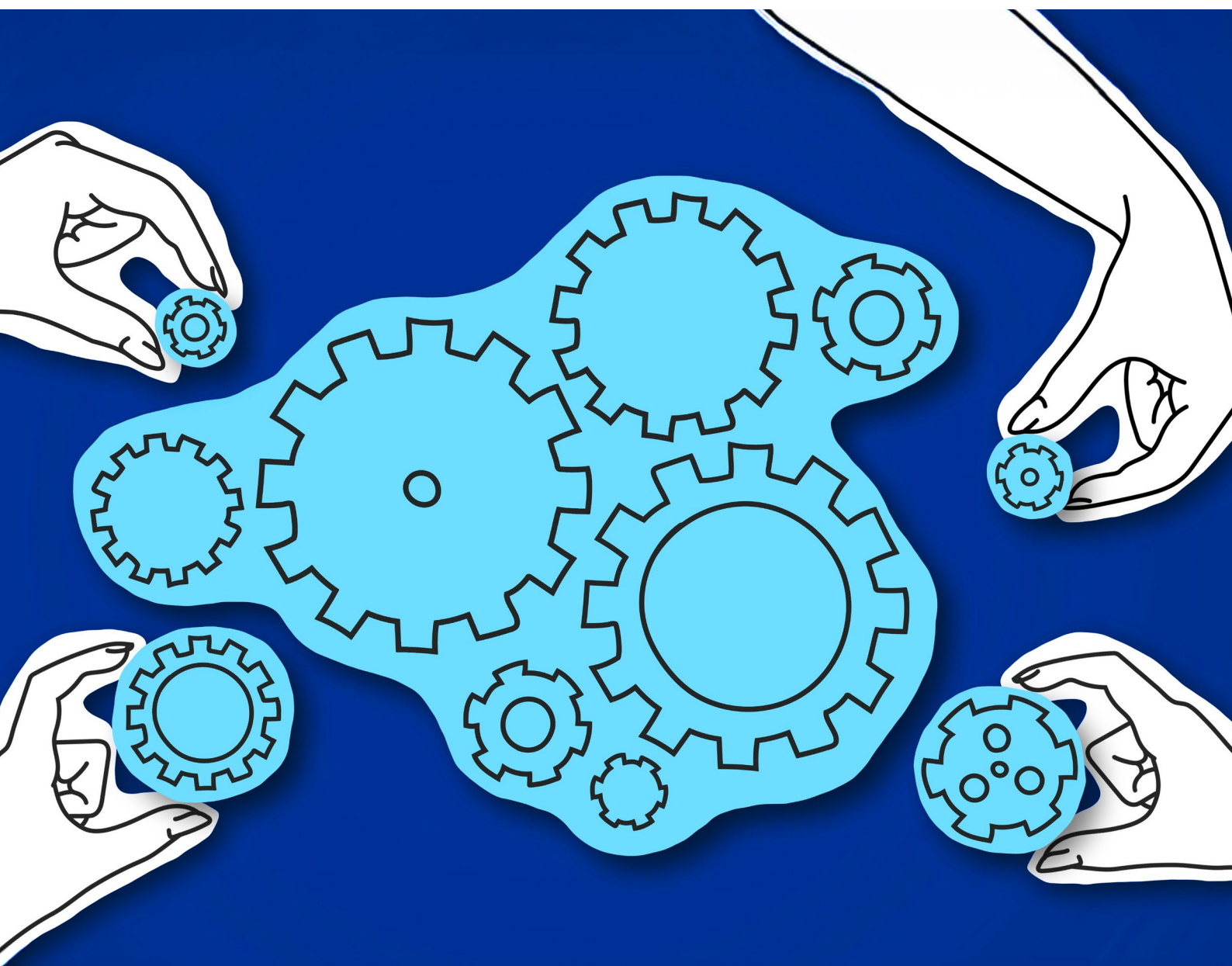


Shaping Healthcare Together:

Patients, Policy & Productivity



2025 Patient & Parliament Summit

Summary

2025 PATIENT & PARLIAMENT SUMMIT

Shaping Healthcare Together: *Patients, Policy & Productivity*

Bristol Myers Squibb Australia (BMS) is committed to working collaboratively with patient communities to shape health policy that improves the healthcare ecosystem and provides improved outcomes for Australian patients.

The fourth annual Patient & Parliament Summit convened this October in Canberra brought together healthcare stakeholders, including 50 patients and patient organisation representatives to discuss the Summit theme of **Shaping Healthcare Together: *Patients, Policy & Productivity***. We focused on the link between healthcare reform and national productivity to demonstrate that timely access to innovative medicines is both a patient necessity and an economic advantage. We also reflected on the opportunities for reform in relation to the implementation of the Health Technology Assessment (HTA) Policy and Methods review and Enhance HTA report recommendations and the importance of patient and consumer evidence.

The Summit included the following key elements:

- A luncheon hosted by the Parliamentary friends of Medicines and Medtech with a Policy Panel; Productivity Lab: A National Conversation on Patients, Policy & Performance
- Meetings with 16 Members of Parliament
- The Shaping Healthcare Together roundtable (for patient organisation representatives) which focussed on patient and consumer evidence and how it can support robust HTA decision making

Throughout the Summit we heard from the patient community about the importance of timely access to medicines, the impact treatment access can make on their lives, and in turn the productivity of Australians. A strong theme throughout the three days of discussions focused on the need for progress to ensure healthcare decision making is underpinned with consideration of the patient voice and lived experiences. The Honorable Mark Butler, Minister for Health and Aged Care, spoke at the Parliamentary Friends of Medicines and Medtech event and acknowledged the role BMS plays in bringing the voice of patients and industry to parliament and working collaboratively to drive meaningful change.

There continues to be a need for all stakeholders, including government, industry, patient organisations and patients to collaborate, co-create and participate in progress towards healthcare reform.

We look forward to continuing to work with you to that end!

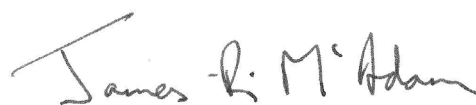
Yours Faithfully,



Owen Smith
General Manager



Hayley Andersen
Director, Patient Advocacy
& Policy



James McAdam
Director, Government Affairs,
Policy & Advocacy

2025 PATIENT & PARLIAMENT SUMMIT

Shaping Healthcare Together: *Patients, Policy & Productivity*

The Patient & Parliament Summit took place in Canberra with a series of events across 3 days, on 7, 8 and 9 October 2025.

Summit Speakers

Hon Mark Butler	Minister for Health and Aged Care
Dr Mike Freeland MP	Parliamentary Friends of Medicine – Co-Chair
Dr Alison Roberts	Commissioner, Productivity Commission
Mr Richard Vines	Co-Founder and Board Director, Rare Cancers Australia
Senator Wendy Askew	Senator for Tasmania (Representing the Hon Melissa McIntosh, Parliamentary Friends of Medicine – Co-Chair)
Jo Watson	Deputy Chair, Pharmaceutical Benefits Advisory Committee (PBAC) Chair, HTA Consumer Consultative Committee
Samantha Maiden	Political Editor for news.com.au
Janelle Bowden	Managing Director, AccessCR





Participants

	Health Care Organisation	Patient representative
	Australia and New Zealand Sarcoma Association Dr Susie Bae Dr Denise Caruso	Julijana Todorovic
	AccessCR Pty Ltd Dr Janelle Bowden Managing Director and Consultant	
	ausEE Inc Sarah Gray Chief Executive Officer	Mardi Storken
	Cardiomyopathy Australia New Zealand Gordon Thoms Director	Leigh Bell
	Crohn's & Colitis Australia Leanne Raven Chief Executive Officer	Kelly Exner

	Health Care Organisation	Patient representative
	Heart Foundation Josh Hodges Head of Advocacy Vanessa Poulsen	Milun Spasov
	Heart Support Australia Dr Christian Verdicchio Chief Executive Officer	Tristan Clow
	Head & Neck Cancer Australia Gemma Neary Marketing and Communications Lead	Carolyn Smith
	Hearts4heart Tanya Hall Chief Executive Officer Fiona Clarkson Project Coordinator	Katherine Cook
	Inherited Cancers Australia Robyn Smith Programs and Advocacy Manager	Dr Elle Saber
	Kidney Health Australia Lydia Lauder National Advocacy and Policy Manager	
	Lung Foundation Australia Lily Grigsby-Duffy Policy and Advocacy Lead	Carly Magnisalis
	Melanoma & Skin Cancer Advocacy Network (MSCAN) Tamara Dawson Founder/Director	Ellie Bowley
	Melanoma Institute Australia A/Professor Jonathan Stretch Deputy Director	Dr Michael Armstrong Mary-Anne Armstrong

	Health Care Organisation	Patient representative
	Melanoma Patients Australia Karen Van Gorp Board Director	David Thiele
	MS Australia Katie Snell National Policy Manager	Ebony Moffat
	Pancare Foundation Dr Mark Buzza Head of Research, Innovation and Advocacy	Nicholas Verry
	Patients Australia Lisa Robins Chief Executive Officer	Luan Lawrenson-Woods
Patient Voice Initiative	Patient Voice Initiative Sarah McGoram President	
	Psoriasis Australia Murray Turner Chief Executive Officer	Janean Huntley
	Rare Cancers Australia Richard Vines Founder Jane Weber Senior Policy Manager	Tiffany McIntyre Monika Thompson
SO BRAVE	So Brave – Australia’s Young Women’s Breast Cancer Charity Rachelle Panitz Founder	Aleisha Nemeth
		Heidi Victoria

	Health Care Organisation	Patient representative
 Medicines Australia	Medicines Australia Elizabeth DeSomer Chief Executive Officer Petrina Keogh Strategic Relations Manager Gail Morgan Head of Government Relations Dr Melanie Shakespear Director Policy & External Engagement Sophie Seck Senior Manager, Ethics & Compliance	
 Australian Government Department of Health, Disability and Ageing	Department of Health, Disability and Ageing Liz Marshall Consumer Evidence and Engagement Unit	

Summit Supporters



Meetings with the following Members of Parliament were convened across the Summit

Senator Wendy Askew	Senator for Tasmania
Ms Jodie Belyea MP	Member for Dunkley (post summit)
Ms Alison Byrnes MP	Member for Cunningham
Hon Pat Conroy MP	Member for Shortland
Hon Mark Dreyfus MP	Member for Isaacs
Ms Cassandra Fernando MP	Member for Holt
Ms Alice Jordan-Baird MP	Member for Gorton
Hon Kristy McBain MP	Member for Eden-Monaro
Ms Louise Miller-Frost MP	Member for Boothby
Hon Shayne Neumann MP	Member for Blair
Mr Llew O'Brien MP	Member for Wide Bay
Senator David Pocock	Senator for the ACT
Hon Amanda Rishworth MP	Member for Kingston (post summit)
Ms Sally Sitou MP	Member for Reid
Mr David Smith MP	Member for Bean
Ms Zali Steggall MP	Member for Warringah



Background

- In September 2024 the Commonwealth Government released the Health Technology Assessment (HTA) Policy and Methods Review Report¹ which included 50 recommendations, together with the Enhance HTA report² from the Co-Designed Enhanced Consumer Engagement Process with a further 10 recommendations.
 - » HTA is the system by which Australia determines whether a medicine³ is safe, effective and cost effective and eligible to be listed on the Pharmaceutical Benefits Scheme (PBS).
 - » Both reports recognise the value consumers' (patients') diverse health care experiences, needs, preferences and perspectives bring.
- In November 2024, at the *Patient & Parliament* Summit,⁴ the Honourable Mark Butler announced⁵ the establishment of the HTA Implementation Advisory Group (IAG) to provide strategic guidance on the delivery of reforms recommended in the HTA Policy and Methods Review and Enhanced HTA reports.
 - » The IAG is focussed on recommendations that deliver:
 - Faster access to innovative medicines
 - Enhanced consumer engagement, &
 - Equity pathways for children and underserved populations.
- In September 2025, the IAG's interim report⁶ was published and the Albanese Government announced it is taking immediate actions including:
 - » Developing new ways to streamline assessment of medicines
 - » Reviewing the Pharmaceutical Benefits Advisory Committee (PBAC) guidelines with a focus on discount rate and comparator requirements (ie the existing medicine that a new one is compared to)
 - » Developing greater understanding of high unmet clinical need and high added therapeutic value
 - » An HTA stakeholder engagement framework with a particular focus on improving consumer and patient engagement
 - » Considering specific issues related to medicines for First Nations people at biannual meetings.
- The Commonwealth's Economic Reform Roundtable⁷ in August brought together leaders to shape national priorities on productivity, fiscal resilience, and sustainable growth.
- Healthcare innovation should be highlighted in this conversation given the strong evidence that timely access to treatment drives economic returns.
 - » For example, the 2024 Productivity Commission report, *Advances in measuring healthcare productivity*,⁸ found that, "the biggest contribution to productivity growth has come from advances in saving lives." It further stated, "Productivity grew particularly strongly in the treatment of cancers, suggesting that advances in treatments, rather than across-the-board healthcare reforms, have been the major driver of growth."
- To ensure a future-ready health system, we must act on the HTA Review's policy recommendations and the opportunity for policy reform. Aligning a more productive and fit for purpose system with the government's focus on delivery and productivity will help ensure that our healthcare system serves Australians better—both now and for generations to come.

To ensure a future-ready health system, we must act on the HTA Review's policy recommendations and the opportunity for policy reform.

Connecting Health Reform with National Productivity

As Australia advances the implementation of the HTA Policy and Methods Review and the Enhance HTA report, central to their recommendations is the call for stronger consumer and patient engagement acknowledging that policy decisions should reflect the needs and values of those most affected.

HTA reform is essential to improving health outcomes and strengthening the economy. For example, early retirement due to poor health costs the Australian economy \$65 billion each year, but improved access to effective treatments could reduce that burden by up to 20 percent.⁹ At the same time, broader access to PBS-listed medicines has helped contain hospital costs – without that growth since the 1990s, hospital spending in 2025 would be \$7.4 billion higher.¹⁰

HTA System Challenges and Their Productivity Consequences

For patients with serious illnesses, delays in accessing life-saving medicines are not just numbers on a page, but months of waiting and uncertainty. On average, it takes **466 days**¹¹ for a new medicine to move from TGA approval to PBS subsidy.

Much of the strain comes from within the HTA system itself with outdated comparator selection, inability to appropriately value innovation and challenging processes for appropriate consideration of consumers' perspectives leading to long approval times and delays to patient access.

Shaping Healthcare Together – Ideas to Actions

To support the Australian National Medicines Policy vision¹² (published in 2022) to achieve the world's best health, social and economic outcomes, policy reform is needed that prioritises the patients voice and enables faster and fairer access to innovative medicines.

Policy reform relies on Government focus on two key actions:

1



Implement the HTA Policy and Methods review and Enhance HTA recommendations with patient voices at the centre, by delivering on policy that recognises faster access to innovative medicines as both a patient priority and a driver of national productivity.

2



Implement policy reform that recognises timely access to innovative medicines, such as PBS access within 60 days of TGA approval, as a driver of national productivity by reducing hospital costs, improving workforce participation, lowering early retirement due to illness, and embedding health innovation into budget planning and long-term economic policy.

Shaping Healthcare Together Summit Overview

The Summit included:

- A dinner to welcome patient organisation attendees and their patient representatives included an introduction and overview by BMS's **Hayley Andersen, Director, Patient Advocacy & Policy** and **James McAdam, Director, Government Affairs, Policy & Advocacy**. The evening also included a presentation from **Samantha Maiden, Political Editor for news.com.au**, who provided a unique insight into politics and public affairs as well as taking questions from attendees.
-
- A **Parliamentary networking event** hosted by the **Parliamentary Friends of Medicines and Medtech** provided an opportunity for patient organisations, together with their patient representatives to share their experiences and their organisation's mission with MPs and senators. The **Hon Mark Butler** provided an address that included his commitment to the priorities set out in the Implementation Advisory Group's interim report and accompanying letter as well as recognition of the important role BMS plays in bringing the voice of patients and industry to parliament.

A Policy Panel, the **Productivity Lab: A National Conversation on Patients, Policy & Performance** was moderated by **Owen Smith, General Manager BMSA** and included speakers **Richard Vines, co-founder and Board director, Rare Cancers Australia** and **Commissioner from the Productivity Commission, Dr Alison Roberts**. The panel discussion explored the intersection between health policy, patient outcomes, and economic performance as well as examining how timely access to innovative treatments, supported by a reformed HTA framework incorporating productivity measures, can drive workforce participation, reduce system inefficiencies, and strengthen long-term national prosperity. **Dr Mike Freeland** and **Senator Wendy Askew (representing Mrs Melissa McIntosh MP)**, co-chairs of the **Parliamentary Friends of Medicines and Medtech**, also provided remarks.





- Meetings with **Federal Members of Parliament** were convened for each patient (where possible), together with their patient organisation representative and a BMS representative to discuss the intersection between healthy Australians and a productive Australia and how access to the most appropriate treatment when needed can enable people to get back to their lives and contributing to their community sooner. Implementing reform of the medicines assessment process via the recommendations from the HTA Review is a critical part of delivering on this promise for Australian patients. MPs were provided with information outlining the need for HTA reform to improve access to new innovations and ultimately, improved patient outcomes.
-
- The **Shaping Healthcare Together** roundtable was convened with representatives from 25 patient organisations together with representatives from the **Pharmaceutical Benefits Advisory Committee (PBAC)**, **Department of Health and Aged Care Consumer Evidence and Engagement Unit (DoHA CEEU)** and **Medicines Australia**. BMS recognises the immense knowledge within the patient community and has convened an annual roundtable since 2018 with the aim of bringing together key healthcare stakeholders to discuss shared issues.

At this year's roundtable we explored themes important to earlier and continuous engagement of patient communities in Health Technology Assessment (HTA) processes and the importance of consumer and patient evidence. The roundtable was facilitated by **Hayley Andersen** and discussions were informed by an overview delivered by **Janelle Bowden, Managing Director of AccessCR** that included a review of progress made since BMS's first annual roundtable towards consumer engagement in HTA.

We also heard from **Jo Watson, Deputy Chair of the PBAC** who spoke to the importance of the stakeholder engagement framework for embedding consumer engagement in HTA in ways that suit the Australian environment, defining appropriate two-way feedback mechanisms between HTA bodies and patient groups, and the nuances of patient evidence and its value for enriching

discussion beyond what traditional clinical trials and other data sources can provide. Specifically, its value in providing insights about a condition, how it impacts everyday life, what are the effects of a considered health technology, and issues with accessing it or healthcare in general. Roundtable participants workshopped three key topics (a summary of the workshop is included on page 17):

- » Strengthening Consumer Evidence
- » Prioritising Consumer Engagement Efforts
- » Early Consumer Engagement opportunities, including “The Promise of PICO”

BMS is grateful to all the patients for joining the Summit and for graciously and generously sharing their stories. A few of the patient testimonials provided are below.

“ I was diagnosed with hormone positive breast cancer in 2017. I was extremely fortunate that the drugs I needed for treatment were accessible through PBS. That gave me peace of mind and meant I could focus my precious time and energy on my health and recovery, rather than advocating or raising funds for my treatment. Because being diagnosed with cancer is tough enough. Getting the right healthcare shouldn't be.

Luan Lawrenson-Woods – Breast cancer

“ Affordable PBS access turned survival into a life I recognise. I went from near-zero capacity to returning to work, contributing, and being present with my family. That's the difference timely, evidence-based PBS access makes; restoring health, productivity, and the chance to truly live.

David Thiele – Stage IV metastatic melanoma

“ Ensuring timely access to a broader range of effective Crohn's therapies will turn sick leave into recovery, appointments into productivity, and ultimately, undoubtedly improve both health and employment outcomes. By recognising the productivity toll of uncontrolled disease and empowering patients and their specialists with real treatment choice, we can reduce time in hospitals, restore predictability to the workweek, and help people like me show up consistently for our jobs and those we care for.

Kelly Exner – Severe refractory perianal Crohn's disease

Amplification of voices

Social media provided the opportunity to amplify messaging about the importance of the patient voice and consumer evidence in healthcare decision making and the link between a healthy and productive population.

Patients Australia
2,650 followers
4w · Edited · 🌐

Collaboration sits at the heart of meaningful healthcare reform.

Last week we joined the BMS Patient and Parliament Summit in Canberra – a gathering uniting patients, policymakers, and health leaders to explore how timely access to innovative medicines can improve outcomes and deliver broader benefits for all Australians.

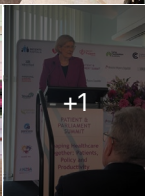
Thank you to **Bristol Myers Squibb** for supporting us to connect with so many dedicated organisations and individuals working towards a stronger, fairer health system, and for providing us with a platform to share our stories with Australia's decision makers.

The conversations across the three days highlighted both the challenges and the shared purpose that drive us all – ensuring patients remain at the centre of every reform.

An extra special thanks to **Luan Lawrenson-Woods** for joining us as our Patient Advocate. We saw first-hand the significant preparatory work, both emotional and administrative, that she put into sharing her experience of breast cancer survivorship and breast reconstruction. Altruism at its finest.

True system reform begins when lived experience is not just told, but really heard – with mind and heart.

#BMSSummit #PatientVoice #HealthReform #Collaboration #PatientCentredC



with Luan Lawrenson-Woods and 4 others

65 Reactions · 5 comments · 4 reposts

ausEE Inc.
536 followers
3w · 🌐

Last week, ausEE Inc., represented by Sarah (ausEE CEO and Founder) and Mardie (patient representative), was pleased to participate in the 4th annual Patient and Parliament Summit in Canberra. ...more



13 Reactions · 1 comment · 1 repost

Patient Voice Initiative
2,822 followers
1mo · 🌐

This week our President, **Sarah McGoram (Fehon) OAM**, joined two days of events in Canberra for the **Bristol Myers Squibb Patient & Parliament Summit**, bringing patients' voices to Parliament.

On Wednesday, hosted by the Parliamentary Friends of Medicine – a Policy Panel, with opening remarks from The Hon Mark Butler MP, Commissioner Alison Roberts, Richard Vines, and Sophie Scamps MP, discussing how access to treatments and therapies and having healthy communities leads to a more productive Australia.

On Thursday, Sarah participated in the Shaping Healthcare Together Policy Roundtable, where 25 patient organisations and policymakers explored priorities for HTA reform, including how best to embed patient input into the process in effective and meaningful ways.

As **Hayley Andersen** of Bristol Myers Squibb noted, "The Patient & Parliament Summit provides an opportunity to progress the critical healthcare decision-making reform agenda. We must continue working together to achieve genuine reform that delivers timely and equitable access to medicines for all Australians. Reform that supports the patient voice is key to ensuring healthcare decision making reflects real experiences, values and priorities."

An insightful and productive few days advancing the conversation of HTA and healthcare reform.



46 Reactions · 5 comments · 3 reposts

Nick Verry · 3rd+
Injury Management Business Partner | Exercise Phys...
1mo · Edited · 🌐

Yesterday I had the absolute pleasure of attending the **Bristol Myers Squibb** annual Patient and Parliament Summit as a patient representative for **Pancare Foundation** at Parliament House in Canberra. ...more



128 Reactions · 10 comments · 1 repost

Melanoma & Skin Cancer Advocacy Network...
1,255 followers
1mo · 🌐

👉 Taking patient advocacy to Parliament House!

A special shout out to Ellie from MSCAN's Community Action Team. Ellie powerfully shared her experience of caring for her mum, who sadly passed away from mucosal melanoma last year.

MSCAN and the patient community are engaged and focused on improving Australia's Health Technology Assessment (HTA) system to ensure the right patients can access the right treatment at the right time.

Thank you **Bristol Myers Squibb** for hosting the annual Patient & Parliament Summit at Parliament House, Canberra. Terrific engagement with parliamentarians and the broader healthcare sector.



33 Reactions

hearts4heart
1,554 followers
4w · 🌐

hearts4heart were thrilled to attend the **Bristol Myers Squibb 4th Annual Patient and Parliament Summit**, uniting patients, policymakers, and health industry leaders in Canberra to build momentum for a stronger, fairer health system in Australia.

♥️ **hearts4heart** Advocate **Katherine Cook** met with Hafiz Jan, Chief of Staff for Holt, to share her story and lived experience, highlighting the critical need for reform that delivers faster and fairer access to medicines.

The Summit included a Policy Panel and Networking event hosted by the Parliamentary Friends of Medicine, featuring The Hon Mark Butler MP, Commissioner Alison Roberts, **Richard Vines**, and Sophie Scamps MP. The discussion focused on how improving access to treatments and fostering healthier communities can help build a more productive Australia.

👉 It also featured the Shaping Healthcare Together Roundtable, which brought together 25 patient organisations and policymakers to explore Health Technology Assessment (HTA) reform priorities and the importance of meaningful stakeholder engagement in shaping future healthcare policy.

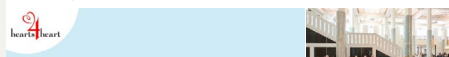
A huge thank you to **Bristol Myers Squibb** and the incredible team who made this event possible. It was an insightful couple of days and a wonderful opportunity to connect with other patient organisations and advocates.

Together, we can drive change that transforms lives and brings hope for the future. ❤️

#PatientAdvocacy #Hearts4heart #HTAReform #Policy #HealthSystem #BristolMyersSquibb #LivedExperience



Katherine Cook - Cardiomyopathy and Heart Failure
"Three years ago, after contracting Covid-19, I was diagnosed with cardiomyopathy and heart failure. I now take six different cardiac medications each day, all listed on the PBS. This means I pay no more than \$30 per script for up to a 60-day supply.
Affordable access to these medications has been life-saving, allowing me to focus on recovery rather than cost.
Thanks to this support, my health has improved enough for me to return to the career I love, nursing and contribute meaningfully to this much-needed workforce in our community."



13 Reactions · 1 comment · 1 repost

Shaping Healthcare Together Roundtable – Summary

Background

It is widely acknowledged that there has been significant progress in patient and consumer engagement in healthcare systems and specifically HTA processes in Australia. It is also clear that more is needed to embed the patient voice in HTA and ensure that healthcare decision making reflects the preferences, values and needs of Australian patients.

Overview

The **Shaping Healthcare Together** roundtable was convened at the Hyatt Hotel in Canberra with representatives from 25 patient organisations together with representatives from the Pharmaceutical Benefits Advisory Committee (PBAC), Department of Health and Aged Care Consumer Evidence and Engagement Unit (DoHA CEEU) and Medicines Australia. The roundtable was facilitated by Hayley Andersen, BMS's Director, Patient Advocacy & Policy.

Jo Watson, Deputy Chair of the PBAC, reflected on three key themes; i) the need for and expectations for a Stakeholder Engagement Framework, ii) mechanisms for two-way feedback between the Department/HTA bodies and patient organisations, and iii) consumer evidence – what it might be, and why it is important.

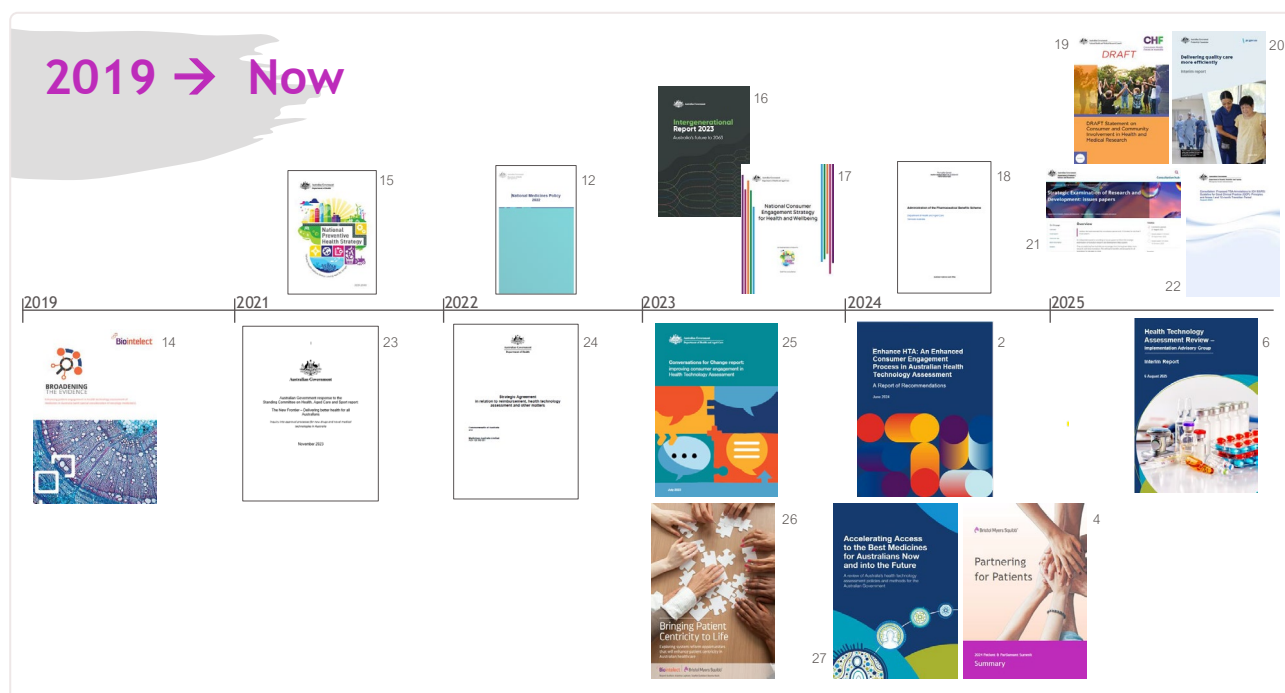
Though the need for consumer engagement in HTA has been well established, and principles for consumer engagement are relatively consistent across policies, there is more work to be done to establish who is responsible and what must be done, how, and when, and to be able to measure and assess progress.

With respect to feedback specifically, there has been an evolution in the approach of the PBAC, from relying on formal feedback through published web outputs to direct interactions. However, these engagements are ad hoc and often particular to the needs of a specific issue, or agenda item of the sponsor. The criteria for such engagements needs to be further defined such that this activity is embedded in the process, and not dependent on item-specific issues or capacity issues.

It was noted that there is a heavy dependence on patient groups and clinicians to provide information and particularly to fill gaps in the information submitted by sponsors. While clinical trials are one source of data, consumer evidence enriches the discussion around a condition, quality of life, outcomes that matter, healthcare practices and access, patient preferences, and the effects of the health technology being assessed, from a patient and family perspective. It helps put the quantitative data into context. Significant work is required to understand what consumer evidence is, how it can be measured and evaluated for HTA, and how it can be used in HTA decision-making. The recent MRFF grant¹³ round is seeking to address some of these questions. Recognising the current limitations and challenges of the collection and analysis of consumer evidence, typically completed 6-8 weeks prior to a PBAC meeting via existing consultation processes, the goal should be for this to occur earlier.

Janelle Bowden, Managing Director of AccessCR provided an overview of the progress made over the past 6 years in consumer engagement. The overview was anchored to recommendations outlined in the 2019 Broadening the Evidence report¹⁴ prepared with the support of Bristol Myers Squibb, noting the evolution in understanding of where the opportunities for greater consumer engagement exist in HTA and additional progress made, as well as where further progress was still required.

DIAGRAM 1: Consumer Engagement Progress



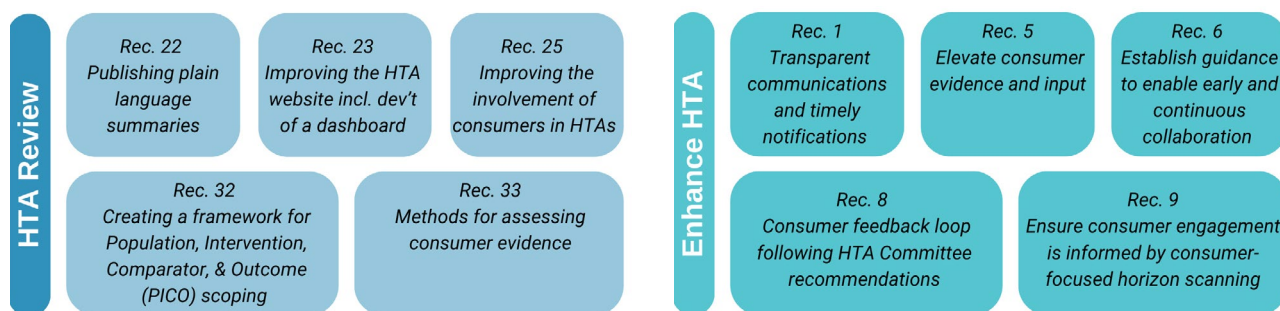
Over the past 5-6 years, there has been a significant amount of policy work and consultation relating to consumer engagement and health – both directly related to HTA (represented below the line in diagram 1), and across other parts of health such as medicines policy (represented above the line in diagram 1).

The 2020 Parliamentary Inquiry into approval processes for new drugs and medical technologies in Australia and the resulting New Frontiers Report was tabled in parliament in 2021²⁸ and provided 31 recommendations, including three specifically related to patient communities (Recommendation 6 – Improving Engagement and Education for TGA and HTA processes; Recommendation 9 – Funding for submissions without a sponsor; Recommendation 28 – considering the patient voice in TGA and HTA processes). The government published their response to these recommendations in November 2023 and included a commitment to ensuring the patient voice was central to health decision making.

Concurrently, the Commonwealth and Medicines Australia signed a 5 year Strategic Agreement²⁴ (which ends in mid-2027) inclusive of plans to work toward improvements in HTA processes to facilitate earlier access for patients to medicines, horizon scanning and new processes to elevate patient and consumer voices in access to medicines.

The HTA Review consultations took place over 2023, and in parallel, the Consumer Evidence and Engagement Unit (CEEU) consulted patient organisations, first through the Conversations for Change²⁵ work (which developed a framework for patient engagement; consumers actively participating, consumers as equal partners, consumers supported and knowledgeable and consumers included in HTA processes and methods). Additionally, the codesign process for enhanced consumer engagement in HTA, a commitment within the Strategic Agreement, was considered by a multistakeholder group across 2023. This resulted in the 2024 Enhance HTA report² with 10 recommendations. The HTA Policy and Methods Review²⁷ also reported in 2024 with 50 recommendations.

The recommendations linked to patient and consumer engagement, evidence and input are highlighted below:



It was noted that the Implementation Advisory Group (IAG) established to advise government on a roadmap for implementing the recommendations from the Reviews were conducting a brief consultation on a draft roadmap²⁹ (see below) at the time of the Roundtable. It was also noted that the draft roadmap outlined significant activities that would lead to greater patient engagement at a number of touchpoints across the reimbursement system.

FOCUS AREA	INITIATIVES	EARLY ACTIONS ANNOUNCED	Year 1	Year 2	Year 3
Access and equity	Embedded First Nations perspectives (rec 1)	Bi-annual stakeholder meetings – specific issues related to medicines for First Nations people	First Nations Advisory Committee established	FNAC work programme finalised	Support for First Nations submissions improved
	Proactive identification of new technologies (rec 47)		Horizon scanning processes mapped, designed and integrated into HTA processes		
	Addressing HUCN (recs 44, 45, 46)	Rapid research into HUCN and HATV	HUCN defined	HUCN identification mechanisms established	HUCN submission incentives identified
	Funding and pricing mechanisms (recs 16, 20, 42)		Current funding mechanisms published	Research conducted on higher pricing usage	New funding framework developed
	Enhanced paediatric access (rec 2)		PBAC and MSAC guideline review of age agnostic approach		Bridging fund need assessed
Modernised assessment pathways	Streamlined assessment (recs 3, 4, 5, 6, 14)	Consultation on trialling new ways to streamline assessment of medicines	Submission decision tree developed	Changes to PBAC committee assessed and implemented	Expanded PBAC role implemented
	Proportionate medicine pathways (recs 7, 8, 9, 41)		Streamlined pathways for submissions piloted	Streamlined approach implemented	
	Proportionate vaccine pathways (recs 11, 12)		New facilitated pathway for HATV piloted	New facilitated pathway for HATV implemented	Expansion of new facilitated pathway for all therapies claiming clinical benefit
	Strengthen cross-governmental HTA co-funding processes (rec 13)		Proportionate pathway for vaccine submissions developed	New processes for proactive vaccine assessment developed and implemented	
	AMR related improvements (rec 21)		National approaches supported and progressed through HTAC and supporting NHRA Negotiations	Outstanding gaps from NHRA assessed	HTA improvements scoped and implemented
	Pathway transparency (rec 19, 36)		Support provided for AMR framework	AMR pathway developed and implemented	
Greater transparency and engagement	Stakeholder engagement	Stakeholder Engagement framework developed	MEAs guidance updated	Therapies targetting biomarkers guidelines updated	MEAs key information agreed and published
	Improving clarity of HTA processes (recs 17, 22, 26, 32, 39, 40)		Plain language capability developed	PICO usage guidelines updated	Mechanisms for PICO transparency developed
	Joint government – industry performance metrics (rec 15)	Rolling review of the PBAC Guidelines prioritising comparator selection and discount rate	Explicit qualitative values framework developed	Guidelines review completed for enhanced consumer input	Pricing policy framework published
			Current pricing processes made available		Timeliness of access to therapies reviewed
Better data and evidence	Data collection and access (recs 27, 28, 29, 30, 31)		Current datasets and RWE associated work programmes mapped	HTA/RWD + Evidence Roadmap developed	RWD usage guidelines updated
	Revising guidelines and supporting information (recs 10, 33, 34, 35, 36, 37)			Guideline review completed for assessing consumer evidence, non randomised and observational evidence and assessing end points	Disease-specific modelling investigated
	Post review framework (rec 18)			Post-review framework developed	
Workforce capacity and capability	Sustained workforce plan (rec 49, 50)		Sustained HTA sector workforce and enabling technology plan developed		
	Visible progress and improvements (rec 48)		HTA improvement reporting processes reviewed		
			Additional mechanisms to increase transparency implemented		

It is noteworthy that the elevation of the consumer voice in HTA is not happening in a vacuum. There is considerable work happening in other parts of the health ecosystem to elevate and incorporate the patient voice. This includes but is not limited to:

- the 2021 National Preventative Health Strategy¹⁵ released and a 2023 draft consumer engagement framework for health and well being,¹⁷ (finalised in 2025)³⁰
- the 2022 National Medicines Policy,¹²
- the National Clinical Trials Governance Framework³¹ that embeds Standard 2, of the National Standards for Quality and Safety in Healthcare, Partnering with Patients.
- the revision of the CHF and NHMRC 2016 joint Statement on Community and Consumer Involvement in Health and Medical Research,¹⁹
- the current development of a National Health and Medical Research Strategy,³²
- development of consumer committees related to TGA work, and
- new international expectations for patient engagement in clinical trials through the revision of ICH Good Clinical Practice (GCP) which the TGA are considering.²²

Across the health ecosystem, the patient voice is being elevated, which is consistent with a lifecycle approach to medicine development and earlier engagement with patient voice. The rate of change, and consultation burden is significant across this lifecycle, and it is critical that all parts of the process are integrated, informed by each other and fit for purpose, if we are to achieve better access to the right medicines, at the right time and place, for patients.

Roundtable discussions explored three topics with a view to contributing to efforts to advance consumer engagement and improve consumer evidence and inputs into HTA. By focusing on strengthening consumer evidence, how and if patient input efforts can be prioritised and opportunities for systematic early engagement of patient communities (specifically considering the PICO process), the Roundtable aimed to contribute to the public discourse on these important topics and provide ideas to support the implementation of the recommendations specific to consumer engagement within the HTA Review and Enhance HTA reports.

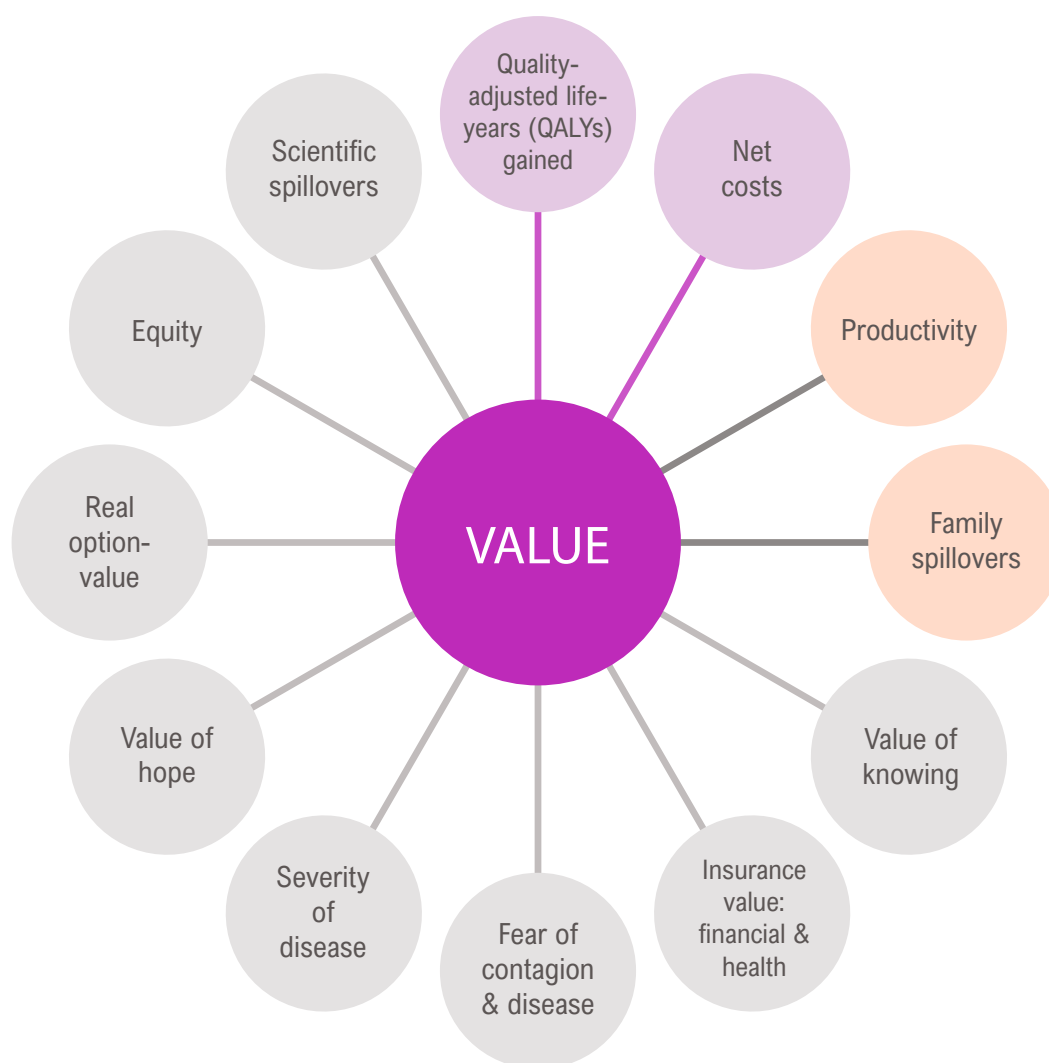


Workshop 1: Strengthening Consumer & Patient Evidence

This section focused on the role and value of consumer and patient evidence to:

- Contextualise clinical benefits in a real-world context.
- Demonstrate value not captured in the clinical or economic data.
- Assist HTA bodies to assess benefits vs harms/burdens from the patient perspective.
- Influence decisions about which outcomes and measures are considered most important.
- Add legitimacy to decisions made when supported by an appreciation of lived experiences.

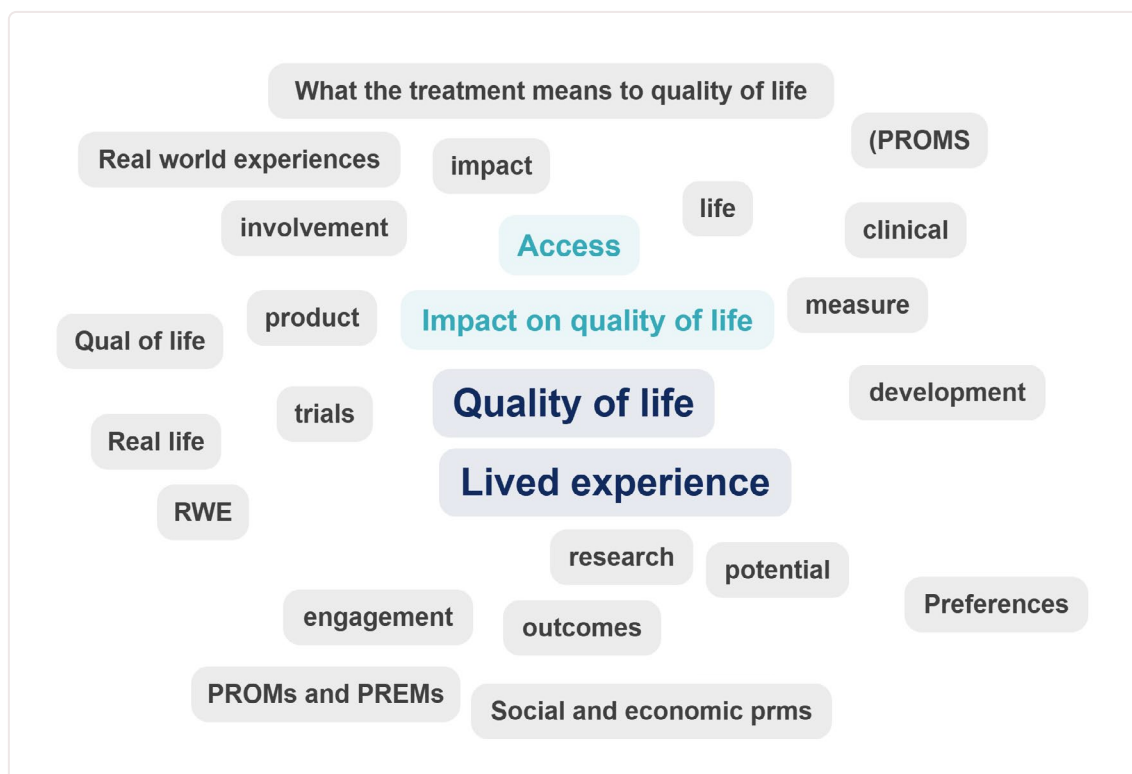
FIGURE 1: The Value Flower³³



Source: <https://about.nested-knowledge.com/2024/03/27/towards-patient-centered-health-technology-assessment/>

Participants were asked to describe the types of consumer evidence they thought should be included in HTA. Contributions to the word cloud are shown in Figure 2. There was a commonality in themes around real life impacts and experiences, such as insights into quality of life, outcomes, preferences and access.

FIGURE 2: What consumer evidence should be included in HTA?



Participants were asked if their organisation collected patient evidence; 86% of participants said their organisation was currently capturing patient/consumer evidence while 14% indicated they were not currently capturing any patient/consumer evidence.

The group discussed current challenges and barriers to collecting consumer and patient evidence. The most common barrier was **resourcing**, including **capacity** and **funding**. Other challenges to capturing patient evidence included **knowledge limitations** about how and what to collect plus **data privacy** and **security** concerns that extended to AI/fake bot issues. Additional discussions included the challenge of **survey fatigue** and how to ensure **diversity** and that all voices are represented. Some patient organisations had experience with partnering with tertiary education institutions but highlighted ongoing issues with intellectual property rights.

Participants highlighted the value of patient evidence for many purposes in addition to the critical role in HTA and were generally supportive of finding innovative ways to empower and support patient organisations to more effectively collect patient evidence and insights. Patient organisations also discussed the potential for collaborating to improve the efficiency and accuracy of evidence as well as to reduce resource and time constraints. Funding sources to support patient organisations to collect and analyse consumer evidence were considered and included both industry and government. It was noted that appropriate governance and independence would be imperative to ensure the integrity and credibility of the consumer evidence.

Workshop 2: Prioritising Consumer Engagement Efforts

This workshop focused on whether it was possible to prioritise consumer engagement efforts and if so, where those efforts would be most important and make the most significant impact in HTA. Sponsor submission categories were outlined, definitions for high unmet clinical need (HUCN) and high added therapeutic value (HATV) were considered and characteristics of sponsor submissions were discussed and attempts made to rank in terms of importance.

The session was framed with a recognition that resources for all stakeholders are limited and that different types of PBAC submissions may benefit from different degrees of consumer input, evidence and engagement based on:

- Category of submission — used for Dept/evaluator resource planning and cost recovery fees
- Complexity of treatment landscape (including comparator considerations)
- Determination of High Added Therapeutic Value (HATV) and/or High Unmet Clinical Need (HUCN)
- Patient relevant outcome measures
- Patient relevant implications (eg time, travel)
- Quality use of medicines / types of administration of a medicine

PBAC sponsor submission categories³³ were discussed and identified as one possible way to prioritise where consumer evidence might be of the highest value.

PBAC Sponsor Submission Categories Summary

Category 1	Category 2	Category 3	Category 4
• First in class • New population • Co-dependent technology • TGA provisional determination	• New indication for currently listed item • material changes to a currently listed indication • change a rec with new clinical, economic, financial information • maybe a new form or strength of an already-listed item not bioequivalent to existing listed	• Adjustments to existing listings with no major change to population or cost-effectiveness • New/changed deed. • change a rec with no new clinical, economic, financial information • A new biosimilar brand for an existing item with no indication changes • Other advice (e.g. nutritional products; equivalence/ substitution/ QUM issues; changing restriction levels)	• Listing of a new item of a listed medicine. • Adding to/altering prescriber bag listings • Changing/adding to form/manner of administration • Change in maximum quantity and/or number of repeats. • Change/addition to the prescriber type(s)

However, it was also recognised that there are a number of other attributes of submissions which made them worthy of investing effort in consumer evidence collection, independent of the Submission category used (see next page).

The IAG released an interim report in August⁶ which identified a need to define the meaning of high unmet clinical need (HUCN) and high added therapeutic value (HATV). To further explore this, participants were asked to consider what the terms meant to them. Their responses were collected as word clouds (Figure 3 and 4).

FIGURE 3: How would you define high added therapeutic value (HATV)?

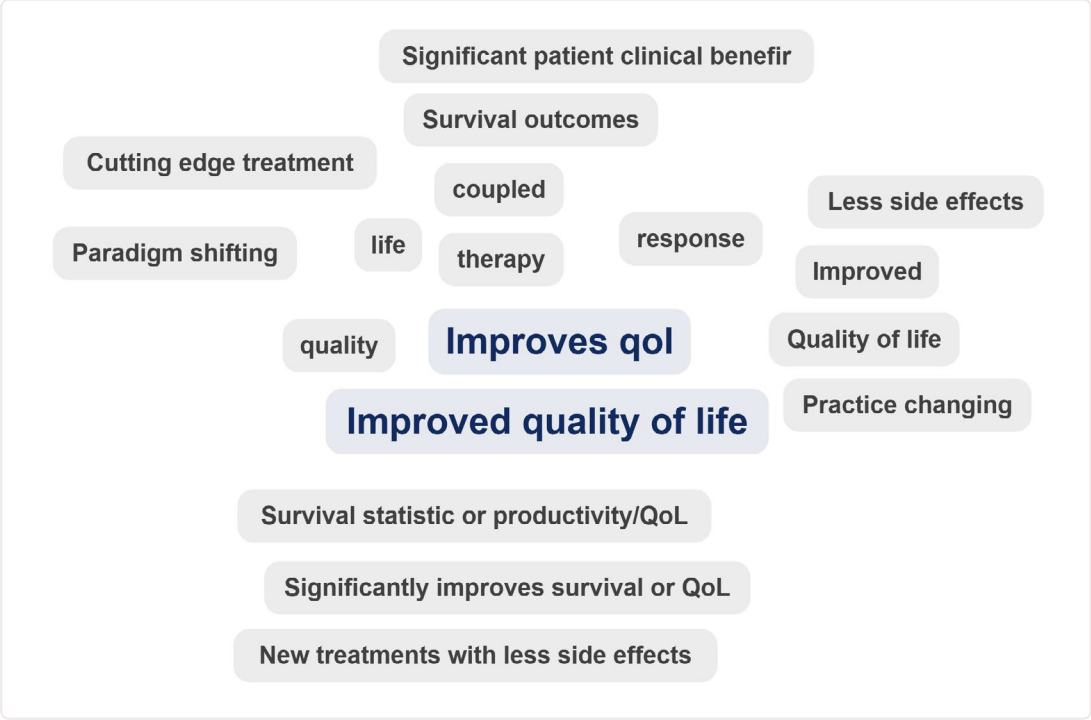


FIGURE 4: How would you define high unmet clinical need (HUCN)?



It was clear that there was strong alignment between participants that central to the definition of HATV is an improvement in quality of life. Survival benefits were also an important indicator of HATV.

For HUCN there was unanimity around a lack of treatment options as key to the definition.

Overall the patient groups were strongly aligned on definitions for these terms and the participant responses were intuitive and swift. This level of clarity and consensus across the patient community is somewhat surprising given the IAG's plans for broad consultation to help define these terms suggesting there may be more varied perspectives amongst other stakeholders.

Next, participants were asked to consider 14 characteristics of PBAC submission types and rank them in order from highest to lowest benefit of consumer evidence and input. The purpose of this exercise was to determine if there were any types of submissions where efforts to collect and submit consumer evidence should be prioritised. Participants could add additional characteristics if needed.

PBAC submission characteristics with typical PBAC category in parentheses:

1. New disease (1)
2. New population (1)
3. First in class medicine (1)
4. New chemical entity (1/2)
5. New mechanism of action(1)
6. Drug with co dependent technology (1)
7. TGA provisional determination (1)
8. HATV (Any)
9. HUCN (Any)
10. New indication of currently listed medication (2)
11. Material changes to a current listing based on new info (2)
12. Changes to a current listing based with no new info (3)
13. New form or mode of administration (4)
14. Comparator consideration (All)
15. Other

There was consensus amongst the participants that it was extremely challenging to differentiate between the 14 characteristics in terms of prioritizing them for consumer input/evidence. As such, it was felt that there would need to be flexibility in any approach to consumer evidence contributions based on sponsor categories. The submission categories (which exist to support departmental resource planning and hence fees) may not be the most appropriate determination of whether consumer evidence is needed and would provide value.

The group asserted that the nuances pertaining to the nature of the submission are what would make consumer evidence of value for medicines in any of the PBAC submission categories. While there is typically an obvious need for consumer evidence to support most category 1 submissions, there was also a lot of discussion about the need for consumer evidence around all category submission types, even when at a surface level it might seem consumer input was unnecessary.

To illustrate, the following category 4 examples were explicitly discussed as submissions for which consumer input/evidence would be valuable:

- Submission of a medicine with a new form or mode of administration, for example an oral formulation, or an injection under the skin (sub cutaneous) instead of into the vein (IV). While these changes might appear minor/beneficial and hence not benefit from consumer evidence, the participants noted the patient impacts might be considerable and hence consumer evidence would be of value.
- Submission for a change in prescriber type. While appearing an administrative change, if the submission was to add prescription rights to a nurse practitioner, this change might be especially important to support access in rural, regional or remote communities, and hence consumer evidence may still be of value.
- Submissions for a change in pack size.
- Submissions for use in children.

Following a review of all characteristics, participants were asked to identify the top 5 characteristics that would benefit from consumer evidence and input. There was a shared perspective that where a medicine being considered by the PBAC was “new” in nature, with respect to disease, form or formulation, mode of administration, mechanism of action, indication, or patient population, then consumer evidence and input would be valuable. The other attributes that appeared strongly in discussions and ranked highly as benefiting from consumer evidence were HATV and HUCN.

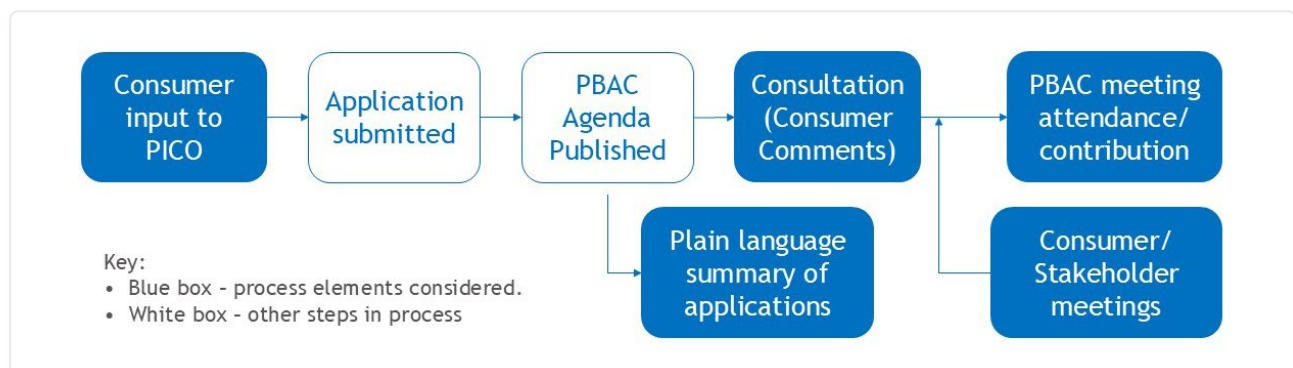
Before moving onto the next activity, participants were asked whether all PBAC submissions need / benefit from consumer evidence/input given resource constraints. The room was divided on this with 53% saying all submissions need consumer input, while 47% felt not all submissions needed consumer input. The discussions highlighted the need for flexibility depending on the medicine and the situation.

The final part of this workshop involved participants considering where in the HTA process consumer contributions would be most useful, for the submission types prioritised for consumer input. Participants were also asked to consider some existing and potential HTA process elements and determine which they thought were important to support patient engagement.

The HTA consumer engagement process elements considered were:

- PICO input
- Plain language summary of applications
- Consumer comments
- Consumer/ stakeholder hearings
- Attendance / contribution at PBAC meeting

FIGURE 5: HTA potential and existing consumer engagement elements considered, in the context of PBAC process.



There was good discussion around the value of each of the highlighted process elements and acknowledgement that some of the potential process elements should be promptly introduced. With respect to the highest priority submission types for consumer engagement, there was overwhelming agreement that **PICO input** from patient organisations would be of value. Specifically there was commentary around the role for patient communities to inform population and comparator determinations as well as the patient perspective on outcomes.

Most participants prioritised **Plain language summaries of HTA applications** (and use of plain language in general) for most submissions and reflections of the Summary of Information for Patients (SIP) pilot were discussed. Attendees discussed the need for further consideration of the SIP pilot, the timing of providing them and the resource required to implement it, the party providing/distributing the summary and the quality in general. There was also discussion of the importance of plain language advice and patient engagement earlier in HTA, and with respect to multistakeholder agreement of the PICO (Population, Intervention, Comparator and Outcome). These discussions were aligned with similar discussion at the SHT roundtable in 2024.

Consumer comments were unanimously deemed an important and an essential part of the current HTA process. There was interesting discussion about the nomenclature of “comments”. It was noted that clinicians are asked to provide advice, while consumers are asked for comments or feedback. There was a strong preference amongst participants to elevate the input and influence of consumers to an equivalent level as other stakeholders by changing the terminology to “consumer advice”, rather than consumer comments.

Participants were in agreement regarding the value of **stakeholder meetings**, noting the distinction from consumer hearings. Jo Watson shared some thoughts on the benefit of stakeholder meetings above consumer hearings based on the increased transparency resulting from having all stakeholders in the room together. For both consumer hearings and stakeholder meetings it was noted that there still was no clarity regarding criteria for which medicines would have a meeting or hearing and participants noted this should be made available.

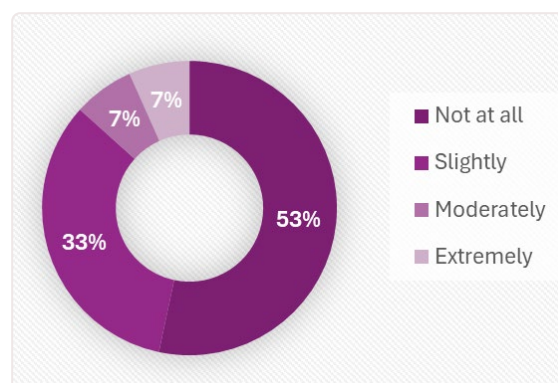
Upon considering the possibility of **attendance/contribution at PBAC meetings** participants agreed that if the HTA process had afforded the opportunity for early consumer engagement and input/advice, then attendance/contribution at a PBAC meeting would be unlikely to add value and may even be detrimental to decision making.

Workshop 3: Early Consumer Engagement & the Promise of PICO

The HTA Policy and Methods Review report, Enhance HTA report and Conversations for Change all highlighted a need for earlier consumer engagement in HTA. The IAG's roadmap prioritises updating PICO usage guidelines and development of mechanisms for PICO transparency as key activities in the first year of implementation of the HTA review recommendations.

As such, in this part of the workshop we unpacked the PICO process as an opportunity for earlier consumer engagement. At the start of the workshop participants were asked how familiar they were with the PICO process; 53% percent indicated they were not at all familiar, 33% indicated they were slightly familiar, 7% indicated they were moderately familiar and 7% indicated they were extremely familiar (Figure 6).

FIGURE 6: Familiarity with PICO



The notion of consumer engagement in the PICO process was recognised as being a new concept that would require further education and exploration.

An overview of the PICO process was provided together with how patients could potentially contribute and be involved in the process.

PICO Defines the Scope of Assessment

- Population:** The group of patients or population for whom the health technology is intended
- Intervention:** The health technology being assessed (e.g., a drug, device, or procedure)
- Comparator(s):** The alternative(s) to the intervention, such as standard of care or other treatments
- Outcomes:** The health outcomes of interest, including efficacy, safety, and QOL measures



❖ MSAC (Medical Services Advisory Committee) & PBAC (Pharmaceutical Benefits Advisory Committee) differ in how they determine the PICO

Early and strategic PICO scoping that includes the patient voice may support:

- greater PICO alignment amongst stakeholders (less potential for discord and delays)
- assessments that better reflect real world patient needs, values, preferences and lived experiences

How Patients and Consumers Can Be Involved:

- Sharing lived experiences to help define the **population**
- Providing relevant experience (positive and negative) specific to the proposed **intervention**
- Highlighting relevant **comparators** (especially if treatment landscape is complex and/or current treatments are burdensome or ineffective) and associated experience (positive and negative)
- Identifying meaningful **outcomes**, such as improvements in daily functioning, emotional well-being, side effect profiles – non-clinical measures

In groups participants were asked to consider the following:

- When should consumer input be sought?
- What would your organisation need to prepare to inform the PICO? What information, from whom? What format? When?
- What sort of input would be important to provide? Where is effort best focussed: P,I,C,O? How should input be provided (written, with/without template, verbally?)

Participants commented that consumer input should be sought as early as possible. There was discussion around the value of a plain language statement that could support patient organisations as they considered the PICO and engaged their patient communities. It was noted that the plain language statement could be added to and evolved as a medicine moved through the HTA process. Again, it was noted that patient organisations would like to receive this information from the sponsor as early as possible.

Participants noted that there may be value in a template or suggested format that could be completed by patient organisations to support their ability to contribute while allowing flexibility to add additional information and attachments.

In terms of prioritising the input patient organisations could provide, all participants agreed that consumer evidence and input would be most beneficial for:

- Population – patient organisations have an inherent knowledge of their patient communities
- Comparator – patient organisations know the standard of care and whether that is being paid for privately by patients or being accessed in other ways
- Outcomes – patient organisations are well placed to address patient preferences, values and needs.

Participants noted that while patient organisations are well placed to gain insights from patient communities and collect evidence through, as was discussed in workshop 1, resourcing and capacity remains a challenge.

Other things that were considered and noted as being potential barriers to consumer engagement at the PICO included managing confidentiality, commercial-in-confidence issues, data protections, resourcing, lack of patient organisations, and the risk of reimbursement via PBS not proceeding.



Next Steps

There was strong consensus that implementation of the HTA policy and methods review recommendations and Enhance HTA recommendations were key to necessary reform to facilitate improved access to medicines together with more systematic consumer engagement that is embedded in processes across the medicines lifecycle.

Patient organisations remained interested in the work of the IAG and were keen to learn more about the roadmap for implementation with several indicating they had or would attend the current roadmap consultation. The group also felt that progress in some areas related to consumer engagement could and should happen in the short term and acknowledged the work done to date towards enhanced consumer engagement.

It was noted that there is a significant resource burden on patient organisations in order to contribute to HTA and this may increase with the focus on consumer evidence. As such mechanisms (particularly funding) to better support this should be explored.

Conclusion

The theme for the 2025 Summit was Shaping Healthcare Together; Patients, Policy & Productivity. The Summit provided a valuable combination of information and insight exchange together with the opportunity to connect industry, the Department of Health, Disability and Ageing, the PBAC, patient organisations and parliamentarians.

The link between healthcare reform and national productivity was highlighted to demonstrate that timely access to innovative medicines is both a patient necessity and an economic advantage. Discussions across the Summit highlighted how early access to innovative medicines together with a willingness by government to invest in innovation can deliver important health and productivity outcomes. This was poignantly captured by Nick, esophageal cancer survivor, who said *“early access to immunotherapy allowed me to continue working throughout my treatment and allowed me to continue to be a dad and be there for my children”*.

Recognising and building upon the significant amount of policy work and consultation relating to consumer engagement and health, both directly related to HTA and across other parts of the healthcare system, including medicines policy, we reflected on the opportunities for reform in relation to the implementation of the HTA Policy and Methods review and Enhance HTA recommendations.

The event was particularly timely given the rich policy environment and the willingness of parliamentarians to listen to the patient voice. The event theme, attendees and setting created a platform for furthering understanding of the importance of access to innovative medicines and the role of consumer evidence to support robust healthcare and HTA decision making. What remained unresolved was how to fund and build capacity within patient organisations to contribute to HTA decision-making, given the increasing responsibility being placed on patient organisations to collect, collate and submit consumer evidence.

For Australians to benefit from the imminent surge of scientific developments, and ensure patients can access treatments when they need them, leading to enhanced health and productivity, we need an HTA system that can be agile and responsive. That system must also listen to those most affected to understand what matters most to them, and deliberately and comprehensively account for the value of the lived experience. Key to healthcare reform is ensuring the patient voice is embedded so that it reflects the values, preferences and needs of Australian patients.

Over 3 impactful days we explored the role of patient evidence and how timely access to innovative treatments can improve health outcomes and provide broader societal and economic benefits for Australians. In this rapidly evolving, dynamic environment, we must maintain the momentum for reform. We all have a role to play in ensuring we progress towards a health system that meets the needs of all Australians.



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The Patient & Parliament Summit, a multistakeholder forum, continues to be recognised as a key platform for stakeholders to come together and collaborate to drive meaningful change. BMS is incredibly grateful to everyone that was part of the 2025 Patient & Parliament Summit and looks forward to working with all stakeholders to advance reform that will deliver a healthcare ecosystem that better serves the needs of Australian patients.





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