

HTA Consultation 2 -Collaborative Consumer Group Response

Introduction

This response is a collaboration of 53 consumer lead organisations (details of the organisations are in Appendix 1) representing approximately 14 million consumers.

Firstly, we would like to acknowledge the dedicated work of the HTA review committee. The Options Paper presents options that have the capability to deliver upgraded and new reforms and policies to improve our health care system.

It is noted that the options paper has truly embedded opportunities for consumer enhancement and consultation initiatives to ensure the values, evidence and expertise of the consumer is an integral and equal stakeholder within the HTA process.

The purpose of our collective document is to highlight our shared concerns about the current system and highlight how consumers can support the system to ensure equitable and universal access to healthcare for all Australians. Given the breadth and complexity of the background papers, not all organisations have the capacity and experience to respond fully, this collective response acknowledges this. This submission does not replace the value and importance of the specific submissions of patient organisations and other peak bodies.

We believe that, if implemented alongside the enhanced consumer engagement process and with some additional strengthening, the options have the potential to address:

- Vision and objectives of National Medicines Policy
- Goals of HTA review
- Objectives of the Strategic Agreement

It is recognised that there are some reforms and policies that will be challenging and will need longer timeframes to guarantee all stakeholders are involved to ensure changes and initiatives meet all community and legislative standards. However, there is also an acknowledgement that the implementation for some sections could be started immediately with a high impact outcome, for example plain language summaries, greater and earlier consumer engagement in HTA, an explicit values framework.

Ultimately, we need a system that is working for the delivery of universal, timely and equitable access to health care for all Australians.

For each of the sections below, the organisations who contributed to this submission would have the ability to recommend expert consumer representatives to attend advisory group meetings and key consultations

Priorities

We recognise the breadth, depth and complexity of the options presented. The key priorities from a consumer perspective are:

- That consumer engagement is mandated through legislation throughout HTA processes and methods, including in pre TGA activities such as horizon scanning
- That consumers are involved in the codesign of outputs or codesign activities associated with implementation of any options.
- That the impact of changes is assessed against KPIs informed by NMP and changes are made if the options are not achieving their intended purpose.
- That assessment of patient need, clinical effectiveness and safety is prioritised ahead of price considerations. We do not support options such as early ESC evaluation or options that make price the primary factor in HTA decision making.
- That options described in Section 1 for increased transparency, communication and stakeholder engagement are implemented in full. (1.1,1.2,1.3,1.4)
- Options to harmonise HTA across Commonwealth and states must address the current inequitable access patients experience in co-funded technologies. There needs to be stronger options to ensure every patient in Australia who requires access to a treatment partially funded by the Commonwealth and partially funded by the states, gets that access within an agreed time frame – e.g. 6 months. (1.4)
- Development of an explicit Qualitative Values Framework codesigned with consumers.
- Options that reduce time to access such as measures to reduce uncertainty, provisional approval, managed entry options, and measures to reduce resubmissions are prioritised.
- Improved use of real-world evidence in assessment pathways.
- Development and funding of a pathway for non-commercial sponsors to make a submission.

Section 1: *Transparency, communication, and stakeholder involvement in HTA*

The options identified in section 1.1 to 1.3 demonstrate the voice of the consumer has been heard in the HTA review. If progressed these options will provide a fundamental platform for engagement to embed the consumer as a valued and equal contributor to the HTA process.

All options in Section 1 will have a high impact to deliver transparency, communication, consumer evidence and First Nations involvement in HTA.

Strengths

We support all the recommendations in Section 1 and see each as essential to retain

Recommendations to strengthen Section 1:

1. The options identified in Sections 1.1-1.3 demonstrate a recognition of the value of the consumer voice in HTA. This recognition should be enshrined through legislation in HTA policy and methods to ensure that consumers and their knowledge (needs, preferences, experiences and perspectives) are safeguarded as a cornerstone of Australian HTA. .

2. Any recommendation made with the primary aim of reducing time to access affordable, quality health technologies, needs to include a maximum length of time for the activity in recognition of the consequences of delay for patients (as per Option 1.4.2).
3. Option 1.1.2 should be strengthened with the adoption of the qualitative values framework described in 3.2, which must be co-designed with consumer.
4. Option 1.2.3 creating a patient/clinician HTA subcommittee to provide information to the HTA committee is supported but not as a replacement for the consumer members on HTA committees and the opportunity for consumers and their representatives (such as consumer and patient organisations) and clinicians to attend committee meetings where specific knowledge/expertise will lead to more robust decision making
 - Section 1.4 - mandated timeframes from approval to access between Commonwealth and States that address current barriers to consistent and equitable access to approved health technologies across Australia. Commonwealth and states are aligned and not competitive

Section 2: Error! Reference source not found.

Options in Section 2 are critical to enable Australians access to the best health care at the right time. These options represent significant change. Transfer from specific pathways to a single entry will require ongoing consultation and communications with all key stakeholders, including consumers. More detail is required to understand if they can achieve their intended objectives.

Strengths

Alignment, early resolution and streamlining HTA process in order to reduce time to access for patients.

Recommendations to strengthen Section 2 :

1. Ensure that the appropriate expertise can inform all decision making, including specific consumer expertise.
2. Multi stakeholder consultations in a defined timeframe to understand and develop a draft single-entry framework.
3. A mandated maximum length of time and KPIs that explicitly measure time to access to ensure that any options with the primary aim of reducing time to access affordable, quality health technologies are achieving the intended aim.

Gaps/areas of concern

1. Consumer do not support options that use price as an entry point for ensuring timely access. HTA assessments should initially prioritise clinical need, safety and effectiveness separately to pricing negotiations/considerations.
2. Prescribing a limited number of resubmissions – we support all efforts to avoid multiple resubmissions as resubmissions represents a delay in access however mandating a limited number of resubmissions may have the unintended effect of disincentivising submissions where this is a high level of uncertainty

Section 3 Methods for HTA for Australian Government Subsidy (technical methods)

Strengths

- Frameworks for inclusion of consumer evidence and RWE
- Measures for addressing uncertainty
- The qualitative values framework will embed considerations of value at appraisal beyond what can consistently and robustly be included in the economic evaluation.

Recommendations to strengthen Section 3:

1. Consumer involvement in all codesign of methods
2. Defining fit for purpose high quality evidence in cases where RCTs are not possible/appropriate (e.g RWE, novel trial design, PREMS and PROMS)
3. Framework to capture PREMS, PROMS and RWD to support consumer submissions

Gaps/areas of concern

- Funding pathways for genomic/pharmacogenomic technologies that currently fall between Commonwealth funding and State funding (e.g Trio sequencing where one person is an inpatient and the other 2 people requiring testing are outpatients).

Section 4 Health technology funding and purchasing approaches and managing uncertainty

Strengths

- Consideration of options to address budget impact but these require more detail
- Approaches to managing uncertainty that enable earliest possible access to HAVT/HUCN technologies
- Measures for understanding the performance of health technologies in practice in particular systemic and cross jurisdictional data collection and data collection infrastructure

Recommendations to strengthen:

1. Several recommendations in this section need further detail and ongoing measurement to ensure that they achieve their desired aim. Whilst budget implications need to be considered, therapies should be considered with an investment paradigm. Cost/benefit and quality of life/community/society impact should be given appropriate consideration. Cost cannot be the overriding factor in access to approved therapies for eligible Australians.
2. Increased transparency will help consumers to hold all parties accountable for resolving issues that cause delays to access, for example, price negotiations. Consumer organisations should be empowered to ensure negotiations continue and are resolved in an expedited manner once a recommendation is accepted by government.

Gaps/areas of concern

- Options that more clearly address potential gaps created by joint Commonwealth and state funding of technologies and the reliance on the NHRA to address these gaps in a timely and equitable manner for patients. In practice this means people in some states

have access to advanced therapies while others either have not access or are required to travel interstate to get access – this must be addressed as a matter of urgency.

Section 5: Futureproofing Australia's systems and processes

Strengths

- Options in this section to move the from the current reactive system to a more proactive system
- A systemic approach and pathway for faster access to therapies for HUCN
- Policy and methods to ensure continuous improvement of HTA

Recommendations to strengthen:

1. Ensure horizon scanning and prioritisation approaches are codesigned and mandate consumer involvement in horizon scanning and prioritisation activities. It is not clear how community perspectives and priorities will be identified and these should inform any horizon scanning and prioritisation activities.
2. Provide transparent and easily accessible information about managed entry and special access pathways such as TGA special access scheme, compassionate access or the Medical Treatment Overseas Plan to ensure access to these mechanisms is equitable – currently these are fragmented and poorly understand by most consumers.

Gaps/Areas of concern

- These options do not provide a pathway or mechanism for non-commercial sponsorship of a submission (e.g consumer or clinician lead or joint consumer/clinician submission)

Appendix 1 Logos of Consumer Organisations endorsing this submission.



Patient Voice Initiative





auseE Inc.

a charity dedicated to improving lives affected by an eosinophilic disease



Myasthenia
Alliance Australia



Huntington's
Australia



HAEMOPHILIA FOUNDATION AUSTRALIA



Australian patient support group for Waldenström's Macroglobulinemia



NEUROLOGICAL
ALLIANCE
AUSTRALIA



PNDU
Parenteral Nutrition Down Under



mnd
Australia



MUSCULAR
DYSTROPHY
AUSTRALIA



parkinson's
australia

National Advocacy • Connection • Awareness



A U S T R A L I A



Prostate Cancer
Foundation of Australia



Lymphoma
Australia

epilepsy
AUSTRALIA



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