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Facilitating early and continuous engagement of patient communities in HTA processes

A Discussion Paper exploring themes important to early and continuous engagement of the patient community in Health Technology Assessment (HTA) processes in Australia. November 2024.

JANELLE BOWDEN, ACCESSCR

ACCESSCR : AccessCR.com.au | BMS : BMS.com/au

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The Paper was authored by Janelle Bowden, AccessCR, with collaborative oversight from Hayley Andersen, BMS Australia, and review by Greg Cook, BMS Australia.

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Executive Summary

While patient input and evidence are increasingly valued in Health Technology Assessment (HTA), what input, when, and how to engage/collect/incorporate input it are still very much under discussion in Australia and globally.

In Australia, there are calls from the patient community (patient experts and patient advocacy groups (PAGs)) for earlier and more consistent engagement across the entire lifecycle of product development, regulatory approval and reimbursement, to improve relevance of, and equitable affordable access to, the medical and technological innovations that support an individual's health.

Other stakeholders, including industry, the Department of Health and aged Care and clinicians are also supportive of earlier and more consistent patient engagement.

Although the timing and level of engagement proposed by various stakeholders might be different, the ultimate objective is the same - getting patients timely access to the right treatment at the right time.

This call to action has been consistent throughout the many consultations related to health-related policies, research, access and HTA, conducted over the past decade.

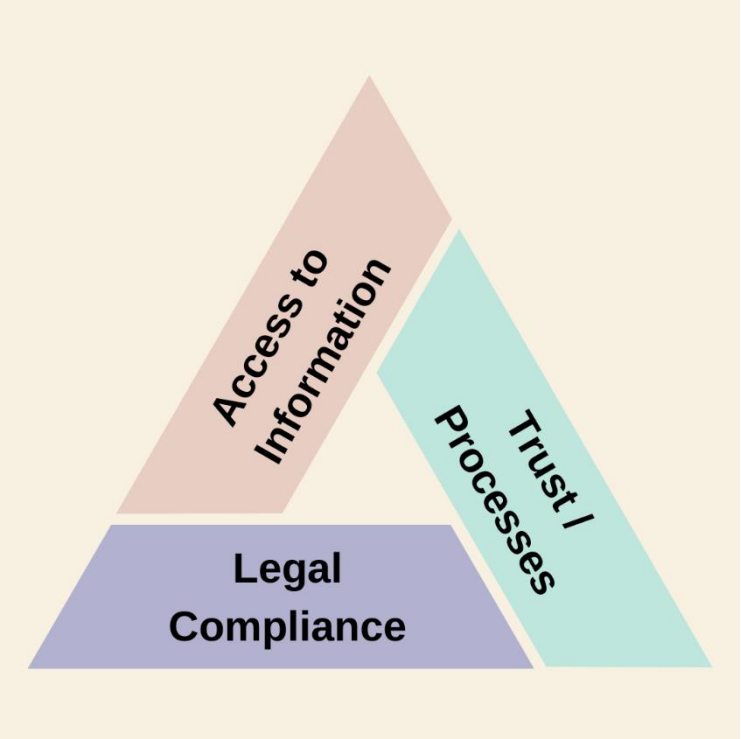
In September 2024, reports from the HTA methods review[1] and Co-Design of Enhanced Consumer Engagement Process[2] consultations were released by government. Government responses to the recommendations remain outstanding.

The Enhance HTA report[2] *recognised consumers' diverse health care experiences, needs, preferences and perspectives bring a unique expertise which must be integral to HTA decision-makers' considerations*, but that HTA processes needed to evolve for consumer engagement to become embedded. Recommendation 6 drew attention to the need to examine how earlier consumer input may be facilitated, compliantly, within current regulations and legislation.

The HTA methods review report[1] (recommendation 25) referenced a need to support consumers to engage with HTA processes through actively engaging consumers across the HTA system and all relevant processes. Recommendations specifically mention the need for plain language summaries of Pharmaceutical Benefits Advisory Committee (PBAC) submissions (recommendation 22) and the Population, Intervention, Comparator and Outcomes (PICO, recommendation 32) to better equip patient communities to provide input to the HTA process, as well as the need for transparency about consumer input and how it was used in HTA decision-making (recommendation 33). Recommendation 23 speaks to the need for access to appropriate, tailored and timely information about individual therapies at specific decision points and milestones.

This Paper does not aim to duplicate the inputs or outputs to those consultations/reports, but rather focus attention on three overarching structural and practical, inter-related themes, which if addressed alongside the reports' recommendations, may facilitate more effective early and continuous consumer engagement and involvement in HTA. These themes are:

- Access & Transparency of Information
- Legal & Compliance Considerations
- Trust & Rules of Engagement



The Shaping Healthcare Together Roundtable provides an opportunity for the PAGs attending to explore these themes further with a view to prioritising where action might be required for each theme, and what actions might enhance capacity for early and continuous engagement, and better quality consumer evidence and inputs into HTA.

Definitions

As there can be differences in use and interpretation of terminology, in the context of this Paper, we are using the terms below as follows:

Patient Centricity: Patient centricity refers to a healthcare approach where the needs, preferences, and values of the patient are prioritised in all aspects of care and decision-making. The mindset of keeping the patient journey, experience and perspective top of mind when making decisions and operationalising work streams (e.g. clinical trials, HTA submissions and patient education materials).

Patient Engagement: The complete spectrum of activities from informing to consulting, to partnering with patients, their caregivers and PAGs. The activities where everyone meets.

Patient Advocacy Groups (PAGs): The groups or PAGs that represent people who either have lived/are living with specific health conditions, or who represent the interests of users of the health and research system more generally. These groups may be formally constituted (such as charities, non-profits, and social enterprises) or informal entities (for example online communities, Facebook groups, support groups).

Patient Expert: a person with experiential knowledge of a health condition, often from living with it themselves. Their illness and system knowledge is enriched beyond their own experience through synthesis of information from the experience of other patients, patient communities, clinicians, scientists, educational opportunities, and/or peer-reviewed literature. They use this expertise to provide insights, support, and advice to other patients, healthcare providers, and researchers, and help identify gaps in needs, care, etc that might be overlooked by other stakeholders such as clinicians, regulators, industry and health technology bodies.

Patient communities: An umbrella term for individual patient experts and patient advocacy groups.

Patient: This term is being defined in the same way as ‘Consumer’ is defined in the Statement on Consumer and Community involvement in Health and Medical Research[60], i.e.: “patients and potential patients, carers, and people who use health care services”. In this Paper, the term ‘patient’ will be used in preference to ‘consumer’ to align with the terminology used more commonly internationally.

Additionally, within Appendix 1, there are definitions of specific terms extracted from legislation that are relevant to this Paper.

Acronyms and Terminology

Acronym (if relevant)	Terminology	Additional information, if appropriate
ABPI	The Association of the British Pharmaceutical Industry	A representative body for the pharmaceutical industry in England, Scotland, Wales and Northern Ireland. https://www.abpi.org.uk/
BMS	Bristol Myers Squibb	https://www.bms.com/au
CEEU	Department of Health and Aged Care's Consumer Evidence and Engagement Unit	This unit helps consumers and patients to be part of health technology assessment (HTA) processes. It also supports the Health Technology Assessment Consumer Consultative Committee.
HCO	Health Consumer Organisation	For this Paper, PAG or Patient Organisation will typically be used, rather than HCO.
HTA	Health Technology Assessment	For this Paper, HTA is going to narrowed to the period post TGA application.
HTA CCC	Health Technology Assessment Consumer Consultative Committee.	A committee of consumer nominees from various Australian government HTA committees. Learn more: https://www.health.gov.au/committees-and-groups/health-technology-assessment-consumer-consultative-committee
HTAi	Health Technology Assessment International	A global, non-profit organisation dedicated to promoting the importance and use of health technology assessment. https://htai.org/
HTAi PCIG	Health Technology Assessment International Patient and Citizen Involvement Interest Group	Learn more at: https://htai.org/patient-and-citizen-involvement/
MA	Medicines Australia	A non-profit organisation representing the research-based pharmaceutical industry of Australia. https://www.medicinesaustralia.com.au/
Patient		Patient is used in this Paper (in preference to Health Consumer) in the broadest possible context to cover people with lived experience of health conditions (see Definitions).
PAG	Patient Advocacy Group	
PBAC	Pharmaceutical Benefits Advisory Council	Makes recommendations to government concerning public funding of medicines. https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings
PICO	Population, Intervention, Comparator and Outcome	Typically defines the scope of an HTA submission.
PLS	Plain Language Summary	
SIP	Summary of Information for Patient Groups	A document summarising information in a HTA application for PAGs.
TGA	Therapeutic Goods Administration	Australian government agency with responsibility for evaluating, assessing and monitoring therapeutic goods as required by the Therapeutics Goods Legislation. https://www.tga.gov.au/

Background

The case for earlier and continuous patient community engagement in HTA

There have been growing calls for greater partnership with the patient community throughout the lifecycle of medicines[3,4] as the value of patient input and evidence to therapeutic product development (in general) and health technology assessment (HTA) processes (specifically) is increasingly acknowledged. The involvement of the patient community in HTA processes ensures the HTA agency is informed by the needs of people living with health conditions, and that the impacts of innovations are contextualised by the experience of those people including whether they are useful, how they are accessed and their impact on everyday life[5].

HTAi's Values and Standards for patient involvement in HTA include 'Fairness' – that patients have the same rights to contribute to the HTA process as other stakeholders, and have access to processes that enable effective engagement[6].

In Australia, there has been slow and steady progress on incorporating the patient voice into HTA decision-making processes. The first consumer nominee was appointed to the PBAC in 1998. In 2017, the consumer member became Deputy Chair of the PBAC for the first time, and a second consumer member of PBAC was appointed. In 2017, the HTA Consumer Consultative Committee (CCC) was also established, bringing together consumer nominees from across a range of HTA committees. The Department of Health and Aged Care's Consumer Evidence and Engagement Unit (CEEU) was established in 2019. The HTA CCC and CEEU have worked to support and improve the ways consumers and patients engage with HTA processes.

For the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) processes, consumers and patients currently have opportunities to provide input to these processes either directly or via representation through:

- public consultations on committee agendas;
- hearings about specific medicine submissions;
- expert clinical consultations about specific medicine submissions, and/or;
- formal stakeholder meetings on specific health technologies (including post market opportunities).

Yet there are still several barriers which prevent patient communities effectively engaging with HTA processes, including having the mechanisms and time/resources to participate, the awareness and technical knowledge/ skills to engage, and knowing what information is useful to submit[7].

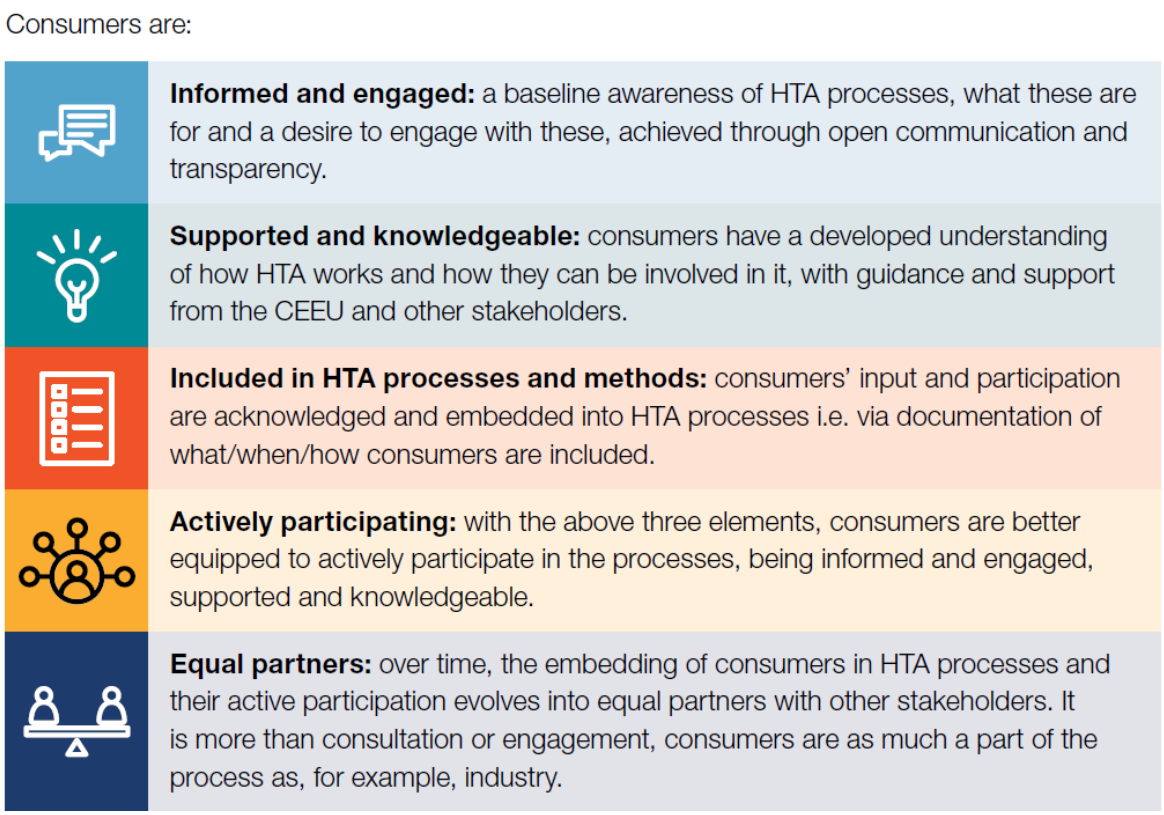
There have been a number of reviews and consultations in Australia that have relevance to health technology access[8,9] and assessment[10]. Some of these reviews have made suggestions for improving consumer and patient engagement in HTA, including:

- More plain language information on HTA processes and deliberations;
- More support for individuals and organisations to contribute to HTA processes;
- More inclusive and active opportunities to participate in HTA processes;
- More documented evidence of consumer input into applications.

The current Strategic Agreement[11] in place between the Australian Government and Medicines Australia (until 30 Jun 27) commits to creating "an Enhanced Patient Engagement Process…to incorporate patient views and experiences early in the assessment of PBS medicine funding by the Pharmaceutical Benefits Advisory Committee (PBAC). Earlier patient involvement will enhance consumer engagement and is anticipated to create efficiencies to PBAC decisions and faster access to lifesaving medicines and treatments."

In advance of this requirement, the Department of Health Consumer Evidence and Engagement Unit (CEEU) conducted a body of work called 'Conversations for Change', involving focus groups and public consultation around what, when and how consumer views and experiences can best be provided during HTA processes. The Conversations for Change report[5] was released in Jul 2023. Five themes emerged from the consultations as necessary for effective consumer involvement in HTA processes (Figure 1).

FIGURE 1: Interdependent themes supporting consumer involvement in HTA processes[5]



Consumers consistently represented a need to be involved early – in clinical research and regulatory processes – to ensure consumer input was effectively informing HTA. The report also highlighted the importance of the following to facilitate earlier and more effective partnership with consumers:

- trust between governments, sponsors and consumers;
- greater transparency of information and data between stakeholders (and guidance to support such activity);
- a compliance framework for industry and mechanisms for dealing with potential conflicts of interest;
- careful consideration of the legislation; and,
- greater acknowledgement and inclusion of consumers within HTA methods.

The Conversations for Change report[5] noted “Supporting early communication from industry to consumer organisations on planned applications for HTA will require changing culture and established practices to enable consumers to access and contribute to application development. This may include considerations such as pre-registration restrictions and Medicines Australia Code of Conduct documents.”

To progress the Strategic Agreement deliverable for an Enhanced Patient Engagement Process, the Department of Health established a Co-Design Working Group of consumers, the medicines industry and other stakeholders in late 2023 to look at how to capture consumer and patient perspectives earlier in the medicines listing process. This group focussed on access to earlier information about new health technologies and improving understanding of consumer issues before a medicine is listed.

A public consultation on the recommendations proposed by the Co-Design Working group was held during March 2024[12] and a report[2] with recommendations was delivered to Government in June 2024.

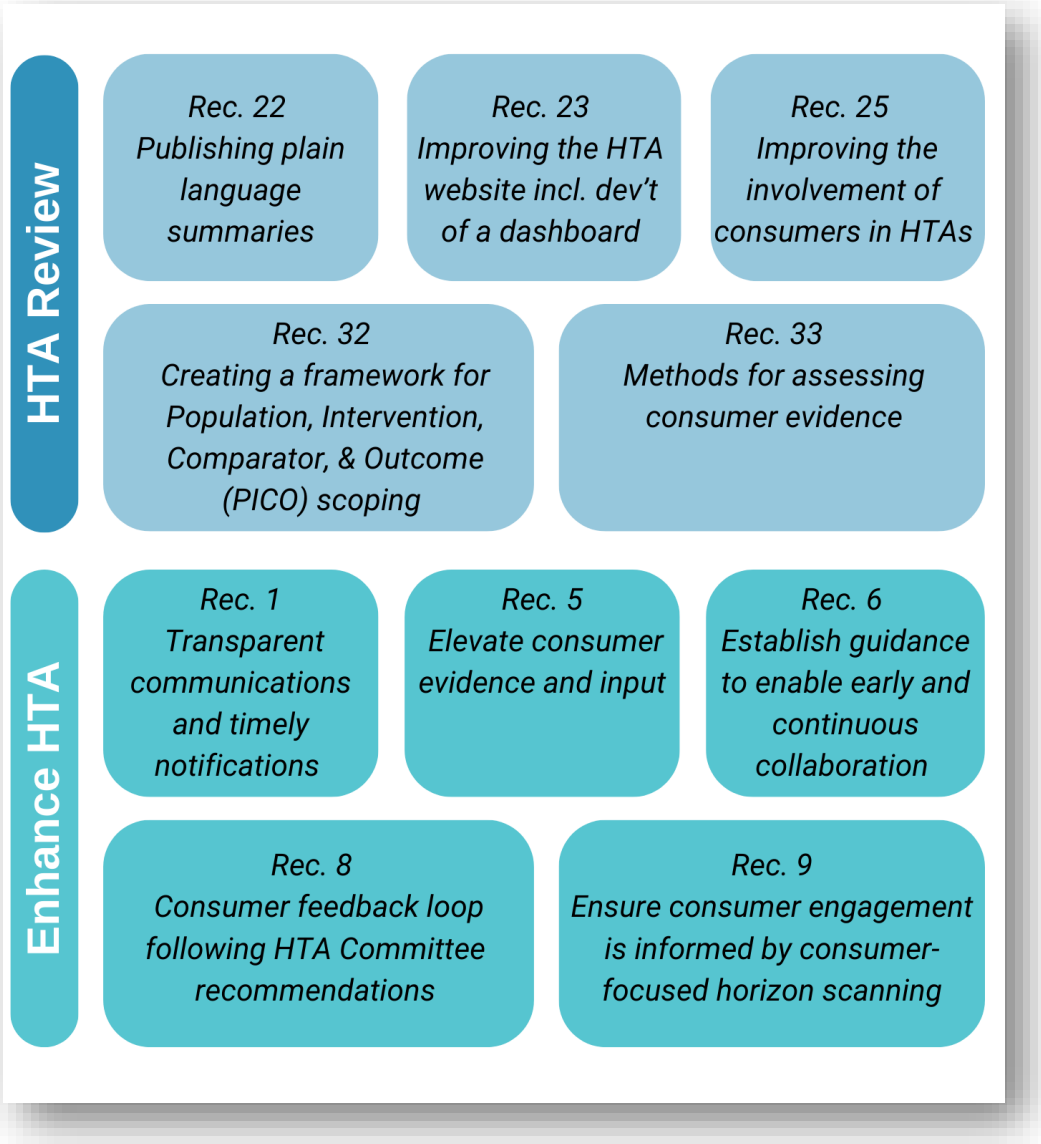
Reports from the HTA Methods Review[1] and Enhanced Consumer Engagement Process[2] consultations were released in Sept 2024. Each report had a number of recommendations, some of which align with themes that will be discussed in this Paper, including access to appropriate, timely, tailored information and consideration of the legislation (for example HTA methods review[1] recommendations, 22, 23, 25, 32 and 33; Enhance HTA[2] recommendations 1, 5, 6, 8 and 9 – see Figure 2).

In a research study conducted by Patient Voice Initiative (PVI) and CaPPRe[14], the patient community expressed dissatisfaction with a lack of early access and genuine patient involvement across the product/treatment life cycle (despite the latter being ranked one of the top 3 most important areas of engagement). The patient community want to be more involved earlier in the life cycle, including clinical trials designs. Reasons for dissatisfaction included a perception biopharmaceutical companies are reluctant to involve patient communities in this area, and that there is very little involvement of patient communities in design of clinical trials, especially in Australia.

Patient communities want to be recognised for their knowledge and treated as equals. There is a perception that biopharmaceutical companies are not willing to learn about patient community needs and individual experiences/journeys and prioritise commercial interests rather than support patient communities. “A patient is the best person to explain living experience and the burden of your condition”; “Biopharmaceutical companies need to include patient advocates and patients to inform them at each stage of medical development”[14].

There is a perfect storm brewing in Australia (and globally) around the willingness and need for the patient community to be engaged early and continuously through the therapeutic product lifecycle, from research to HTA processes and beyond.

FIGURE 2: Key recommendations toward supporting patient expert and PAG engagement in HTA from recent reports[1,2] aligned with themes within this Paper.



This Paper presents three themes for the Shaping Healthcare Together Roundtable attendees to consider and discuss for their impact on early and continuous engagement.

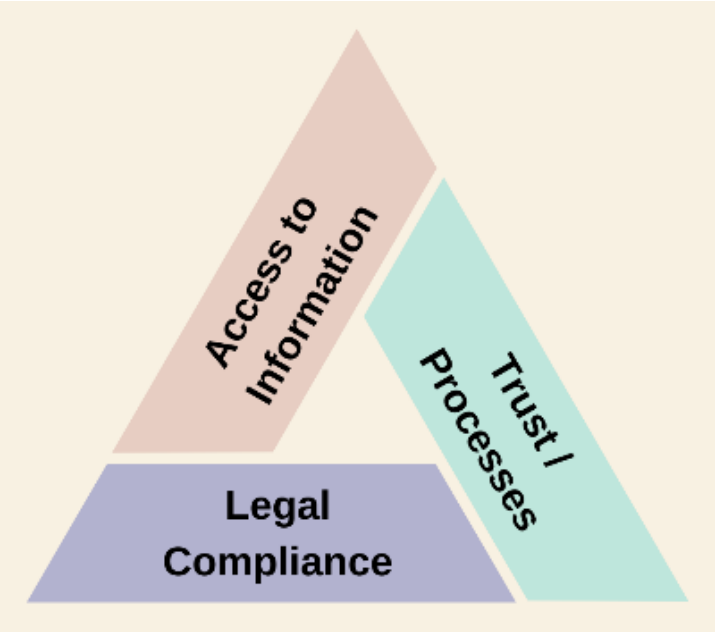
What are the underpinning themes this Paper will consider?

In reflecting on consultations and experiences to date, a multitude of factors were identified that will help facilitate future changes on what and how patient communities engage with HTA processes. These include:

- awareness of HTA, HTA processes and the opportunity to provide input;
- who is engaging (e.g. a patient/carer, patient expert, patient advocacy group (PAG)) and their time, knowledge, skills, experience and interest to engage;
- the size (and hence capacity/resources/staff) to engage, collect and input appropriate patient evidence and experience;
- the nature and nuances of the health condition – for example, whether rare or common, whether acute, chronic or life-threatening, the degree of impact on quality of life, satisfaction with the current care/treatments available for it and access to those services;
- the nature, cost, innovativeness, accessibility and acceptability of the health technology being assessed;
- the interest, capacity and knowledge of a company or its staff to engage with the patient community;
- the time, resources, experience, interest of researchers, regulators and HTA bodies to engage with and support patients and integrate their inputs within processes.

These nuances are all acknowledged as factors, however, won't all be specifically discussed in this Paper. Instead, we will focus on three broad inter-related/inter-dependent themes we believe impact on the ability of the patient community to engage early and continuously throughout the extended HTA lifecycle, and input effectively:

- Access & Transparency of Information;
- Legal & Compliance Considerations;
- Trust & Rules of engagement.



Additional notes on this Paper

There is increasing interest and input from individual patients and patient experts into HTA processes. Because the Shaping Healthcare Together Roundtable audience is primarily PAGs, this Paper preferentially considers how the 3 pillars might impact PAGs.

We recognise however that while patients and patient experts may experience some of the same challenges as PAGs, there may need to be different solutions required to enhance their ability to engage. By concentrating on PAGs, this Paper in no way means to diminish the urgency and importance of addressing individuals' ability to engage with HTA, as we see this as vitally important for ensuring diverse perspectives and experiences are contributing and considered.

We also acknowledge the range of touchpoints for consumer engagement throughout HTA processes[12,13, 15]. The generalised themes presented in this Paper have relevance for improving engagement across all HTA phases.

It is noted that the recognised term in Australia used to represent those with lived health experiences is 'Consumer', although this is contentious for many. This Paper uses the term 'Patient' instead of 'Consumer', with the same broad meaning, to align with the terminology more frequently used internationally.

This Paper will briefly acknowledge the following challenges with respect to their impact on patient engagement in HTA processes, but these topics are beyond the scope of the Shaping Healthcare 2024 Together Roundtable.

- PAG Funding and resourcing
- Investment in the "infrastructure" to support consumer engagement across the spectrum of HTA phases in general

Overarching Themes

1. Access to/transparency of information

This section focuses on the following considerations:

- The information patient communities would like access to;
- Industry barriers to sharing information;
- The role of government/HTA bodies in supporting access to information;

Transparency in communication and documentation is noted as one of seven important patient engagement quality criteria[16]. The HTA Methods Review[1] reported that stakeholders often cannot find the information they need relating to HTA policies, systems or submissions. Further, stakeholders are not satisfied with existing plain language explanations of HTA pathways and guidelines.

The Conversations for Change report[5] noted an optimal outcome with respect to 'consumers are informed and engaged' was for consumers and consumer organisations to have access to the same information as all stakeholders and committees, but that greater transparency around information was a challenge to be overcome.

In practice, suggestions in that report[5] included being informed when an application is submitted and open for consultation, direct and earlier/automatic notification on potential applications and publication of HTA committee recommendations, and plain language summaries of applications so consumers can comment before the assessment process. These themes have been replicated in subsequent reports[1,2], as previously mentioned.

Different individuals and organisations (and staff within organisations) have different information needs. Those preparing HTA inputs may have different levels of information need compared to those helping prepare a grant application or trial protocol, a person reviewing a plain language information sheet or results summary, or those supporting patients undergoing treatment or those trying to access trials open for recruitment. There is a challenge therefore in creating a framework for when and how (and to whom) information can be shared, whilst acting compliantly and avoiding perceptions of being promotional.

The Enhance HTA report[2] noted that "Consumers have different levels of experience and knowledge of HTA processes, shaped by their prior engagement. Consumer feedback highlights the need for clearer and more transparent communication about HTA processes, tailored to diverse audiences with varying levels of familiarity, ensuring greater equity of access to information."

This Paper recognises the movement to empower consumers, including through shared-decision making in healthcare, noting neither of these outcomes are possible in a void of information. It is beyond the scope of this Paper to address the need of patients and families for access to information to support their personal healthcare journeys. However, it is recognised that information from anywhere in the world is now broadly available to anyone with internet access, be that through search engines, patient communities, the dark web or AI query tools. As such, for the continued empowerment and safety of Australian patients, consideration will need to be given to how quality, accurate, locally relevant information is made available in the context of an Advertising Code that is grey on what constitutes promotion vs information.

What information patient communities want, for what, when

Patient communities desire information that can inform their networks about their health condition and healthcare options (current and future) and improve their ability to provide input across the therapeutic development lifecycle, from research to HTA.

Across the medicines lifecycle, the types of information patient communities have identified as valuable include:

- Pipeline information – what's coming, where development is at (horizon scanning)
- Clinical trials open to recruitment;
- Clinical trial results summaries;
- Notification of a health technology being assessed by a HTA committee[5]
- Plain language summaries of HTA applications, including the PICO[1,5]
- Timely notification and information on opportunities to be involved in consultations, consumer hearings and stakeholder meetings convened by HTA committees[2,5]
- Evidence that patient relevant outcomes (identified by consumer input) have been considered by HTA committees[1,5]
- Feedback/Sharing of what consumer input to HTA committees was valuable, and suggestions for future input[5]
- Additional information on the status of a medicine at different stages of its lifecycle[1] (for e.g., on the Medicines Status Website[2)].

Outside specific product related information as above, there is also a need for information about the order and detail of HTA processes and what's required at each stage[2] in general.

Recommendation 1 of the 'Enhance HTA' report[2] identified timely notification of the following information in particular as useful for supporting consumers to be prepared and provide input regarding:

- New medicines or new used of existing medicines under evaluation by the TGA;
- Health technology being considered by HTA Committees (including plain language information of a submission, along the lines of the Summary of Information for Patients pilot project, focussed on the PICO).

Patient communities will have a range of uses for the information they access. These might include:

- Horizon scanning on behalf of their communities about current and future research, health technologies, or services;
- Education of range of stakeholders (patients and families);
- Contributing as partners in research (such as trial design, feasibility and conduct);
- Contributing input to HTA processes.

Access to adequate, meaningful information in a timely manner enhances patient communities' ability to plan, identify gaps, contribute input and make decisions, at both an individual and organisational level.

The following provides an overview of two examples of types of information patient communities may like access to, and the challenges with accessing that information.

Clinical trial protocol summaries

Clinical trials have a wicked problem that impacts both trial sponsors and patients: Trial recruitment. Sponsors can struggle to find participants and patients can struggle to find and access trials. There are many factors that have an impact on the recruitment, but a key element is access to information. If patients don't know about a trial, they don't have a choice to participate. If patients are not provided with appropriate information, they may not consent to participate. If patient partners don't have full access to the background on a product or idea, they can't help sponsors design the trials in a way that is inclusive, minimises burden, and respects participants with the information they need at the start, during and after the trial.

Clinical trial protocol summaries are a brief summary written in plain language that helps the general public more easily understand a study's goal, research questions, and design. They provide an opportunity to educate patient communities about available trials. Trial registers ask for a lay summary of a trial and Clinicaltrials.gov[17] provide advice on creating one.

Best practice indicates such summaries should be co-created with the target patient population and provided as a resource for patient communities. However, the ambiguity of current legislation around what could be considered promotional can lead companies to take a conservative approach to both activities (i.e. co-creation and sharing of information).

Summary of Information for Patient Groups (SIP)

The Summary of Information for Patient Groups (SIP) is a plain language summary of a medicine undergoing HTA evaluation designed to support patient and carer expert into HTA. This approach was developed by the Scottish Medicines Consortium and adapted for international use by the HTAi Patient and Citizen Involvement Interest Group (PCIG)[18]. The international template is typically around 10 pages long and has 4 core sections – a submission summary, details around the current landscape (the condition, diagnosis and treatment options), the new medicine (how it works, how it is administered and it key attributes), plus further information, glossary and references.

The SIP is produced by a company, then reviewed by a HTA body for completeness, and to ensure the content is balanced and does not include promotional elements, before being made available to the patient community.

Australia piloted use of a SIP in late 2020-early 2021[19]. BMS was the first to pilot a template with 2 submissions, and then an additional 7 other companies were invited to pilot the template. The template used was customised from the HTAi template, then further localised based on feedback during the pilot. An evaluation of this pilot has not been released, nor the template yet implemented, though the latter is a recommendation in recent consultation reports[1,2].

Recent reports[1,2] make recommendations around inclusion of early (pre-submission) consumer input to inform equitable access to new medicines or new uses of existing medicines. It is noted that consumer input on the defined PICO and implementation considerations may better inform submission content, and reduce the need for multiple reimbursement submissions, supporting timely access to the health technology (Enhance HTA[2] recommendations 5, 6). As will be discussed in the second theme, current legislative requirements restrict the potential for these early engagement activities.

Industry barriers to sharing of information, beyond promotional considerations

Companies producing therapeutic goods and services are the ultimate sources of truth and gatekeepers of information about their products. They have the data and can decide with whom and when they share certain information.

The commercial reality for companies means that to remain sustainable, they need to maximise the value of their patents, and protect time in market, which may reduce their willingness to have information released earlier in the development lifecycle given the potential impacts to the competitive landscape.

The Enhance HTA report[2] calls for the design of a plain language template summarising submissions, with a focus on the PICO, in partnership with the medicines industry, the Department, and consumers. Commercial-in-confidence considerations are noted.

Further agreement and transparency around what information is considered commercially sensitive is needed to improve understanding and trust between stakeholders about the information it is reasonable to expect is available in the public domain (or to targeted recipients), and to guide development of the templates that may be used to disclose information at various timepoints across the medicines lifecycle.

It is also noteworthy that company pipelines are constantly changing – with products coming and going. Balance between engaging early in a product's development verses the risk that product will not continue development or experience a transfer of ownership (and the potential for disappointment or frustration within a patient community). Equally, some products are only acquired at a late phase of development, so early engagement by the acquiring company with the patient community may not have been possible.

Finally, the knowledge, processes and human resourcing for patient engagement can pose a barrier to the provision of information. Companies have varied resourcing for engaging with patient communities, and varied policies and processes around what can be shared with whom.

Legal departments may take a very conservative approach. While Medicines Australia attempts to support companies with guidance and expectations on complying with the regulations through their Code Resource Toolkit[61], ultimately, each company will have its own culture, policies and procedures which will govern its activities.

All these factors combined can make it difficult for companies to provide information, for patient communities to access information, and for the investment of time needed to understand the nature and needs of the patient community and develop the trusting, professional relationships that can benefit both parties.

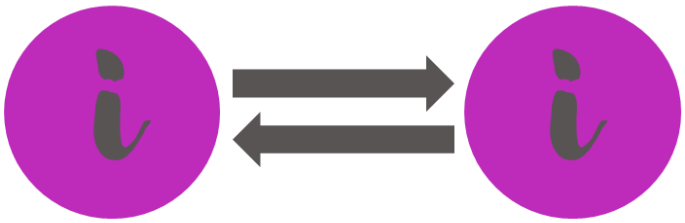
The role of government/HTA bodies as avenues and caretakers of information

As government appointed committees, supported by the public service, HTA bodies are trusted both as sources of balanced, non-promotional information, and holders of personal, sensitive or commercial-in-confidence information.

HTA bodies have to balance transparency, with their responsibility as data custodians. And, just as for industry and patient communities, the capacity of HTA bodies to do all that patient communities and industry desire is limited by their resourcing (funding, staff, and systems).

Several reports[1,2,5,15] have referenced the need for development of a better online portal to enable consumer to get access to information throughout the HTA lifecycle on the status of medicines, consultation and input opportunities, and outcomes of HTA decision-making. Additionally, the recent reports[1,2] noted the need to invest further in the Department's capacity to support and coordinate consumer engagement activities across HTA pathways.

Investment in both these activities, if made, will help support early and continuous engagement of consumers throughout the process.



A note on two-way information exchange

It is noteworthy that there is value in and a need for two-way flow of information - between industry and patient communities, industry and government, and government and patient communities.

Companies need to hear and gather information from patient communities to better understand their health conditions and experiences of healthcare and treatments, to inform health technology development and access decisions. Governments also need to understand the same information, but for the purpose of deciding whether to approve and fund those health technologies.

Increasingly PAGs will play an important role in collecting and collating data about their patient communities and their experiences. In a 2021 survey of members of HTA bodies and affiliated organisations[20], 81.8% of respondents felt patient advocacy groups be primarily responsible for generating and submitting patient preference evidence in HTA, although note the constraints of time, resources and money as a barrier. Future consideration will need to be given to how this activity will be funded, the custodianship of this data and with whom/how it will be shared.

Use of plain language

“Plain Language is a clear way of writing and sharing information so that people can understand it the first time they read or hear it[21].”

The use of language that is not inclusive or tailored to the needs of patients may result in the involvement of only those patients with higher levels of education, more financial security, and more available time.

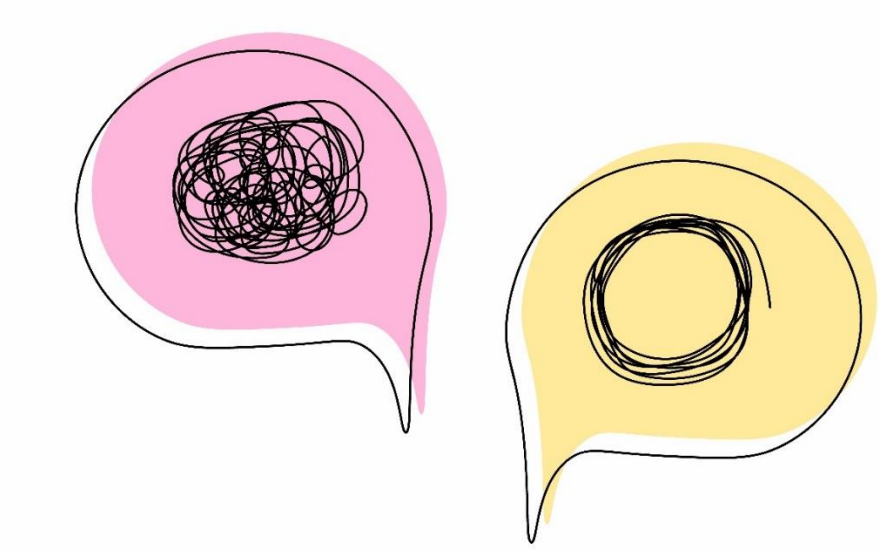
Recommendation 1 of the ‘Enhance HTA’ report[2] highlights the need for accessible, plain language communications across the health technology pathway, from education about HTA processes, to clinical trial protocols, information on medicine registration, and public funding processes and decisions. The HTA Methods review[1] (recommendation 22) specifically calls for the publishing of plain language summaries of PBAC submissions.

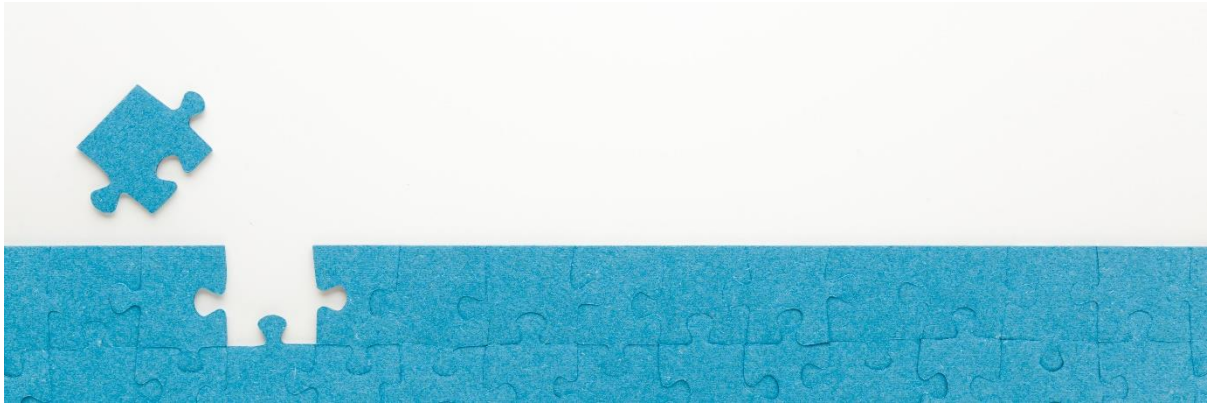
Being able to access clear and transparent information is the necessary first step toward understanding and potentially providing input and evidence into HTA processes.

There are any number of tools, guides, advice to support the use of plain language at various part of the HTA lifecycle from clinical trials to HTA[17,19,21-31] as well as in the development of contracts with patients[32,33]. As noted by Dews et al[29], the use of complicated legal language is another potential barrier to effective patient involvement.

Preparing information for a lay audience is not without its complications. Besides the compliance issues that will be discussed in the next section, there can be other ethical issues. For example, in the context of plain language trial results[24], Pal et al raised ethical challenges like maintaining fair and balanced representation of results, exacerbating positive publication bias, and feeding the ‘infodemic’ in medical research literature.

Patient communities can potentially play (and want to play[14]) an integral role in co-designing patient friendly and relevant information which will be most useful and helpful to the public and patients, provided there is a legal construct to allow for such activity to occur.





Knowledge Gaps

- What information is difficult to access?
- What is the highest priority in terms of information PAGs would like access to, that could make the largest impact to PAGs ability to engage early and continuously, or improve the quality of their HTA input?
- Where do PAGs typically get information, and from whom?
- Where is information made available, and by whom?
- What is considered commercially sensitive information? What can be made public, and/or shared by PAGs, and to whom?
- Is there consensus among Medicines Australia members about what is/isn't commercially sensitive?
- Are Confidentiality agreements useful for facilitating information transfer?
- What processes, pathways and contexts could be defined to improve access to information for patient experts and PAGs, as relevant to their 'work' (as compared to patients wanting information for their own health)?
  Potential example ideas:
  - Mailing lists to subscribe to, where information needs can be tailored/specified.
  - Principles based document/framework outlining what information and when patient experts and PAGs can access specific types of information, for the purpose of their work.
  - Accreditation or a 'qualification' of PAGs and patient experts to enable their access to information?
- What other opportunities exist for action to improve access to information?

2. Legal & Compliance Considerations

The Enhanced HTA report[2] proposes prudent examination of how earlier consumer input may be facilitated within existing regulations and legislation. This would allow for subsequent development of guidance for how stakeholders may work together, while supporting adherence to the regulatory and legislative requirements. The following section outlines key elements of specific legislation pertinent to the facilitation of early and continuous consumer engagement.

Background to Australia's Therapeutics Goods Act, the Advertising Code and the Medicines Australia Code

Australia's Therapeutics Goods regulations aim to protect Australian consumers by ensuring the quality, safety and efficacy of therapeutic goods they have access to.

The Therapeutic Goods Act 1989 (the 'Act') describes the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The Act is supported by the Regulations, and various Orders and Determinations which provide further detail of matters covered in the Act and can be amended from time to time. The Therapeutics Goods Administration (TGA) is responsible for administering and assessing compliance with the Act and related legislation[34].

The Therapeutics Goods Advertising Code[35] (the 'Code') sets out the minimum requirements for advertising therapeutic goods to the public. It's a legislative instrument made under section 42BAA of the Act. Compliance with the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021[36] (2021 Advertising Code) has been required since 1 Jul 2022.

The Advertising Code specifically relates to advertising to the public. However, as prescription medicines cannot be advertised to the public, the Code is not applicable. Additionally, advertising to Health Care Practitioners is exempt from the Advertising Code per Part 2, Section 6 of the Advertising Code.

Instead, it is a standard condition of registration for prescription medicines that "Promotional material (other than Product Information) relating to the registered good must comply with the requirements of the Code of Conduct of Medicines Australia." It is this condition of registration which links compliance to the Medicines Australia Code of Conduct (MA Code)[37] as a regulatory requirement. It does not matter if the sponsor of the medicine is an MA member or not.

The Medicines Australia (MA) and the Medical Technology Association of Australia (MTAA) Codes of Conduct[37,38] support their members to act ethically and comply with applicable laws.

The MA Code defines "Promote" as, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.

Complaints about potential breaches of promotional guidelines in the MA Code are dealt with through an MA Code Complaints process.

The MA Code is principles-based and accompanied with guidance documents that provide further practical suggestions for meeting Code requirements. An example guide is the Medicines Australia - Guidance for industry: Communicating ethically with patients and their representatives[39].

While the Advertising Code does not apply to prescription medicines (because you cannot advertise prescription medicines to the public), industry may consider the TGA's guidance on implementing the Advertising Code along with MA's guidance documents to inform their interactions with patient groups.

What is considered advertising/promotional (TGA guidance)

The TGA's website and guidance documents[40,41] provide advice for companies on complying with the Advertising Code, including information about what is considered promotional or not. While the Advertising Code is irrelevant for prescription medicines, the pharmaceutical industry may still reference this guidance to determine they are acting in non-promotional ways when interacting and sharing information with patient communities i.e., complying with the requirement not to advertise to the public.

This section provides excerpts from TGA guidance as it related to what may or may not be considered promotional for reference.

Not all information released to the public about therapeutic goods is advertising. However, if information released to the public intends (from the end viewer's point of view) to directly or indirectly promote the use or supply of a therapeutic good, then the TGA advise they would likely consider it to be advertising and it must meet legislative requirements as set out in Act and the Code[40,41].

Information that is purely factual and balanced and is disseminated for the appropriate use of the goods (for example, consumer medicine information or instructions for use for approved goods) is unlikely to be considered promotional[40].Characteristics of promotional material include[40]:

- unsolicited information rather than solicited information;
- unbalanced information (for example, it focuses on the positive qualities of a therapeutic good and omits or downplays the negative qualities such as possible side effects or limitations of use);
- the use of superlatives, for example, describing a therapeutic good as 'the best' or 'works fastest';
- the use of descriptive adjectives or statements that are emotive (for example, describing a therapeutic good as 'brilliant' or 'changed my life');
- information that is disseminated on multiple occasions with regular or semi-regular frequency (for example, three times a week during the evening news);
- any information that is disseminated by, or on behalf of, manufacturers, sponsors, retailers and any other party with a financial interest in the sale of the goods referenced.

The following is taken into consideration when the TGA decide whether information is an advertisement[40]:

- the context in which the information or activity occurs;

- the audience the information is directed to, what their likely take-out message is and are they likely to consider it to be promotional;
- the use of non-verbal and unwritten messages (such as pictorial elements). These may be just as important in assessing the communication and can alter the take-out message that viewers receive.

Advertising is not limited to a specific type, or types, of media. It can include articles published in journals, magazines and newspapers, displays on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and material posted on the internet, point-of-sale materials, leaflets, booklets and other promotional materials that include specific product claims and which are supplied separately, product reviews and even product trade names[40].

Depending on content and context, some content may not be considered advertisements, such as[40]:

- reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make therapeutic or promotional claims;
- information relating to human health or diseases where there is no reference to therapeutic goods;
- advertising for health services that does not refer, either directly or indirectly, to therapeutic goods;
- correspondence, possibly accompanied by material of a non-promotional nature, to answer a specific unsolicited question about a therapeutic good.

(The TGA advises on their website that a fact sheet providing more information on the differences between advertising and other activities is currently under development.)

The TGA has a set of principles for managing advertising compliance which include considering non-compliance that presents the highest risks to public health, safety and confidence in TG regulation, and the impact on the reasonable consumer. They respond proportionately on a case-by-case basis using a risk-based approach[42] and publish their current enforcement priorities[43].

Impacts of the MA Code, associated guidance & the Advertising Code

There is widespread agreement between government, industry and the public that Australia does not want or support direct-to-consumer advertising of regulated therapeutic goods. As a result, therapeutic goods can only be advertised to those specified under Section 42AA, subsection 1 of the Act (see Appendix 1), summarised as health practitioners (as defined in the Act), wholesalers, and appropriate purchasing officers/organisations.

As a principles-based document, the MA Code provides a framework to support appropriate and ethical decision making when interacting with healthcare practitioners, patient communities and the general public. It is not prescriptive about what is and isn't promotional, and acknowledges the context, alongside what/how information is provided, is important in evaluating whether information directly or indirectly promotes the use or supply of goods. The MA Code is supported by non-binding guidance documents which discuss risks and potential strategies to mitigate those risks in various scenarios, to remain compliant with being non-promotional with all these stakeholder groups.

For noting, under MA Code Edition 19, companies may share information with patient organisations and their representatives, and this may include information about prescription medicines if there is a genuine need for the information, the content is relevant to their specific expertise and interest in the therapeutic area, and is non-promotional. In MA Code Edition 20, just released, an additional affirmative line (11d) has been added to make this clear.

MA Code, Edition 20, Section 11: Support for Health Consumer Organisations

d) Companies may share information with patient organisations and their representatives. This may include information about prescription medicines if there is a genuine need for the information, the content is relevant to their specific expertise and interest in the therapeutic area, and is non-promotional.

When the difference between 'informational' and 'promotional' is subject to the eye of the beholder, and a wide range of types of materials and activities could potentially be in scope, there is considerable grey area in what could be perceived as advertising.

Companies have a lot to lose if they are accused of advertising to the public. Unsurprisingly therefore, they may take a very conservative approach in interpreting the TGA's Advertising Code guidance and MA Code and supporting documents when deciding how they engage with patients and patient communities, and what information they share, how and when.

For patient experts and PAGs supporting their communities, access to information enables them to be more effective, meaningful partners along the extended HTA lifecycle, from the research phase, through to making inputs to HTA processes and beyond. Patient experts and PAGs often hold critical knowledge that well complements clinician knowledge of a health condition, its treatments and access to them, because of their particular focus on that condition and role in synthesising information and experiences from a wide range of sources.

However, as patient experts and PAGs are not recognised in the Act as different to the general public or as legitimate stakeholders to whom information about therapeutic goods can be shared, their ability to fully engage meaningfully, early and continuously throughout the HTA lifecycle can be hampered.

Examples of (presumed) unintended practical consequences of the interpretation of what's possible include:

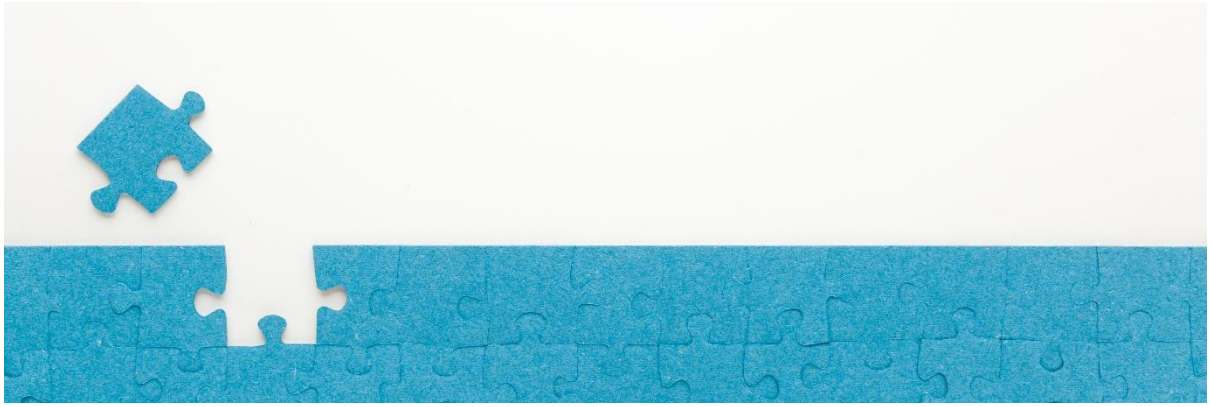
- Inability for patient experts and PAG representatives to attend conferences with an industry trade hall, or to attend scientific research sessions where product names may be mentioned. (There is inconsistency in how conference organisers allow/manage patient community attendance. Some conferences organisers act conservatively, limiting attendance or access to trade halls/sessions for fear of inadvertently putting companies at risk of promoting products to the public and hence losing sponsorship, exhibitors , attendance or funding for their conferences.)
- Reluctance to provide published results of clinical trials with patient communities.

- Inability of patient communities to be provided with trial protocol summaries, trial result summaries or links to that information already in the public domain that could help them support their communities with horizon scanning, access research opportunities or being aware of advances for their health condition.
- Inability to provide pipeline information to patient communities which may support horizon scanning initiatives for specific patient communities
- Inability for patient communities to access information about goods and services that have applied for TGA registration and/or public funding (reimbursement) in order to provide meaningful inputs to the government, TGA or HTA bodies on the value to their patient communities of those goods and services.
- The impracticability of sharing information about a new treatment (by class or name) when there is only 1 drug available/in that class – this is especially valid in rare disease/indications, conditions with unmet needs, or with emerging technologies.
- The global nature of the world and accessibility of information over the internet raises the risk that patient communities may source information from overseas that is not applicable/relevant in the Australian context.

A note on the Competition and Consumer Act 2010

Companies also have responsibilities under the Competition and Consumer Act 2010, the purposes of which are promoting competition and fair trading, and to protect consumers in dealings with a business[44]. The author of this Paper is not a legal expert and is unfamiliar with all the requirements of the Competition and Consumer Act 2010, and all its implications for the therapeutics industry.

However, the author offers as a potential example with respect to access to information for consumers, the ACCC's advertising and selling guide[45] which references the need for businesses selling health and medical products and service to provide consumers with accurate and truthful information so they can make informed decisions. This may be difficult to comply with where information about the safety and efficacy of a product is still limited (e.g. the product is unregistered or newly registered, used in a rare condition, or is first in class), and where the interpretation of when and the nature of information that might be considered 'promotional' or 'advertising' is unclear.



Knowledge Gaps

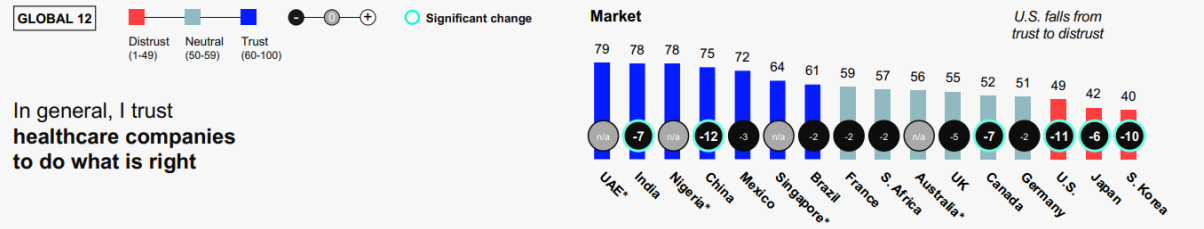
- Examples of positive/negative impacts from the regulatory environment or Medicines Australia Code of Conduct on access to timely information sought by the patient community.
- Is the MA Code / Advertising Code perceived to hamper access to the information patient communities need, and how?
- Is there agreement/consensus on what is promotional? What information, in what context, to whom, and when? How can we make this clearer?
- What information is considered non-promotional?
- Do PAGs feel that information provided may be perceived as being for promotional purposes?
- Does the regulatory environment need to change, or are there workarounds? Is the MA Code edition 20 addition to section 11 enough to facilitate greater information sharing?
- What processes, pathways and contexts could be defined to improve access to information whilst maintaining compliance with the legislation.
  Potential example ideas:
    - Providing context for the exchange when providing information
    - Further exploring with MA and TGA the scenarios that present challenges to patient engagement and information sharing, to identify potential solutions.

3. Trust & Rules of Engagement

Trust between stakeholders is necessary for effective, working relationships and genuine, meaningful partnerships. When organisations have different drivers, building trust can take more time and effort. To build trust, organisations need to be clear and honest about their boundaries, act with integrity and transparency, find and agree common principles, beliefs and goals, demonstrate competence in their own knowledge and capabilities and be genuinely interested in and respectful of the expertise and capabilities of the other, and be consistent. In a world of changing staff, priorities and resources, maintaining consistency is difficult and requires commitment.

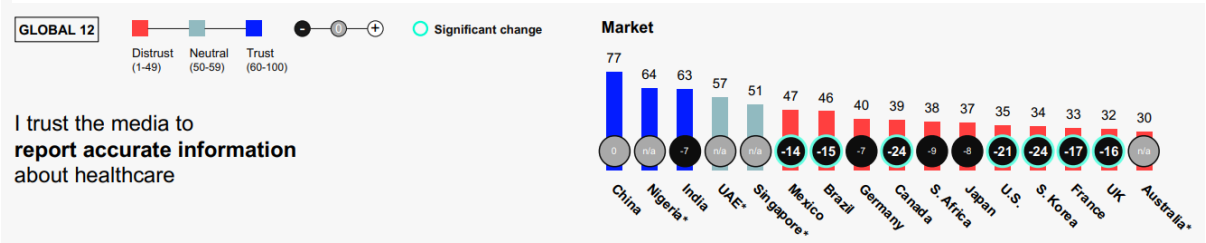
The 2024 Edelman Trust Barometer Trust and Health report[46] showed that trust in health care companies in Australia was neutral, sitting at about the average global trust level of 58 (Figure 3).

FIGURE 3: Trust in Healthcare Companies Declines across Markets and Demographics[46, page 6]



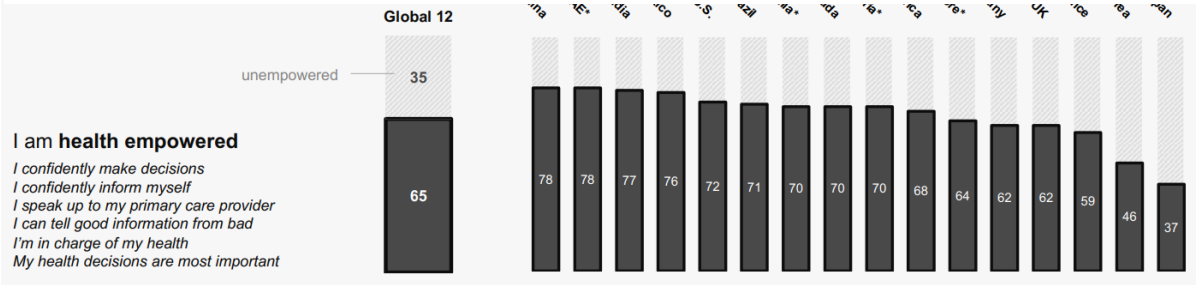
However, Australia has one of the highest levels of distrust globally in media reporting healthcare information accurately. 2024 was the first time this was measured in Australia, but the trend globally is that trust in media reporting on health is dropping (Figure 4).

FIGURE 4: Trust in Media on Health Reporting Plummets[46, page 7]



Per this report[46], 70% of Australians feel empowered to manage their health, slightly higher than the global average (Figure 5).

FIGURE 5: Globally, 2 in 3 Feel Empowered to Manage Their Health[46, page 14]



Edelman[46] reported on the link between trust in the health ecosystem and level of empowerment and how people felt about their health. The more people trusted the health ecosystem, and felt empowered, the better they reported their health to be (Figure 6).

Empowered, trusting consumers were more likely to vet health information, engage in preventative care, be fully vaccinated, share or forward health news and be supportive of health innovation (Figure 7).

While there were some nuances in trust of sources depending on age, income, political leanings, and level of trust and empowerment, interestingly, healthcare CEOs are significantly distrusted in Australia as sources of public health information (Figure 8).

Additionally, Heads of health NGO's were almost as distrusted as a source of truth on health issues as healthcare CEO's. Nurses were the most trusted source (Figure 9).

FIGURE 6: High Trust and Empowerment Lead to Better Personal Health Outcomes[46, page 17]

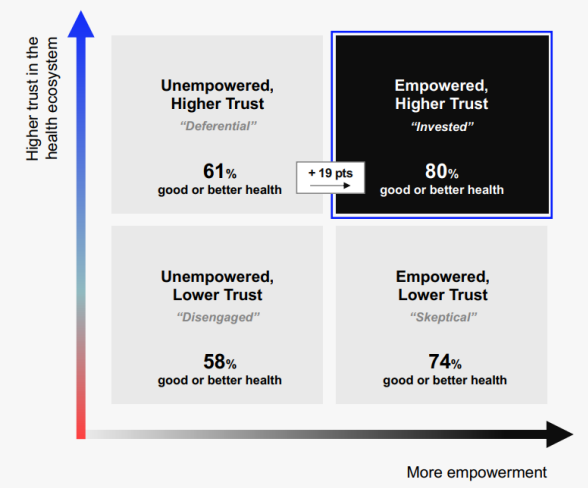


FIGURE 7: Leverage the Invested as Partners for Trust and Better Health Outcomes[46, page 33]

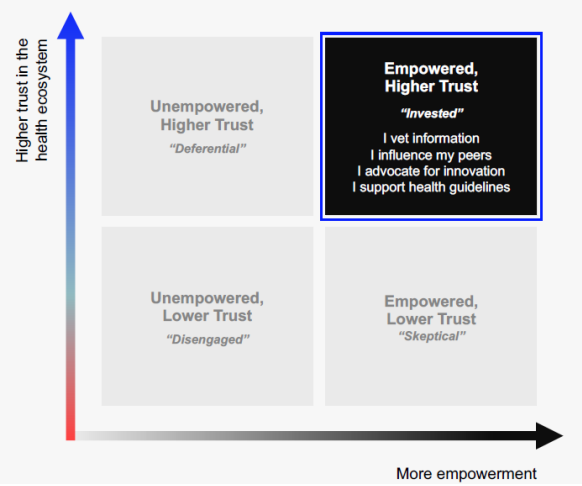


FIGURE 8: My Provider Most Truster as a Source of Truth on Health[46, page 45]

Significant change*

Distrust (1-49) Neutral (50-59) Trust (60-100)

+/- Apr 2022 to Apr 2023	Global 12 %	Global 12 +/-	*Australia %	*Australia +/-
My primary care provider	83	2*	83	-
Pharmacists	73	-3*	77	-
My friends and family	70	-6*	71	-
My CEO	50	-9*	47	-
Healthcare CEOs	45	-7*	35	-
Government leaders	39	-7*	37	-
Journalists	35	-10*	24	-

FIGURE 9: My Provider Most Truster as a Source of Truth on Health[46, page 46]

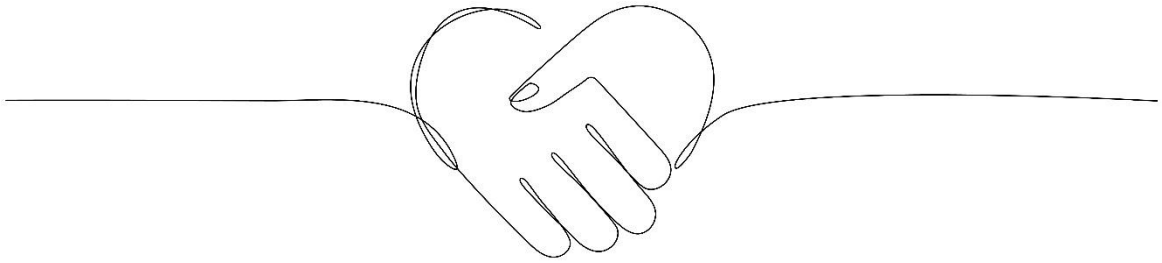
Significant change*

Distrust (1-49) Neutral (50-59) Trust (60-100)

+/- Apr 2022 to Apr 2023	Global 12 %	Global 12 +/-	*Australia %	*Australia +/-
Nurses	79	0	85	-
Medical scientists and health experts	74	-1	72	-
National health authorities	61	-3*	60	-
Global health authorities	58	-4*	54	-
Heads of health NGOs	49	-7*	43	-
Content creators with formal medical training	40	-	32	-
CEOs	36	-10*	27	-
Spiritual or religious leaders	32	-7*	25	-
Celebrities or sports figures	28	-10*	20	-
Content creators without formal medical training	24	-	19	-

Being a source of reliable trustworthy information was found to be a key factor across sectors (business, NGOs and Government) for building trust in health.

Trust is a critical foundation for opening the door to positive attitudes and relationships that have beneficial outcomes for both the industry and patient's own health.



The importance of transparency to maintaining trust and reputation

There is risk to both reputation and trust for all stakeholder groups (government, industry and patient groups) if information, working relationships, and funding arrangements are not transparent.

Regarding Information

As discussed above, there is valuable information held by government, industry and PAGs that is of value to the other. However, each stakeholder will have sensitivities around what can be shared with who, when and how.

- Industry has commercial sensitivities and must be seen to be non-promotional;
- Patient experts and PAGs often have access to personal and sensitive information, and there will be considerations around privacy, consent, and how the collection of that information has been funded;
- Governments have access to vast amounts of information about use of healthcare, therapeutic goods and services, and public funding, and are accountable to the public for the appropriate use and sharing of that information.

Maintaining the reputation and trust of the community, whilst balancing the public good (potential health benefits) that information-sharing can provide is a fine line.

Regarding working relationships/funding arrangements

The reputation and integrity of both industry and patient groups can be called into questions when there is inadequate transparency about the nature of their relationships and funding.

In 2020, the Australian Health Minister accused a pharmaceutical company of 'astroturfing' in parliament[47], suggesting a company was using a PAG to facilitate their lobbying agenda. Equally, academics have called out patient groups for their lack of transparency[48-52], limiting the ability of the public to make informed assessments about how a group's activities may be being influenced by companies, creating suspicion and damaging trust.

Under the Medicines Australia (MA) Code, companies are required to report any transfer of value to health consumer organisations (Figure 10). These reports are made publicly available for each calendar year and can be accessed on the MA website[53].

FIGURE 10: Transparency Reporting: Health Consumer Organisations – Medicines Australia[53]

What must be reported?

Each company must provide to Medicines Australia for publication on its website, a report listing health consumer organisations to which it provides financial support and/or significant direct/indirect non-financial support. The published report must include:

1. the name of the health consumer organisation; and
2. a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the nature of the support; and
3. the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

There are a range of practices amongst PAGs in how they report industry interactions[54]. For charities with an ACNC registration, there will be variable 'categorical' reporting of income sources in their annual report[62].

In the absence of specific guidelines, a 2020 Workshop of researchers, consumers and consumer groups[50] developed a list of suggested best practices for PAGs for reporting industry relationships (Figure 11). It is not known however to what extent these suggestions have been taken up by PAGs.

FIGURE 11: Participant suggestions on best practices for operationalising the principles of honesty and transparency[50, Table 3]

Honesty / transparency – suggested examples of best practice included public reporting of:

a. all money received from industry including: actual dollar amounts of each payment, in-kind support including invited attendance at industry-funded meetings, use of funds, rejected funding, any 'strings' attached to funding, percentage of total organisation funds coming from the pharmaceutical industry;

b. the organisation's policy on funding

c. details about current or previous financial relationships between Board members and the pharmaceutical industry

d. all contracts with pharmaceutical industry funders

e. all information must be easily accessible including to non-members, e.g. on the website and/or annual reports and newsletters if these are available to non-members.

Patient Voice Initiative/CaPPRe research uncovered a perception from patient communities that biopharmaceutical companies are not invested in understanding their needs, experiences and journeys, and they don't value their knowledge, especially when it doesn't align with a company's business objectives[14]. Additionally, the research noted a lack of transparency in the funding opportunities that may exist from pharmaceutical companies (content and amount).

A range of suggestions were proposed in the above mentioned workshop[50] to support PAGs considering entering into relationships with pharmaceutical companies to help ensure patient-centredness, values alignment, independence, governance and accountability. The UK's Association of Medical Research Charities has also produced a guide[55] for charities working with industry that provides suggestions for dealing with some of these issues.

Understanding the rules of engagement

"Consumers want an equal partnership with other stakeholders in the HTA process and to work closely with industry and clinicians in contributing towards evidence and applications that may lead to better health outcomes[5]."

Working together however can be difficult when there is a lack of understanding around how each stakeholder works internally – the drivers, sensitivities, processes, resourcing and staff (who to contact for what).

Patient Voice Initiative/CaPPRe research noted if companies are difficult to work with due to a lack of clear information/transparency/guidance on how to do so, or the engagement feels one-sided and transactional, it can lead to dissatisfaction[14].

There is substantial inconsistency in how companies operate, how they will engage with PAGs and patient experts, and what information they will provide. There is often little public information about how or who to engage, which then relies on groups having the networks, or good fortune, to find the right person who has the interest, willingness and/or decision-making authority to engage, answer questions, provide requested information or funding.

The UK's ABPI guidance on working with patient organisations[56] makes reference to the value of a single point of contact: "It is very helpful if a company can provide a consistent and single point of contact for the patient organisations it plans to work with, and takes time to support them through the process: commercial structures can be complicated for others to navigate, and representatives of patient organisations often have very limited time or resources to devote to administration."

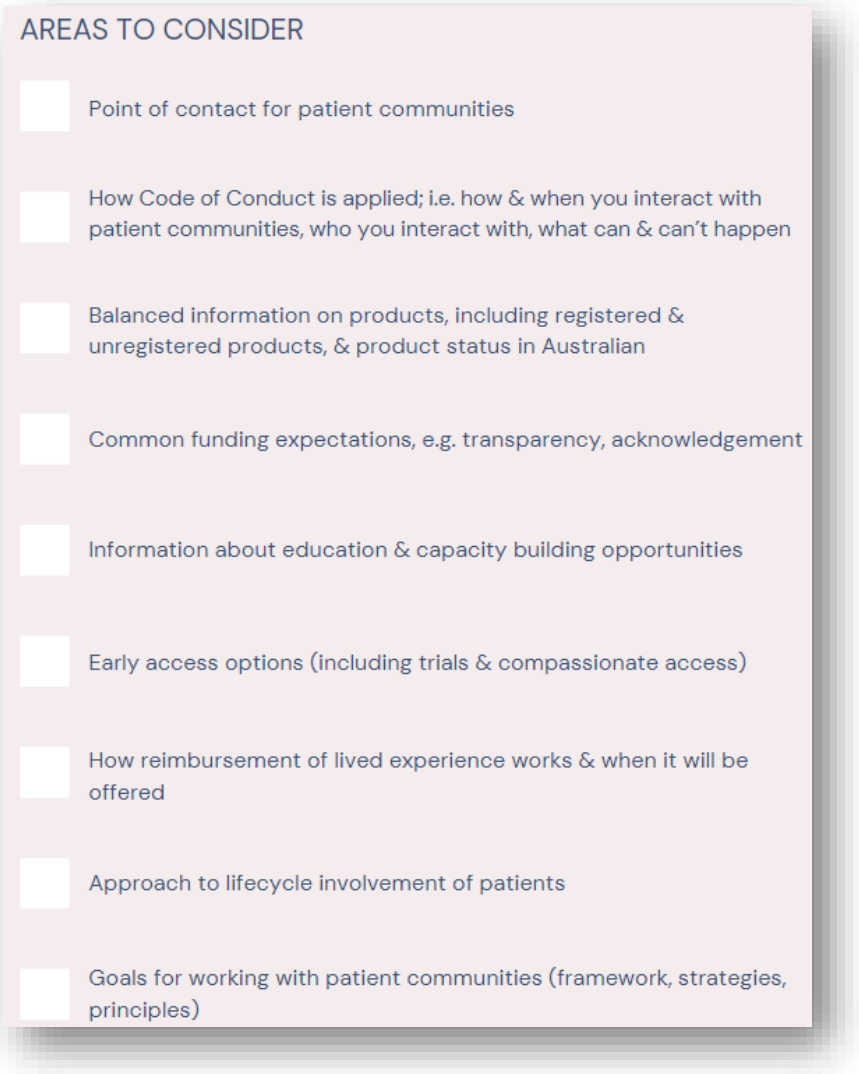
Pharmaceutical companies can be large, and global. In the absence of knowing who the local contact is, or perceived delays or lack of interest locally to support, patient experts and PAGs can sometimes sidestep local affiliates in their search for information, answers or support. This can sometimes be counterproductive to good local outcomes and may not yield the answers PAGs need simply because the commercial reality is that Australia, in most instances, is a small percentage of overall revenue for global businesses. That means local companies and company affiliates (as well as patients), understanding their sphere of influence, will need to be strategic and 'pick their battles'.

In 2023, the Patient Voice Initiative and CaPPRe, published research on the needs and preferences of patient organisations, online patient communities and patient advocates when interacting with biopharmaceutical companies[14]. From this, a list of considerations for

pharmaceutical companies with respect to how they engage was developed. It included detail on the types of information patient communities would like access to in a clear, transparent and easy-to-access way[57] (Figure 12).

FIGURE 12:

Interacting with Patient Communities: Areas for Pharmaceutical companies to consider[57]



It is equally challenging for government and industry to understand the patient community landscape and how patient groups work. PAGs have many different structures, informal and formal, from online Facebook groups, to large charities. They may be run as volunteer organisations where whomever can help at the time does the job at hand, or large enough to have substantial paid workforces with defined roles. Some will work with industry, while others will not. And, the relationships between PAGs can be challenging to navigate.

In the UK, the Association of Medical Research Charities (AMRC)[55] recommends that "charities should aim to have an established point of contact in their partner company and a specific member of staff who leads on managing the relationship." It is therefore good practice for patient communities to make it just as easy for government and industry to access to the right people within their organisations, as patient communities need in reverse.

Who is the right 'patient' voice?

"While consumers may vary in their experience of engaging in HTA processes, any consumer has the potential to contribute the 'expertise' of their lived experience to better inform the assessment of health technologies[2]."

The Conversations for Change Report[5] noted a need to "establish disease specific consumer expert/advisory panels, to provide information on the specific needs of the patient populations", as a practical way to help ensure 'consumers are included in HTA processes and methods'. This was reiterated in Recommendation 3 of the "Enhance HTA' report[2].

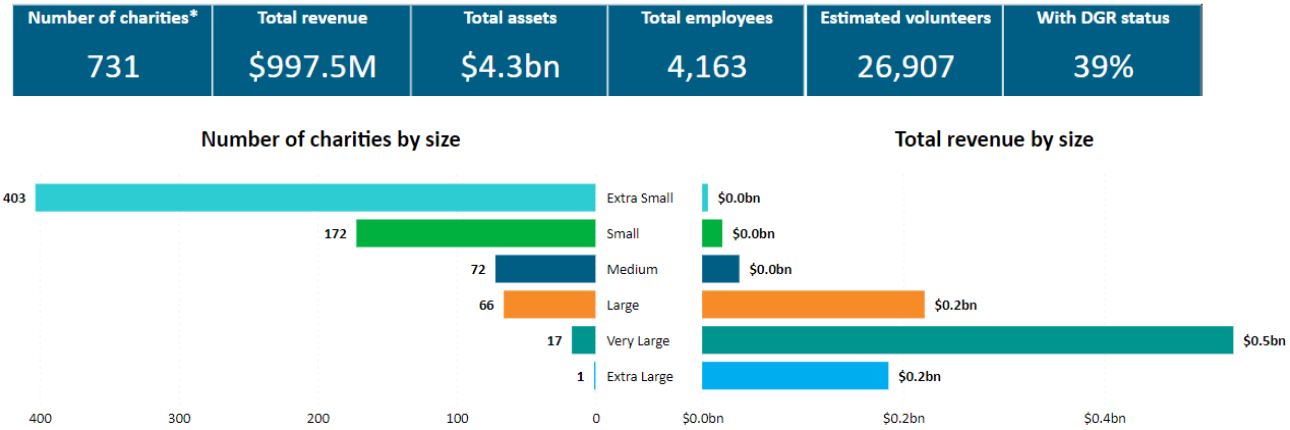
There is a sophistication in knowledge, experience and networks to engage in different aspects of the HTA process. Patient experts and PAG representatives develop this knowledge over time, essentially 'learning by doing', as there are not accredited courses (nor potentially the time and money to attend courses) on various phases of product development and HTA. There are organisations that provide limited, free or paid, informal or formal education opportunities to help elevate the knowledge base, but no validated competency framework or accreditation process that allows individuals or organisations (or their staff) to be recognised as 'experts' for the purposes of advisory panels and input opportunities. The European Patients' Academy on Therapeutic Innovation (EUPATI)[58] is one example of a public-private partnership turned non-profit that provides education to increase the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development (R&D). There is considerable international discussion about what is the appropriate or required training for patient experts and organisations to engage in specific activities. While there is no one agreed approach, or exemplar model that is comprehensive, equitable or easily accessible at this time, this is a rapidly evolving space.

Because of limitations in their own resources, government and companies will have a preference for engaging with an alliance or few key PAGs as it is less resource intensive than engaging with that multiple patient experts and groups. However, the variations in patient expert/PAG interests, shifting alliances and capacity for grass roots support/engagement can make it difficult for industry and government to identify 'the right voices' to engage with, and ensuring those voices capture enough diversity to be representative.

In the 2024 Australian Charities and Not-for-profits Commission (ACNC) report[59], there are 731 health charities of various size registered, collecting almost a billion dollars in revenue, employing over 4000 people and supporting a volunteer workforce of nearly 27000 people (Figure 13). These numbers do not account for the many unincorporated or informal patient networks and patient experts.

Patient experts and PAGs have a role in helping other stakeholders navigate the patient community to ensure input into health technology development and HTA processes is inclusive of diverse voices and experiences, and relevant information is shared broadly, such that better health outcomes are achieved for more of the Australian community.

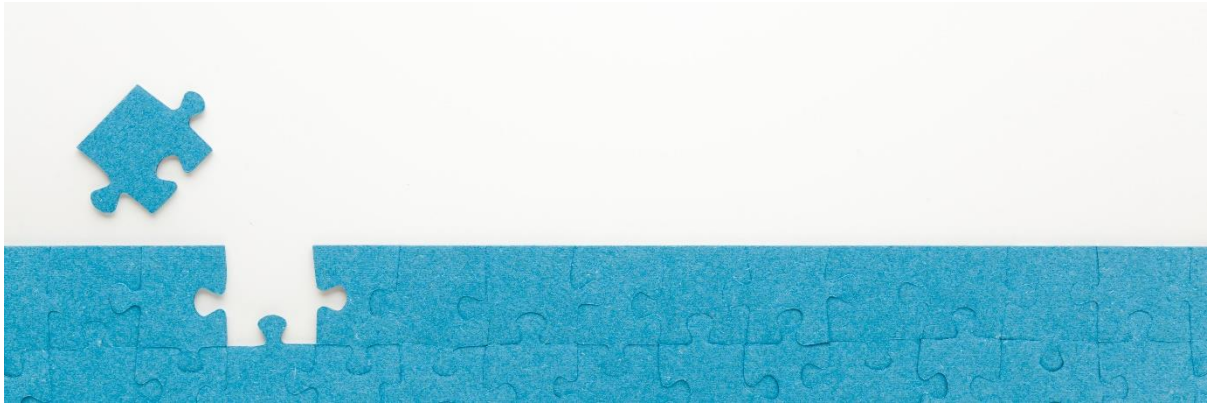
FIGURE 13: Key statistics on health charities, 2024[59]



Respectful engagement – acknowledging different agendas

There are tensions between the agendas of different stakeholder groups to navigate – from the public interest/public good/fiscal responsibility requirements of government, to the advocacy, access and support needs of PAGs and commercial realities for industry.

There is a need for respectful, educated engagement between all parties, to achieve the best possible outcomes for all. In the heat of the issue, or when frustrations arise, it is important the fight does not get 'personal'.



Knowledge Gaps

- Whose responsibility is it to initiate engagement in therapeutic development and HTA processes (patient experts, PAGs, industry, government)? How should engagement be initiated?
- What are the simple barriers for PAGs to initiating engagement (e.g. working out whom to contact; see also Figure 12)?
- What are PAGs experiences with getting information and contacts from companies? What information is needed to facilitate contact (Figure 12)? How do we improve PAGs and companies' ability to engage (e.g. the right contacts)?
- What is the role for patient community alliances in facilitating engagement, trust, and policy reform?
- How difficult is it to contract with companies? (e.g. Patient Focussed Medicines Development initiatives re plain language contracts[63], fair market value[64])? What support is needed by PAGs?
- What commitments should each stakeholder group make, to improve trust and transparency between parties, in the process, and with the public?
- How do we ensure diverse voices and experiences are engaged?
- What examples exist internationally of best practice information sharing and/or engagement between industry, government and patient experts/PAGs?

Other considerations – outside scope of the Roundtable

PAG funding and resourcing

The Conversations for Change Report[5] noted a need to provide "resources and funding for consumers organisations to collect or coordinate data on lived experience and PROs, provided with support from other stakeholder groups", as a practical suggestion to ensure 'consumers are supported and knowledgeable'.

Patient communities themselves report insufficient funding from industry, as well as a lack of information and transparency on funding opportunities, time delays and burden in applying and receiving funding, and an imbalance with larger organisations getting all the funding[46].

There are complications and implications around funding of patient experts and PAGs, including:

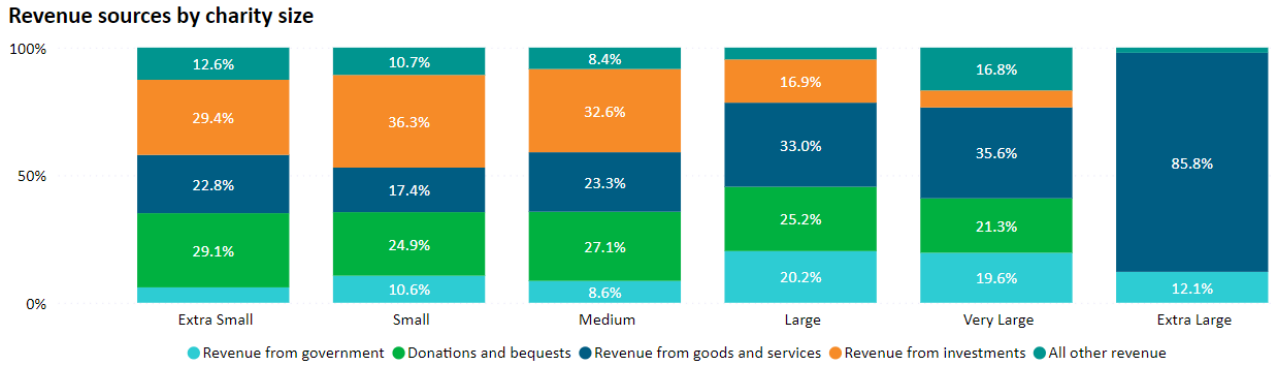
- Who should provide the funding;
- What should be funded;
- Who can apply and receive funding;
- Selection bias/picking winners, and the implications for not funding organisations;
- Managing perceptions and conflicts of interest, and hence trust, reputation, integrity for both funder and funded;
- Transparency and reporting on funding (funder and funded);
- For patient experts, tax & social security implications, income reporting and reputation.

A 2020 workshop[50] reported an appetite of PAGs for more funding options, including government support.

Previously published analysis[49], also reported at this workshop, showed industry provided $34.5 million in funding to PAGs over 2013-2016, with the top ten groups receiving 45% of that funding. It also reported only half of Australian PAGs in that period publicly disclosed their pharmaceutical industry funding and less than 20% had publicly available policies on corporate sponsorship[54].

It is not clear exactly how much funding PAGs receive from government, although for most registered health charities, government typically contributes a small proportion of overall revenue (Figure 14). Interestingly, the larger health charities appear to attract more government revenue.

FIGURE 14: Sources of revenue by size of charity[59]



Addressing the issue of funding is outside the remit of this Paper. However, we acknowledge that limited resources within patient communities does impede continuous engagement in HTA, and that there will need to be efficient mechanisms for and investment in these communities (likely through a mix of sources) if early and continuous engagement, as well as better quality patient evidence and inputs to HTA processes are sought.

The need for investment

As recognised in the HTA methods review[1] and Enhanced HTA[2] reports, there is a need for investment in the infrastructure (including policy, frameworks and processes for engagement), training, data and human resources, to enhance early and continuous engagement across medicines development and HTA, by all stakeholders – the government, industry and PAGs.

The HTA Methods Review[1] noted "improving communication and engagement processes, enabling proactive activities such as horizon scanning, streamlining funding and approval pathways, and establishing and operating a bridging fund all require additional resources and investment in the workforce and system capabilities." However, "these recommendations cannot be delivered effectively with current departmental appropriations".

Patient communities, industry and the public will no doubt be awaiting with interest the government's response to these reports, and subsequent budget announcements, to see if, when and how this investment to support early and continuous engagement of consumers in HTA processes will be made.

Conclusion

Per the Conversations for Change report[5], "Consumer involvement should be a continuous pathway extending from clinical trials to regulatory process, throughout subsidisation considerations and into post-market reviews." With the release of the HTA methods review[1] and Enhanced HTA[2] reports, the environment is ripe for positive change across the whole life cycle, especially with respect to HTA decision making.

This Paper identifies three themes that impact patient communities' ability to engage early and continuously in, and input meaningfully to, HTA.

The Shaping Healthcare Together Roundtable provides an opportunity to engage PAGs in a conversation about the relative impacts of each theme in influencing their ability to engage effectively and identify potential strategies for further investigation and development. Outputs from the Roundtable will be extremely useful enablers as we move forward with recommendations from the HTA Methods review[1] and Enhance HTA[2] reports.

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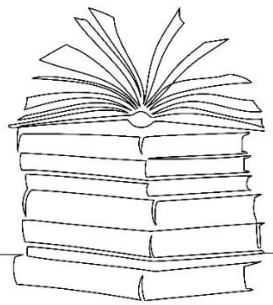

Appendix 1: Legislation

The following texts have been extracted from the various legal instruments that may be relevant to/inform discussion at the Roundtable. The texts highlighted in yellow may have specific interest when considering where/why there are barriers to the sharing of information, and/or who has the power (or the mechanism) to make change/amendments.

Therapeutic Goods Act 1989 (the 'Act')

Extracted from: version C2024C00263VOL01 and VOL02 : Compilation No. 85

Compilation date: 1 July 2024

Includes amendments: Act No. 50, 2024

Registered: 8 July 2024

3(1)) Definitions (*only those deemed relevant to this Paper are included*).

advertise, in relation to therapeutic goods or vaping goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

(a) is on the label of the goods; or

(b) is on the package in which the goods are contained; or

(c) is on any material included with the package in which the goods are contained.

(For noting, Intention is assessed not only by what the person responsible for the content intends (direct intent), but also by what the average consumer would reasonably view as being intended by the content (indirect intent). This means that if members of the public would reasonably consider that the information is intended to promote the use or supply of the identified goods, then the TGA would be likely to consider it an advertisement[41].)

health practitioner means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

(a) Aboriginal and Torres Strait Islander health practice;

(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);

(c) medical;

(d) medical radiation practice;

(e) nursing;

(f) midwifery;

(g) occupational therapy;

(h) optometry;

(i) pharmacy;

(j) physiotherapy;

(k) podiatry;

(l) psychology.

indications, in relation to therapeutic goods, means the specific therapeutic uses of the goods.

label, in relation to therapeutic goods, means a display of printed information:

(a) on or attached to the goods; or

(b) on or attached to a container or primary pack in which the goods are supplied; or

(c) supplied with such a container or pack.

medical practitioner means a person who is registered or licensed as a medical practitioner under a law of a State or an internal Territory that provides for the registration or licensing of medical practitioners.

nurse practitioner means a person who is registered, or authorised (however described) to practise, as a nurse practitioner by or under a law of a State or an internal Territory that provides for the registration of nurse practitioners, or the authorisation of persons to practise as nurse practitioners.

pharmacist means a person who is registered as a pharmacist under a law of a State or an internal Territory that provides for the registration of pharmacists.

product information, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

registered goods means:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

sponsor, in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

(d) exports, imports or manufactures the goods; or

(e) arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

supply includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and

(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and

(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods or vaping goods in persons; and

(d) supply by way of administration to, or application in the treatment of, a person.

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); or

(ba) determined to be therapeutic goods under subsection 7AAA(1);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7 and goods determined to be therapeutic goods under subsection 7AAA(1)) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or

(f) goods (other than goods declared to be therapeutic goods under an order in force under section 7 and goods determined to be therapeutic goods under subsection 7AAA(1)) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented; or

(g) goods covered by a determination under subsection 7AA(1) (excluded goods); or

(h) goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination.

Therapeutic Goods Advertising Code means the code in force under section 42BAA.

therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

(b) influencing, inhibiting or modifying a physiological process in persons; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons.

Section 42AA, Chapter 5, part 5-1 : advertising and generic information.

42AA (1) This Part does not apply to advertisements directed exclusively to:

(a) health practitioners; or

(aa) persons who, under a law of a State or internal Territory, are registered or licensed to practice in any of the following health professions:

(i) chiropractic;

(ii) dental therapy, dental hygiene, dental prosthetics or oral health therapy;

(iii) osteopathy;

(iv) paramedicine; or

(b) persons who are:

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

(iii) purchasing therapeutic goods on behalf of a registered charity; or

(iv) purchasing therapeutic goods on behalf of a government or government authority (including a foreign government or foreign government authority); or

(v) purchasing officers, or practice managers, for a person mentioned in paragraph (a) or (aa) (other than a person in a retail pharmacy who, under a law of a State internal Territory, is registered or licensed to practice in the health profession of pharmacy); or

(c) herbalists, homoeopathic practitioners, naturopaths, nutritionists or practitioners of traditional Chinese medicine registered under a law of a State or Territory; or

(d) a class of persons specified under subsection (1A).

(1A) The Minister may, by legislative instrument, specify a class of persons for the purposes of paragraph (1)(d).

(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies prescribed for the purposes of this subsection.

(3) For the purposes of subsection (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.

(4) This Part does not apply to advice or information given directly to a patient by a person referred to in paragraph (1)(a), (aa) or (c) or subsection (2) in the course of treatment of that patient.

42B Definitions (*Note: This is all the definitions listed*)

generic information, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic

goods, but does not include:

(a) an advertisement about the goods; or

(b) generic information included in an advertisement about the goods; or

(c) bona fide news.

prohibited representation means a representation referred to in subsection 42DJ(1).

registered charity means an entity that is registered under the *Australian Charities and Not-for-profits Commission Act 2012* as the type of entity mentioned in column 1 of item 1 of the table in subsection 25-5(5) of that Act.

required representation means a representation referred to in subsection 42DJ(2).

restricted representation means a representation referred to in section 42DD.

42BAA Therapeutic Goods Advertising Code *(For noting, this is the whole 42BAA section)*

(1) The Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods.

(2) Despite subsection 14(2) of the Legislation Act 2003, an instrument under subsection (1) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021[h] (2021 Advertising Code).

Reviewed version: F2023C00019 Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

Compilation No. 1

Compilation date: 20 December 2022

Includes amendments up to: F2022L01650

Name

This instrument is the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*.

3 Authority

This instrument is made under section 42BAA of the *Therapeutic Goods Act 1989*.

4 Therapeutic Goods Advertising Code

Schedule 1 constitutes the code relating to advertisements about therapeutic goods for the purposes of section 42BAA of the *Therapeutic Goods Act 1989*.

Schedule 1: Part 1 – Preliminary

2 Objects of this Code

The objects of this Code are to specify requirements for advertisements about therapeutic goods so that advertisements:

(a) promote the safe and proper use of the therapeutic goods by minimising misuse, overuse or underuse; and

(b) are ethical and do not mislead or deceive the consumer or create unrealistic expectations about the performance of the therapeutic goods; and

(c) support informed health care choices; and

(d) are not inconsistent with current public health campaigns.

3 Simplified outline of this Code

This Code specifies requirements for advertisements about therapeutic goods.

Part 1 deals with preliminary matters, including the definitions of key terms.

Part 2 specifies the advertisements to which the Code does, and does not, apply.

Part 3 specifies general requirements for advertisements about therapeutic goods.

Part 4 deals with mandatory statements and other required information that must be included in advertisements about therapeutic goods.

Part 5 specifies additional requirements for advertisements about analgesics, sunscreens and therapeutic goods for weight management.

Part 6 deals with testimonials and endorsements used in advertisements about therapeutic goods.

Part 7 deals with samples and incentives offered in advertisements about therapeutic goods.

Part 8 defines ***serious*** form of a disease, condition, ailment or defect, and specifies public interest criteria, for the purposes of restricted representations.

Part 9 deals with advertisements about therapeutic goods comprising price information.

4 Definitions

Note 1: A number of expressions used in this Code are defined in subsubsection 3(1) of the Act, including the following:

(a) advertise;

(b) current Poisons Standard;

(c) directions for use;

(d) health practitioner;

(e) included in the Register;

(f) indications;

(g) label;

(h) medical device;

(i) medicine;

(j) Register;

(k) registered

Additional potentially relevant definitions in this Code:

advertiser means a person who:

(a) advertises, by any means, therapeutic goods; or

(b) causes the advertising, by any means, of therapeutic goods.

health professional means a person mentioned in paragraph 42AA(1)(a), (c) or (d), or subsection 42AA(2), of the Act.

instructions for use has the same meaning as in the Medical Devices Regulations.

intended purpose has the same meaning as in the Medical Devices Regulations.

Note: The definition of ***intended purpose*** in the Medical Devices Regulations is as follows:

intended purpose, of a medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device; or

(b) the instructions for use of the device; or

(c) any advertising material applying to the device; or

(d) any technical documentation describing the mechanism of action of the device.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002.*

other therapeutic goods means therapeutic goods that are not medicines, biologicals or medical devices.

patient information leaflet has the same meaning as in the Medical Devices Regulations.

prominently displayed or communicated, in relation to a statement in an advertisement, means:

(a) either:

(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as is necessary to be noticed by a viewer or listener.

public health campaign means a campaign about a public health matter that is conducted, approved or funded by one or more of the following:

(a) the Commonwealth;

(b) a state or territory;

(c) a Commonwealth, state or territory statutory authority.

Regulations means the *Therapeutic Goods Regulations 1990.*

short form advertisement means**:**

(a) in relation to a radio advertisement—an advertisement that is 15 seconds or less in duration;

(b) in relation to a text only advertisement—an advertisement that consists of 300 characters or less for which there is no reasonable capacity to include a picture, logo or other imagery as part of the advertisement;

but does not include an advertisement that is published on social media.

TGO 91 means the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines.*

Note: TGO 91 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

TGO 92 means the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines.*

Note: TGO 92 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

Part 2 - **Application of this Code** *(Selected relevant sections only)*

5 Advertisements to which this Code applies

(1) This Code applies to advertisements about therapeutic goods other than advertisements specified in section 6.

(2) This Code applies, in relation to a particular advertisement, by reference to its likely impact on a reasonable person to whom the advertisement is directed.

(3) In applying this Code to an advertisement, the total presentation and context of the advertisement is to be taken into account.

6 Advertisements to which this Code does not apply

(1) This Code does not apply to an advertisement that is:

(a) directed exclusively to a person mentioned in section 42AA of the Act; or

(b) part of, or otherwise comprises, a public health campaign; or

(c) made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* made under section 42DK of the Act, as in force or existing on 20 December 2022.

Note: The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* is published on the Department's website at www.tga.gov.au.

Price information

(2) This Code, other than Part 9, does not apply to an advertisement about therapeutic goods that only contains price information about medicines that are registered goods and contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not a substance that is included in Appendix H of the current Poisons Standard).

Genuine news

(3) This Code does not apply to genuine news that is broadcast or published in any medium by:

(a) a broadcaster; or

(b) a datacaster; or

(c) the SBS; or

(d) a person of a kind prescribed by the Regulations for the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act.

Note 1: Subsections 42DLB(11) and 42DMA(3) of the Act, define ***broadcaster, datacaster*** and ***SBS*** as follows:

broadcaster has the meaning given by clause 3 of Schedule 2 to the *Broadcasting Services Act 1992.*

datacaster means a person who holds a datacasting licence (within the meaning of the *Broadcasting Services Act 1992*).

Part 3 - **General requirements** *(Selected relevant sections only)*

11 Scientific or clinical representations

(1) This section does not apply in relation to:

(a) labels of therapeutic goods; or

(b) consumer medicine information; or

(c) instructions for use; or

(d) patient information leaflets.

(2) An advertisement about therapeutic goods that makes a scientific or clinical representation must:

(a) only contain scientific or clinical terminology that is clearly communicated and able to be readily understood by the audience to whom it is directed; and

(b) be consistent with the body of scientific or clinical evidence applicable to the goods.

(3) An advertisement about therapeutic goods that refers to scientific or clinical research, expressly or by implication, must:

(a) identify the researcher; and

(b) identify the financial sponsor of the research where the advertiser knows, or ought reasonably to have known, that information; and

(c) sufficiently identify the research by proper citation to enable consumers to access that research.

Part 4 - **Mandatory statements and other required information** *(nothing relevant)*

Part 5—Additional requirements for advertisements about particular therapeutic goods

Covers Analgesics, complementary medicines, sunscreens, TGs for weight mgmt

Part 6 - Testimonials and endorsements *(Selected relevant sections only)*

(6) An endorsement about therapeutic goods must not be given, whether expressly or by implication, by any of the following:

(a) a government or government authority, unless otherwise permitted by the Act or Regulations;

(b) a hospital, or healthcare facility, other than a community pharmacy;

(c) employees or contractors of a body mentioned in paragraphs (a) or (b);

(d) a current or former health practitioner, health professional or medical researcher;

(e) a person who represents themselves as being qualified or trained to diagnose, treat or prevent disease, ailment, defect or injury in persons;

(f) an organisation that represents the interests of healthcare consumers, or represents the interests of persons mentioned in paragraph (d), unless the advertisement discloses:

(i) the name of the organisation; and

(ii) whether the organisation has received, or will receive, any valuable consideration for the endorsement.

Part 7 - **Samples and incentives** *(nothing relevant)*

Part 8 - **Restricted representations** *(Selected relevant sections only)*

29 Restricted representations—public interest criteria

For the purposes of paragraph 42DF(4)(c) of the Act, the public interest criteria for dealing with restricted representations are as follows:

(a) whether the representation would be likely to exploit, or take advantage of, vulnerable consumers, or particular groups of consumers, impacted by the disease, condition, ailment or defect; and

(b) whether the representation would be likely to delay or discourage consumers from seeking timely medical attention, where the attention is necessary to prevent negative health consequences, morbidity or mortality, or deterioration or progression of the disease, condition, ailment or defect; and

(c) whether the representation (itself or together with other representations) would be likely to have a negative impact on public health; and

(d) any other public interest criteria that the Secretary considers relevant.

Note: This section mentions the public interest criteria that the Secretary must consider when deciding to approve or refuse the use of a restricted representation under section 42DF of the Act.

Part 9—Price information *(nothing relevant)*

Competition and Consumer Act 2010

Available at: https://www.legislation.gov.au/C2004A00109/latest/text

Appendix 2: Medicines Australia Documentation

Medicines Australia Code of Conduct Edition 19

The following provides excerpts from Edition 19 of the MA Code[37]. For noting, Edition 20 of the MA Code was adopted and released on the 30 October 2024, and will be effective from 30 March 2025. Where there are differences to Edition 19 relating to the provided excerpts, these are noted. If no change noted, then the text is consistent across both editions.

MA Code 19 - https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/20221103-PUB-Edition-19-FINAL-VERSION-2.pdf

MA Code 20 - https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2024/10/MA002_Code-of-Conduct_V4_final.pdf

Part A: Principles (as relevant to this Paper)

2. Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry.

3. As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use. The same standards apply to all other Company communications.

5. Consistent with our ethical undertakings, nothing is offered or provided by a Company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.

6. Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.

Part B: Ethical Interactions with Healthcare Professionals (selected excerpts)

Section 2: Requirements for Material Directed to Healthcare Professionals

Material directed to healthcare professionals refers to any material that is developed by the company for distribution to healthcare professionals. Material may be distributed in any manner or form.

• Companies are responsible for ensuring that materials directed to healthcare professionals covered by this section are only able to be viewed or accessed by healthcare professionals.

Section 4. Events

4.3 Trade displays

• In the case of international or Australasian congresses held in Australia, it is acceptable to display or supply information regarding a product or an indication not approved for registration in Australia, provided any material used clearly identifies that it refers to a product or indication not approved in Australia, and that the product or indication (as appropriate) is approved overseas.

• If the primary audience is broader than healthcare professionals, a Company should carefully consider whether the promotional trade display or the information to be made available from a trade display involves the promotion of products to the general public, which may contravene the Commonwealth Therapeutic Goods Act.

• Companies hosting a trade display at a third party scientific or medical conference where nonhealthcare professionals have registered to attend should make reasonable efforts to request the conference organisers to include a note in the conference program that staff at company trade displays are precluded by law from giving information about specific products to non-healthcare professionals.

Section 8. Scientific Exchange with Healthcare Professionals (relevant bits)

Scientific exchange between appropriate Company personnel and healthcare professionals and/or the scientific community can enhance understanding, support patient care (including compassionate access), assist research planning and approaches to clinical care.

• Scientific exchange includes but is not limited to responses to medical information enquiries, disease awareness activities, discussion of pipeline information/corporate commitment to research, satellite symposia during official congress programs, and non-promotional Company events.

• It is reasonable where healthcare professionals are seeking clarity and/or additional information on products not approved in Australia and/or subjects not covered in the Australian Product Information for Companies to provide such information.

• Only Company Medical Department personnel may engage in exchange with healthcare professionals or the scientific community around unregistered products or off label topics. Such exchange must be non-promotional in intent, content and nature. Any information relating to unregistered products or off label topics must be clearly identified as such and must meet the requirements of this Code. Such activity should be approved by the Country Medical Director or equivalent.

*For noting: Section 8 edition 19 is in **Edition 20 as Section 7: Scientific exchange**. The preamble and dotpoints above have also been updated to:*

Legitimate scientific exchange between appropriate Company personnel and healthcare professionals, the scientific community and other relevant stakeholders (such as payors, government officials) must be for the purposes of enhancing scientific understanding, improving patient care, improving access to medicines (including compassionate access), supporting quality use of medicines or assisting research and/or stakeholder budgetary planning. The intent of such activities must be non-promotional with a focus on exchange being two-way communication.

a) It is reasonable where healthcare professionals or other relevant stakeholders are seeking clarity and/or additional information on products not approved in Australia and/or subjects not covered in the Australian Product Information, for Companies to provide such information.

b) It is reasonable for Companies to anticipate the needs of appropriate stakeholders for scientific and medical information. Such information/material must only be provided or made available to those stakeholders whose need for or interest in can reasonably be assumed for the conduct of their role. Material should be tailored to the audience to whom it is directed.

c) The Company Medical Department may engage in scientific exchange regarding unregistered products, uses or other off label topics. In some instances non-promotional roles, such as market access, regulatory affairs, may be permitted to engage in Scientific Exchange. Such exchange must be non-promotional in intent, content and nature and must be distinguished from promotional activities.

d) Scientific Exchange activities must be overseen by the Company Medical Director or their delegate.

e) Any information relating to unregistered products or off label topics must be clearly identified as such and must meet the requirements of this Code. Such materials must be approved by the Company Medical Director or their delegate.

Part C - Ethical Interactions with relevant stakeholders

11. Appropriate Communications with Relevant Stakeholders

(whole section)

Communication with stakeholders who have a role in the research, development, registration, listing or monitoring of a therapeutic good is inherent in the National Medicines Policy and in the concept of the quality use of medicines. Companies are permitted to communicate proactively or reactively with relevant stakeholders, provided that discourse is limited to information that may assist the stakeholder in their role.

• This communication is to be non-promotional in nature and is not to be made with the intention to inform patient-level prescribing, or any other clinical decision making relevant to individual patients.

• This communication should only be conducted by appropriately qualified and selected company personnel.

• It is appropriate for Companies to solicit information to assist in understanding relevant aspects of the healthcare environment relating their products.

• Relevant stakeholders include (but are not limited to): i. Member of government or relevant government agency: (a) any therapeutic goods regulator; (b) any therapeutic goods reimbursor; (c) any business regulator (ACCC, ASIC, etc.); (d) parliamentarians and their representatives. ii. Health consumer organisations and patient advocacy groups; iii. Healthcare professional organisations; iv. Supply chain and distribution organisations; v. Current users of the product (patient/consumer) and their carers; and vi. The media.

For noting: Edition 19 section 11 is in ***Edition 20 as Section 10: Appropriate Communications with Relevant Stakeholders***

Changes made:

- *Dotpoints are now a, b, c, etc:*
- *The words in italics have been added to the first dotpoint: a)* This communication is to be non-promotional *and balanced* in nature and is not to be made with the intention to inform patient-level prescribing, or any other clinical decision-making relevant to individual patients.

- *The list of relevant stakeholders is the same as edition 19, although v. has changed from '*Current users of the product (patient/consumer) and their carers' *to* 'Current users'
- *There is a more detailed section regarding information sharing with/by the media*

12. Support for Health Consumer Organisations (whole section)

• Medicines Australia recognises and supports positive and beneficial relationships between industry and health consumer organisations. Companies may enter into relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

• When entering into relationships with health consumer organisations, Companies should refer to Working Together–A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, developed through collaboration between Medicines Australia, the Consumers Health Forum of Australia and other health consumer organisations. The manual is available on the Medicines Australia website www.medicinesaustralia.com.au

• Companies should consider on a case by case basis whether any offer or proposal to sponsor or fund a health consumer organisation or any of its programs is capable of withstanding professional and public scrutiny.

• The selection criteria for sponsorship to enable patients and representatives from a health consumer organisation to attend third party scientific and medical conferences should be based on their specific interest in a therapeutic area.

For noting: Edition 19 section 12 is in ***Edition 20 as Section 11: Engagement with Patient Organisations***

Changes made:

- *Dotpoints are now a, b, c, and there are no changes to the text in a, b and c.*
- *Dotpoint d is: "*d) Companies may share information with patient organisations and their representatives. This may include information about prescription medicines if there is a genuine need for the information, the content is relevant to their specific expertise and interest in the therapeutic area, and is non-promotional."

Part D: Ethical Interactions with Patients and the General Public

13. Interactions with the General Public (whole section)

• Consumer Medicine Information, risk management materials and Product Information are credible, non-promotional sources of information about a Company's products. A Company may make these documents available to members of the general public, providing they appear in their entire form and are not amended, abridged or displayed in a promotional manner.

• Requests from individual members of the public for medical advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their doctor.

• Where a specific request is made by a patient or a member of a patient's family about a product which has been prescribed, the company may clarify matters in a non-promotional manner using the Consumer Medicine Information, relevant risk management materials or a patient aid and should otherwise recommend inquirers to consult their doctor.

• Product-specific programs, product information, and patient aids should be provided only to patients already prescribed the product and must not be promotional. Items that are likely to be used outside the home, and thus visible to the general public, may be branded with a Company name and/or a Company logo only.

*For noting: Edition 19 section 13 is in **Edition 20 as Section 12: Interactions with the General Public.** There were no other changes to the text in this section.*

Part E: Transparency of interactions with Healthcare Professionals and with Consumers

15. Transparency Reporting (just intro paragraph though the entire section provides more details on the requirements of pharmaceutical companies to report their interactions with PAGs)

• Transparency reporting is a public benefit which provides visibility for consumers of payments and transfers of value made by Australian Companies: i. to Australian healthcare professionals who are engaged in patient care; ii. as a sponsorship of a third party organisation to conduct educational activities for Australian healthcare professionals who are engaged in patient care; and iii. to health consumer organisations to deliver valuable services to Australian patients.

*For noting: Edition 19 section 15 is in **Edition 20 as Section 14.** There were no other changes noted to the text in this section.*

Part F: Code Governance

16. Administration of the Code of Conduct

Medicines Australia is committed to the fair and ethical administration of the Code of Conduct, including the establishment of a Code of Conduct Committee (Code Committee), Code of Conduct Appeals Committee (Appeals Committee), and the Monitoring Committee. This Code sets out the requirements for undertaking each of these activities, and detailed guidelines for lodging a complaint, responding to a complaint, and raising an appeal can be found in the Code Tool Kit.

a) Medicines Australia provides a robust and independent complaint and appeal process where all parties are entitled to fair and equitable treatment. If these general principles are not met, the complaint may be returned for more information, or the review may be conducted in the absence of a complete response.

b) On receipt of a complaint which is not covered by this Code, Medicines Australia has the discretion to refer the complaint(s) to a relevant organisation for consideration under its own Code, having regard to the category of the therapeutic good and the target audience for the conduct subject to complaint.

*For noting: Edition 19 section 16 is in **Edition 20 as Section 15.** There were no other changes noted to the text in this section.*

Definitions

Health consumer organisations are not-for-profit organisations that represent the interests and views of consumers of health care. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

Promote means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.5

Promotion, Promotional or Promotional claim means any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information.

Promotional material means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

For noting: In Edition 20, there are were slight changes in the definitions equivalent to the above:

Health consumer organisations see Patient organisations.

Patient Organisations (also referred to as health consumer organisations) are not-for-profit organisations, mainly composed of patients and/or caregivers, that represent the needs and interests of patients, their families and/or caregivers. They may range from small volunteer groups or large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

Promote means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to encourage or discourage the purchase, sale, supply and/or use of therapeutic products6.

Promotion, Promotional or Promotional claim means any statement made by a Company or Company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or non-quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information.

Promotional material – same as edition 19

Guidance for industry: Communicating ethically with patients and their representatives

Available at: https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2024/03/Patient-Interactions-Guidance-March-2024-V3-published.pdf

This Guidance[39] addresses common questions about the application of the Code to particular scenarios between industry, patients, their carers, their families, and Health Consumer Organisations*. It supports the industry's application of the Code but is not binding.

The Guidance highlights several scenarios, and their inherent risks and provides some practical considerations that a company may employ to mitigate such risks. These considerations are not compulsory; instead, they are suggestions for a company to consider and employ as they see fit and to support a consistent approach to ethical decision-making across the industry.

For simplicity purposes of this Guidance, the reference to HCOs* in this document collectively captures patient organisations and patient representatives interchangeably, however, it is not to be confused with the Code's definition of Health Consumer Organisation.

Scenarios Discussed:

1. HCOs* Attending Company Or Third-party Educational Events
2. Communicating With HCOs * About Special Access Programs
3. Engaging HCOs * Regarding PBAC Submissions
4. Disease Awareness Where Only One Treatment Is Available
5. Sharing Clinical Trial Information With HCOs