolve and implement. An

effective, industry driven, approach to horizon scanning should include:

- A review of the 2022 horizon scanning workshop (committed to in the 2021 Strategic Agreement between Medicines Australia and the Commonwealth).
- Effective and proactive collaboration with patient advocacy organisations to ensure the patient voice is included and elevated.
- Consultation with clinicians and researchers Strong collaboration with government to ensure that interim, short term steps taken can be leveraged in future horizon scanning processes

It should be noted that regulatory and Medicines Australia Code of Conduct restrictions constrain this opportunity due to rules around off label and direct to consumer conversations. Third party involvement would likely be required to conduct research, collate and share information for consumer audiences.

Opportunities for Government

A government driven, formalised horizon scanning process has the greatest potential to strengthen horizon scanning in Australia. This should be established with the following taken into consideration:

- Though government driven, activities should be inclusive of all voices from throughout the healthcare ecosystem.
- Opportunities to leverage steps taken to strengthen horizon scanning
- Independent third parties may be best placed to conduct horizon scanning. An example of this approach is the role the NIHRIO play in the UK.
- Research conducted to inform horizon scanning should capture input from a broad range of stakeholders. Research to capture information could include surveys, workshops or similar.
- Patients should be central to horizon scanning and processes should be built around the elevated role of patients as the principal beneficiary of any new therapies or treatments.
- The outputs of horizon scanning processes should be designed to meet the needs of a broad range of stakeholders to ensure maximum impact.

Horizon scanning is widely recognised as having considerable value to Australia's medicines processes. It will be critical to secure the necessary funding required to facilitate a streamlined, consistent and inclusive approach to horizon scanning in the near future.

Conclusion

Horizon scanning for innovative medicines and technologies has the potential to support the activities of a broad range of stakeholders throughout the healthcare system including the government, industry, patients and patient advocacy organisations. In Australia there is no formalised horizon scanning process for new medicines and scanning for innovative technologies, formally carried out by HealthPACT, has been found to be ineffective. Patient advocacy organisations conduct a range of horizon scanning activities but face a number of barriers – particularly around capacity and capability.

There is an opportunity to strengthen horizon scanning in Australia to ensure that stakeholders throughout the ecosystem are empowered with the knowledge to effectively prepare for the arrival of new medicines or technologies. This being the case, Australia should work to establish a systematic and inclusive horizon scanning process for new health technologies. Here there's an opportunity to leverage existing activities in this space, such as the planned annual horizon scanning forum outlined in the latest Strategic Agreement, to help work towards establishing a gold standard horizon scanning system in Australia.

References

1. Medicines Australia . Strategic Agreement 2022-2027. Medicines Australia . [Online] 2021. [Cited: 11 November 2021.] <https://www.medicinesaustralia.com.au/policy/strategic-agreement-2022-2027/>.
2. Optimizing Precision Medicine for Public Health . Bilkey G., Burns B., et al. . s.l. : Frontiers in Public Health , 2019. <https://doi.org/10.3389/fpubh.2019.00042>.
3. Hillel A., Haderi A., Steele R. Curative cell and gene therapies and healthcare system disruption . European Pharmaceutical Review. [Online] 20 May 2021. [Cited: 25 November 2021.] <https://www.europeanpharmaceuticalreview.com/article/154305/curative-cell-and-gene-therapies-and-healthcare-system-disruption/>.
4. Delivering cellular and gene therapies to patients: solutions for realizing the potential of the next generation of medicine. Elverum K., Whitman M. 27, s.l. : Gene Therapy, 2020, Vols. 537–544.
5. Precision Medicines in Non-Small Cell Lung Cancer: Current Standards in Pathology and Biomarker Interpretation . Brown N., Aisner D. et al. . s.l. : American Society of Clinical Oncology , 2018, Vol. Volume 38.
6. Advances in cancer immunotherapy 2019 - latest trends. Kruger S; et al. 268, s.l. : Journal of experimental and clinical cancer research, 2019, Vol. 38.
7. Estimating the clinical pipeline of cell and gene therapies and their potential economic impact on the US healthcare system . Quinn C., Young C., Thomas J., Trusheim M. 6, s.l. : Value in health, 2019, Vol. 22.
8. Budget impact and cost-effectiveness: can we afford precision medicine in oncology. Doble B. 245, s.l. : Scandinavian Journal of Clinical and Laboratory Investigation , 2016, Vol. 76. <https://doi.org/10.1080/00365513.2016.1206437>.
9. Estimating the financial impact of gene therapy. Wong C., Li D., Wang N., et al. . s.l. : MedRxiv, 2020. <https://doi.org/10.1101/2020.10.27.20220871>.
10. Facing the dynamics of future innovation: the role of HTA, industry and health system in scanning the horizon. Oortwijn W . 2018, HTAi Policy Forum Scientific Secretary 2017.
11. NIHR Innovation Observatory. Who we are and what we do. NIHR Innovation Observatory. [Online] 2021. [Cited: 25 November 2021.] <https://www.io.nihr.ac.uk/what-we-do/>.
12. KCE . Horizon scanning for pharmaceuticals: proposal for the BENELUXA collaboration . s.l. : KCE, 2017.
13. PCORI. PCORI health care horizon scanning system. PCORI. [Online] 2019 June 2019. [Cited: 25 November 2021.] <https://www.pcori.org/impact/evidence-synthesis/pcori-health-care-horizon-scanning-system>.
14. Horizon scanning of new and emerging medical technology in Australia: its relevance to Medical Services Advisory Committee health technology assessments and public funding . O'Malley S., Jordan E. s.l. : International Journal of Technology Assessment in Health Care, 2009, Vol. 25:3. doi:10.1017/S0266462309990031.
15. Evohealth. Cell and Gene Therapies: Rising to the Challenge. s.l. : Evohealth, 2021.
16. Australian Government, Department of Health. Strategic Agreements with the Medicines Industry . The Pharmaceutical Benefits Scheme. [Online] 7 September 2021. [Cited: 21 March 2022.] <https://www.pbs.gov.au/info/general/medicines-industry-strategic-agreement>.
17. Evo Health . Cell and gene therapies rising to the challenge. s.l. : Evo Health , 2021.
18. BioPharma Dispatch. BioPharma Dispatch. The long wait over for Gilead's CAR-T therapy. [Online] 5 August 2021. [Cited: 20 November 2021.] <https://pharmadispatch.com/news/the-long-wait-over-for-gileads-car-t-therapy>.
19. Brodie M. Will CAR-Ts break the health budget. s.l. : Pharma in Focus, 17 February 2020.
20. —. Kyriah deal done says Hunt . s.l. : Pharma in Focus, 28 January 2020.
21. Medicines Australia . Federal government takes first major step in adopting new wave of personalised medicine for Australian patients . Medicines Australia . [Online] 2019. [Cited: 29 November 2021.] <https://www.medicinesaustralia.com.au/media-release/federal-government-takes-first-major-step-in-adopting-new-wave-of-personalised-medicine-for-australian-patients/>.
22. Greg Hunt MP. Novel life-saving cancer therapy now available in Australia . Greg Hunt. [Online] 15 April 2019. [Cited: 29 November 2021.] <https://www.greghunt.com.au/novel-life-saving-cancer-therapy-now-available-in-australia/>.
23. Medical Services Advisory Committee. Public Summary Document. Application No. 1519.1 - Tisagenlecleucel (CTL019) for treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL). s.l. : Australian Government , 2019.



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