Painaustralia

Submission

Office of Health Technology Assessment[1] (HTA) Policy and Methods Review

Public consultation 2:

Focus on options for reform set out in the Options paper[2] developed by the Reference Committee through the Health Technology Assessment Policy and Methods Review (after considering evidence and input received as part of public consultation 1)

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<https://surveys.bastioninsights.com.au/jfe/form/SV_9vQrOS2nEqEbZFc>

[1] <https://ohta-consultations.health.gov.au/ohta/hta-review-consultation-2/>

[2] <https://ohta-consultations.health.gov.au/ohta/hta-review-consultation-2/supporting_documents/HTA%20Review%20%20Consultation%202%20%20options%20paper.DOCX>

Painaustralia—submission

Submission—Office of Health Technology Assessment (HTA) Policy and Methods Review (Public consultation 2)

About Painaustralia

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Our members include pain and other specialists, health practitioners, health groups, consumer organisations, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue.

Our aim is to have the voice of people living with pain, their families and carers represented in all aspects of health policy and decision making.

Introduction

Painaustralia welcomes the release of the HTA Reference Review Committee's HTA Policy and Methods Review Consultation options paper[3] (the Options paper) and the opportunity to provide feedback on its potential options for reform as part of the second HTA Review public consultation round.

Painaustralia acknowledges that the Reference Review Committee has identified a number of areas where HTA and funding approaches could be improved to better meet the needs of Australians.

Previous Painaustralia advocacy

The Options paper distills three overarching themes regarding HTA arrangements that closely align with the views and position advanced by Painaustralia in its submissions to the: (i) HTA Policy and Methods Review public consultation 1 (June 23)[4] and (ii) House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel technologies in Australia (October 2020)[5].

These overarching themes are: (i) **complexity**—that HTA arrangements are complex to navigate for most stakeholders; that this complexity has increased over time; and while some complexity is necessary—good decisions need to account for required complexity but also that numerous aspects of the HTA and funding system could be simplified; (ii) **inclusive stakeholder engagement**—while 'Australia has a world class HTA system that works well in many aspects', stakeholders 'are concerned about how consumers, patients, First Nations peoples and others are included in HTA processes and decision-making'; and (iii) **evidence, valuation and duration of the process**—concerns regarding the consideration and weighting of different types of evidence; how health technologies are valued; and the length of time it takes for health technologies to be funded and made accessible.

[3] Report of the Health Technology Assessment Policy and Methods Review Reference Committee January 2024. The HTA Reference Review Committee is overseeing the Health Technology Assessment Policy and Methods Review.

[4] <https://www.painaustralia.org.au/static/uploads/files/painaustralia-submission-to-hta-review.pdf>

[5] <https://www.aph.gov.au/DocumentStore.ashx?id=4304ca2d-ba91-48f1-adb2-d5fd91f5cc0e&subId=695317>

Proposed options for reform

After reviewing Australia's HTA policies and methods, considering stakeholders' experiences, expert input, and extensive research—Painaustralia notes that the Review Reference Committee has identified the following *issues*:

- Australia's HTA processes and how they are used in practice give rise to circumstances where 'health technologies are not funded in the shortest possible time';
- globally, there are factors relating to limited commercial incentives to develop certain types of products;
- while 'evidence sources' other than 'traditional clinical trial-based evidence of clinical efficacy, safety and cost effectiveness may be considered and factored into decision making', current guidance material (such as the PBAC guidelines), public summaries and other material is not clear as to how "other evidence sources" can be included, how it is used by, and to what extent it can modify the advice of the HTA committee;
- a lack of transparency and clarity across the HTA system that impacts the performance of many stages and features of the system. This includes: key stakeholders such as patients and clinicians having unequal knowledge of an application, evidence submitted with it, and the process for its assessment; while large amounts of information is available, it is often not conveyed in a fit-for-purpose manner contributing to a lack of transparency;
- the involvement of patients, consumers, clinicians, First Nations peoples and other stakeholders 'does not occur early and regularly enough through the HTA continuum to realise the full potential value of their involvement';
- Australia's system for funding health technologies does not proactively examine unmet need to proactively identify possible health technologies to address these needs. Similar to many other international jurisdictions—Australia's HTA system is reactive with a reliance on companies supplying health technologies to make submissions for subsidy with no mechanism for the system to request submissions. Further, Australia 'does not systematically scan what health technologies are available, or imminently available elsewhere in the world that might address needs in Australia better than the currently available options';
- Australia 'does not have sufficient systems to evaluate whether subsidised health technologies work as well as expected after the original subsidy assessment'. Further, Australia does 'not routinely or systematically measure how well health technologies that have been funded perform compared to alternatives—that is, whether patients and the Australian community are better off from accessing the health technologies that have been funded.[6]

To respond to the *issues* identified—the Review Reference Committee proposes five overarching reform option areas each with detailed actions. The proposed reform options reflect key proposals

[6] It noted that there is some collection of data and analysis to measure the performance of health technologies in different jurisdictions and for specific products, such as those funded under provisional approval or interim arrangements, and those selected for post market reviews. However, the quality and integration of this information is not fit-for-purpose to inform decision-making. Further, improvements must be made to the data capture, quality, and availability to measure the performance of the HTA systems and processes, including transparency of different stages and their responsible actors within the system.

made by participants in consultations and the Reference Committee's consideration of the evidence received to date as part of the HTA Review. These option areas are:

Option area #1—Transparency, communication, and stakeholder involvement in HTA

Option area #2—Health technology funding and assessment pathways

Option area #3—Methods for HTA for Australian Government Subsidy (technical methods)

Option area #4—Health technology funding and purchasing approaches and managing uncertainty

Option area #5—Futureproofing Australia's systems and processes

Painaustralia notes that many of the issues identified and proposed reform option areas (and associated actions) are relevant to multiple stages and features across the HTA framework and system.

PA comment on options for reform

Painaustralia welcomes the comprehensive review and analysis of HTA policies and methods in Australia including its consideration of stakeholders' experiences, expert input, and extensive research as set out in the Options paper.

Painaustralia observes that its position and recommendations—in the context of pain treatment and management— for formal HTA approaches are broadly reflected in the reform option areas and associated actions. Specifically, Painaustralia is of the view that formal HTA approaches *must* consider:

- The use of new and emerging technologies—including the identification and accommodation of therapeutic advances for the treatment and management of pain that may enter the regulatory or reimbursement systems (or both).
- Continuous process improvement to facilitate earlier patient access to therapeutic innovations in a timely, equitable, safe and affordable way.
- The complexity of pain and the need to utilise cost assessments for base economic evaluations that adopt societal cost based perspectives to fully account for the costs and benefits of interventions.
- Strengthening the patient and consumer voice in assessing therapies at an early stage in review processes.

Painaustralia has carefully considered the five overarching reform option areas and associated actions. Painaustralia broadly supports the proposed reforms and their underlying intent. Painaustralia acknowledges that other stakeholders are better placed and more qualified to provide detailed comment on some of the reforms—in particular those relating to elements of: health technology funding and assessment pathways; methods for HTA for Australian Government Subsidy (technical methods); and health technology funding and purchasing approaches and managing uncertainty.

Painaustralia, however, wishes to make specific comment on the following proposed reform option areas and actions:

Option area #1—Transparency, communication, and stakeholder involvement in HTA

Painaustralia welcomes the proposed reforms to improve transparency and communication of HTA pathways, processes and decisions (1.1) including the publication of plain language summaries and improvements to the HTA webpage comprising development of a dashboard.

Further, the development of a consumer, clinician and other stakeholder engagement framework (1.2) to ensure these views are considered in HTA processes is supported. Measures to strengthen consumer evidence collection and utilisation; the involvement and consideration of First Nations peoples in HTA and decision-making (1.3); and supporting collaborative HTA working practices with state and territory governments through the development of a central and standardised data sharing system and increased opportunities for consultation and work sharing (1.4) are also supported.

Painaustralia emphasises that the aforementioned proposed reforms must ensure engagement of all relevant or affected stakeholders and mitigate any potential for uneven influence or an overreliance on the views of some individuals, organisations or groups. Painaustralia considers that stakeholder engagement mechanisms must be designed to ensure that all relevant organisations, irrespective of size, have the capacity and opportunity to be involved in and participate in consultations.

Any co-design engagement process must support the capture of voices at an early stage in the review process to support decision making that has a full 'understanding of issues arising from new technologies, innovations and associated implications for consumers'.[7] Painaustralia suggests that the values developed by the Health Technology Assessment International (HTAi) special interest group, for patient and citizen participation are instructive for the proposed stakeholder engagement framework.

Option area #2—Health technology funding and assessment pathways

Painaustralia supports the proposal to streamline and align HTA pathways and advisory committees to achieve a single entry point for HTA and support a national consistent HTA approach (2.1).

With regard to early resolution mechanisms for submissions of major new therapeutic advances in areas of unmet clinical need Painaustralia supports the proposal detailed in Alternative option 2: Introducing an optional resolution step **before** HTA committee consideration, with additional post committee resolution (2.2).

Regarding the development of a disease specific common model (reference case) for disease areas with high active product development (2.2)—Painaustralia supports the development and adoption of a consistent model structure for specified disease areas where there are several potential therapies/ technologies under development (as identified through horizon scanning). Painaustralia emphasises that this will require input from a wide range of stakeholders to ensure a comprehensive representation of the disease area. In Painaustralia's view the development of disease specific models would strengthen and support consistency in decision-making as models across different technologies for the same disease/condition will be more easily comparable. Further, the investigation of international collaboration on the development of disease-specific common models is supported.

[7] Australian Government—Department of Health. (2023) Strategic Agreement in relation to reimbursement, health technology assessment and other matters between the Commonwealth and Medicines Australia, p. 12.

It is Painaustralia's view that the development of a disease specific common model would assist formal HTA approaches to recognise the nature and complexity of pain. Chronic pain is considered to be 'one of the most difficult conditions to treat'.[8] Contributing factors for this include that it is challenging 'to assess the short-term and long-term effects of any particular treatment that you use. Pain is very individual'.[9]

Option area #3—Methods for HTA for Australian Government Subsidy (technical methods)

Regarding economic evaluation (3.3)—Painaustralia supports the valuing of long-term benefits for interventions. Painaustralia reiterates its view that HTA assessment processes must consider the complexity of pain. To effectively do this, cost assessments must adopt societal cost based perspectives that include evaluation of: (i) direct costs and outcomes—including direct costs borne by the health care system (for example, drug costs, costs of hospitalisation) and direct outcomes (quality of life impact) on the patient; and (ii) indirect costs, outcomes and effects—including productivity loss of patients due to illness and gains due to participation in the workforce due treatment interventions; and indirect outcomes (quality of life impact) on those affected by caring for an ill patient (for example, carers, parents).[10]

Formal HTA processes must also fully value preventative interventions in assessment processes. Assessment processes in addition to reviewing the costs and benefits to the patient and health system must also consider broader societal impacts (including productivity and socio-economic considerations).[11] When the impact of interventions outside the scope of the health system are not factored into assessments—the full value of preventative interventions remain unaccounted and those consumers who the community expects to receive the benefit of advances in technology and treatments will actually miss out.

Painaustralia supports measurement outcomes of economic evaluation modelling (3.3) that includes: overarching impacts to the budget; changes to variables such as the incremental cost-effectiveness ratio (ICER) that may require adjustment in response to any changes to the base case discount rate.

Further, any workshops conducted, as proposed, to assist in this regard must ensure that participants are representative of the Australian population, workshops/consultation should include a population representative sample (including representation of key stakeholder groups) and ensure measurement is free from selection bias. Further, as proposed, workshops of this kind could be assisted through use of the explicit qualitative value framework.

[8] Marcia Meldrum (associate researcher in the department of psychiatry and biobehavioral sciences at the University of California, Los Angeles) quoted in Collier, R. (2018) 'A short history of pain management', *CMAJ*, Jan 8, 190(1), pp. E26–E27.
[9] Ibid.
[10] op.cit. Hanley et al., p. 20; GlaxoSmithKline Australia and ViiV Healthcare. (2018) *The Pharmaceutical Benefits Scheme in Australia—An explainer on system components*, February, report prepared by GlaxoSmithKline Australia Pty Ltd and ViiV Healthcare Pty Ltd with the assistance of Deloitte Access Economics Pty Ltd, accessed 28 May 2023, <https://au.gsk.com/media/6259/gsk-viiv-the-pbs-in-australia-feb-2018.pdf>.
[11] GlaxoSmithKline Australia Pty Ltd and Hears Pty Ltd. (2019) *The Value of Vaccines Ensuring Australia keeps pace with community values and international practice*—Infographic, accessed 28 May 2023, <infographic-valueofvaccines-digital-final.pdf>; op. cit. Hanley et al.

Option area #4—Health technology funding and purchasing approaches and managing uncertainty

Regarding understanding the performance of health technologies in practice (4.3)—Painaustralia supports reforms to optimise access to and use of real-world data (RWD) in HTA. The proposed establishment of a multi-stakeholder advisory group, reporting to government, to co-design and oversee the development and implementation of enabling systems, pathways, evaluation, and research to optimise access to and use of RWD in HTA would be a constructive measure.

Option area #5—Futureproofing Australia's systems and processes

Painaustralia supports measures to proactively address areas of unmet clinical need and gaps in the PBS (5.1). Painaustralia concurs that any such measures would 'require methodological development, implementation planning, and adequate resourcing including joint investment across stakeholder groups'. It is Painaustralia's view that the development of a priority list of high unmet clinical need; identification of therapies to meet priority lists; and early assessment and prioritisation of potentially promising therapies would assist in this regard.

Formal HTA approaches must identify and accommodate major therapeutic advances for the treatment and management of chronic pain that may enter the regulatory or reimbursement systems (or both).[12] The contemporary evidence base underpinning therapeutic innovations for pain management supports the use of therapies that include consideration of the pain experience from a biomedical and biopsychosocial perspective. This includes both pharmacological and nonpharmacological therapies.

Regarding mechanisms for continuous review and improvement (5.4)—Painaustralia strongly supports a program of continuous review and improvement for current HTA policies and methods. The effective implementation of the five proposed program components[13] will facilitate earlier patient access to therapeutic innovations in a timely, equitable, safe and affordable way.

Conclusion

Thank you for the opportunity to provide input into this round of consultation. Painaustralia looks forward to the final recommendations and report of the HTA Review Reference Committee. It is vital that the outcome of such a review future-proofs formal HTA approaches for the next 30 years.

Importantly, for Australian's suffering from chronic pain—reforms to HTA policy and methods must consider: (i) advancements in therapeutic innovations available for treating and managing pain; (ii) the nature and complexity of pain; (iii) current and emerging models of care for people living with chronic pain; (iv) the use of current and emerging technologies to support access, self-management and care processes; (v) economic evaluation of the cost-effectiveness of multidisciplinary chronic

[12] Australian Government—Department of Health. (2023) Strategic Agreement in relation to reimbursement, health technology assessment and other matters between the Commonwealth and Medicines Australia, p. 12.
[13] (1) Be informed by consultation of internal and external stakeholders as well as research of international and interjurisdictional best practise to pick topics for review; (2) Have a transparent forward schedule of the consultation and planned elements and features for review; (3) Have a set time period for the reviews to be carried out (e.g. 12 months for the review of each topic or set of topics); (4) Include guidance such as the PBAC guidelines. Consideration should be given to the development of the guidance as 'living guidelines', which may be continuously updated with the evolution of new technologies and methodologies; and (5) Capacity and capability of the HTA system.

pain management interventions; (vi) reduce disparities in access to pain treatment and management; and (vii) prioritise the perspectives from individuals living with pain.

It is Painaustralia's view that consideration of these important factors in a consistent way will strengthen formal HTA processes now and into the future for Australians affected by chronic pain. The proposed reform option areas and associated actions as developed by the Review Reference Committee through the Health Technology Assessment Policy and Methods Review are a positive and critical step in achieving this goal.