Facilitating early and continuous engagement of patient communities in HTA Processes

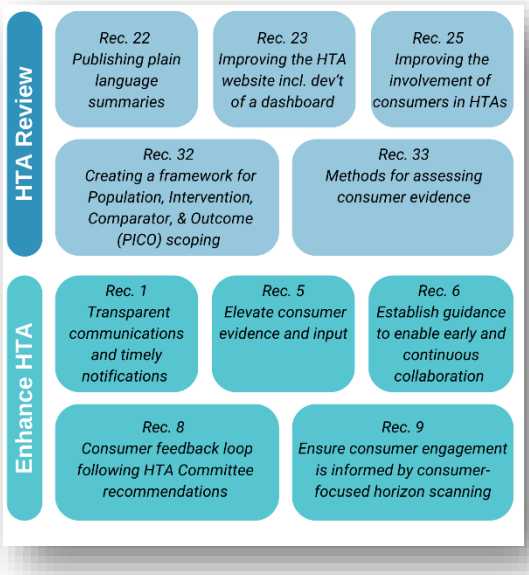
BMS Australia Shaping Healthcare Together Roundtable 19 Nov 2024
Summary Brief

The case for earlier and continuous engagement

Patient experts and patient advocacy groups (hereafter referred to collectively as patient communities) in Australia desire earlier and more continuous engagement in medicines development, from clinical trials and regulatory approval to reimbursement decision making processes i.e. throughout the entire Health Technology Assessment (HTA) lifecycle. While patient input and evidence are increasing in value in HTA, how, when, with who to engage and what is valued as input are still very much under discussion.

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, and over time, this has evolved to 2 consumer members of the PBAC (one as Deputy Chair), the establishment of the Consumer Evidence and Engagement Unit and HTA Consumer Consultative Committee, a pilot summary of information (for PBAC submissions) project plus consultations that have allowed for inputs on patient engagement in research and HTA.

This year, the Conversations for Change, HTA methods review and Enhance HTA reports were released with recommendations relating to the needs and opportunities for patient engagement across the lifecycle of HTA. The recommendations included themes around access to appropriate, timely, tailored information and consideration of the legislation (summarised below).

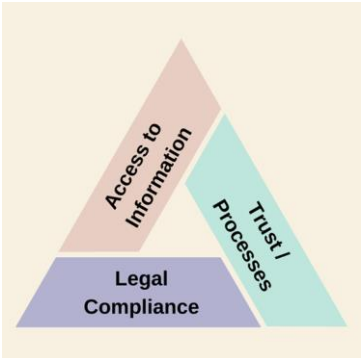


There is a perfect storm brewing in Australia (and globally) around the willingness and need for the patient community to be engaged early and continuously through the therapeutic product lifecycle from research to HTA processes and beyond.

While there can be many factors that are important for facilitating how, when and what patient communities engage throughout HTA, three overarching themes have been selected for discussion at the Shaping Healthcare Together Roundtable for their impact on early and continuous engagement:

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

This Summary Brief touches on the detail that is explored more deeply for each theme in the Paper.



Access and transparency of information

Transparency in communication and documentation is an important patient engagement quality criteria. The HTA Methods Review 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.

It is optimal for patient communities to have access to the same information as other stakeholders and committees, in plain language, however achieving that transparency has some challenges.

Different individuals and organisation have different information needs, e.g. whether horizon scanning, preparing HTA input, partnering on grant applications or trial protocols, plain language communications like consent documents, recruitment materials, or submission summaries. There is also varied knowledge of the HTA processes amongst stakeholders.

In a digital world where information is accessible from anywhere in the world, ensuring patient communities understand what is applicable in Australia is also important.

Outside of compliance considerations discussed below, companies have commercial considerations which will influence what and when information can be shared. There are also ethical considerations when communicating information on pipelines that may constantly change, plus variable company capacities (people, processes) responsible for engaging patient communities.

As a trusted source of balanced, non-promotional information, government and HTA bodies have a role as conduits and caretakers of information. Accessible pathways and portals to information are critical for patient communities to engage early and continuously during HTA processes.

Information is not just needed by patient communities. Patient communities are increasingly gathering experiential information about their health conditions, which has value to both industry and government/HTA bodies. Consideration is needed for how this two-way information flow might be facilitated in a sustainable, compliant way.

The following are examples of the types of questions that will be explored at the Roundtable:

- What information would you like to be able to access to support early and continuous engagement?
- When have you been unable to access information or engage? What do you think were the barriers?
- What processes/pathways could improve access to information?

Legal and compliance considerations

Australia's Therapeutics Goods legislation aims to protect Australian consumers by ensuring the quality, safety and efficacy of therapeutic goods they have access to. It includes provisions which prevent promotion of therapeutic goods to the public.

The Enhanced HTA report proposes prudent examination of how earlier consumer input may be facilitated within existing regulations and legislation to develop guidance that can support engagement between stakeholders and adherence to the regulatory and legislative requirements.

The Therapeutic Goods Act, Therapeutic Goods Advertising Code, and Competition and Consumer Act detail regulations that must be observed by industry in order to be compliant with respect to patient community engagement and provision of information.

Additionally, the principles-based Medicines Australia (MA) Code of Conduct and supporting documents provide further guidance. This includes understanding what could be considered promotional material, and what the TGA considers when evaluating whether information is an advertisement.

Characteristics of promotional material that are particularly relevant include:

- unsolicited information rather than solicited information;
- information that is disseminated with frequency;
- any information that is disseminated by, or on behalf of, manufacturers, sponsors, retailers and any other party with a financial interest in selling the goods

Legal and compliance considerations continued...

Advertising is not limited to a specific type, or types, of media. It can include, for example, articles published in journals, magazines and newspapers, displays on posters, images, videos, material posted on the internet, point-of-sale and promotional materials that include specific product claims and which are supplied separately, product reviews and even product names.

Conservative interpretations of the MA Code of Conduct can impact patient communities ability to engage, upskill and access information (e.g. access to conferences, clinical trial information & results, and HTA submissions).

The following are examples of the types of questions that will be explored at the Roundtable:

- Are there examples where regulations or the MA Code have positive or negative impacts on access to information or engagement?
- Does the regulatory environment need to change?
- Is there consensus on what could be considered non-promotional information/activity?
- What processes and pathways could balance compliance with access to information? Would patient accreditation help?

Trust and 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 upon 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, in government, companies and patient communities, maintaining consistency is difficult and requires commitment.

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

Transparency around information-sharing (who shares what with whom when), working relationships and funding relationships are important for all stakeholders to maintain trust, integrity and the reputation of their own organisations.

Inadequate transparency is a problem for both industry and patient communities. Industry battles perceptions of astroturfing, while patient communities face suspicions about how they activities are influenced.

Reporting requirements and best practices for industry and patient communities can help maintain reputation, trust and perceptions of independence.

The Patient Voice Initiative/CaPPRe research into the perceptions of patient communities and their satisfaction with how companies are engaging with them highlights areas companies can consider in their interaction with patient communities.

The patient community landscape is constantly growing and changing. Communities range from informal to formal, online Facebook groups to large charities. Patient communities have a role in helping industry navigate this landscape, including how to access a community, transparency around who a community is and its capacity/interests, and ensuring inputs are inclusive of diverse voices and experiences so health technology and HTA processes benefit more of the Australian population.

Questions we may explore include:

- What are the real-world and systemic barriers to engagement?
- What, how and where are the opportunities to build trust and transparency between government, industry and patient communities? Are there international examples that could be leveraged?
- What role might patient community alliances have in facilitating engagement, trust and policy reform?