HTA Policy and Process Review – Where to now?
Role of the Implementation Advisory Group.

Andrew Wilson
Nicole Millis
Kirsten Pilatti

For the
Implementation Advisory Group
HTA Policy and Process Review

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  - House of Representatives Standing Committee 'The New Frontier – Delivering better heath for all Australians'
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- Summary of HTA Review Process
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National Medicines Policy 2019-20 Review

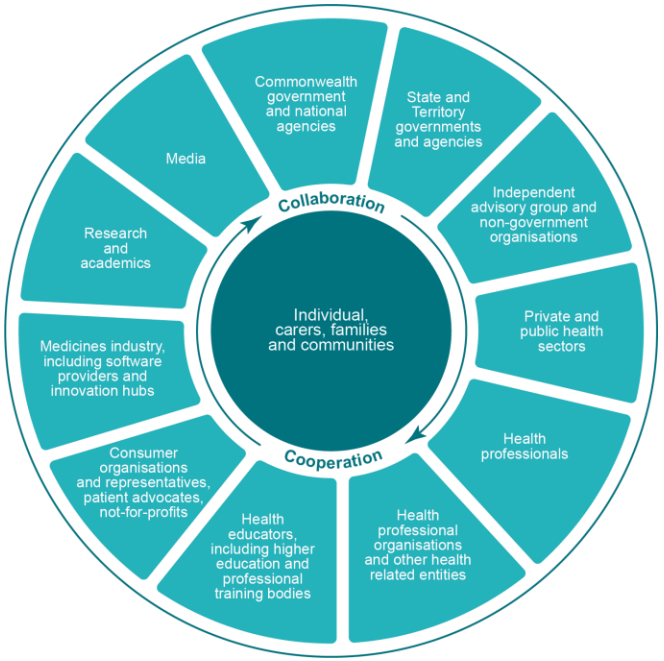
Vision

– **To achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.**

Aims

- Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians.
- Medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care.
- Support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research, and the successful development of medicines and medicines-related services in Australia.

Patient Centrality



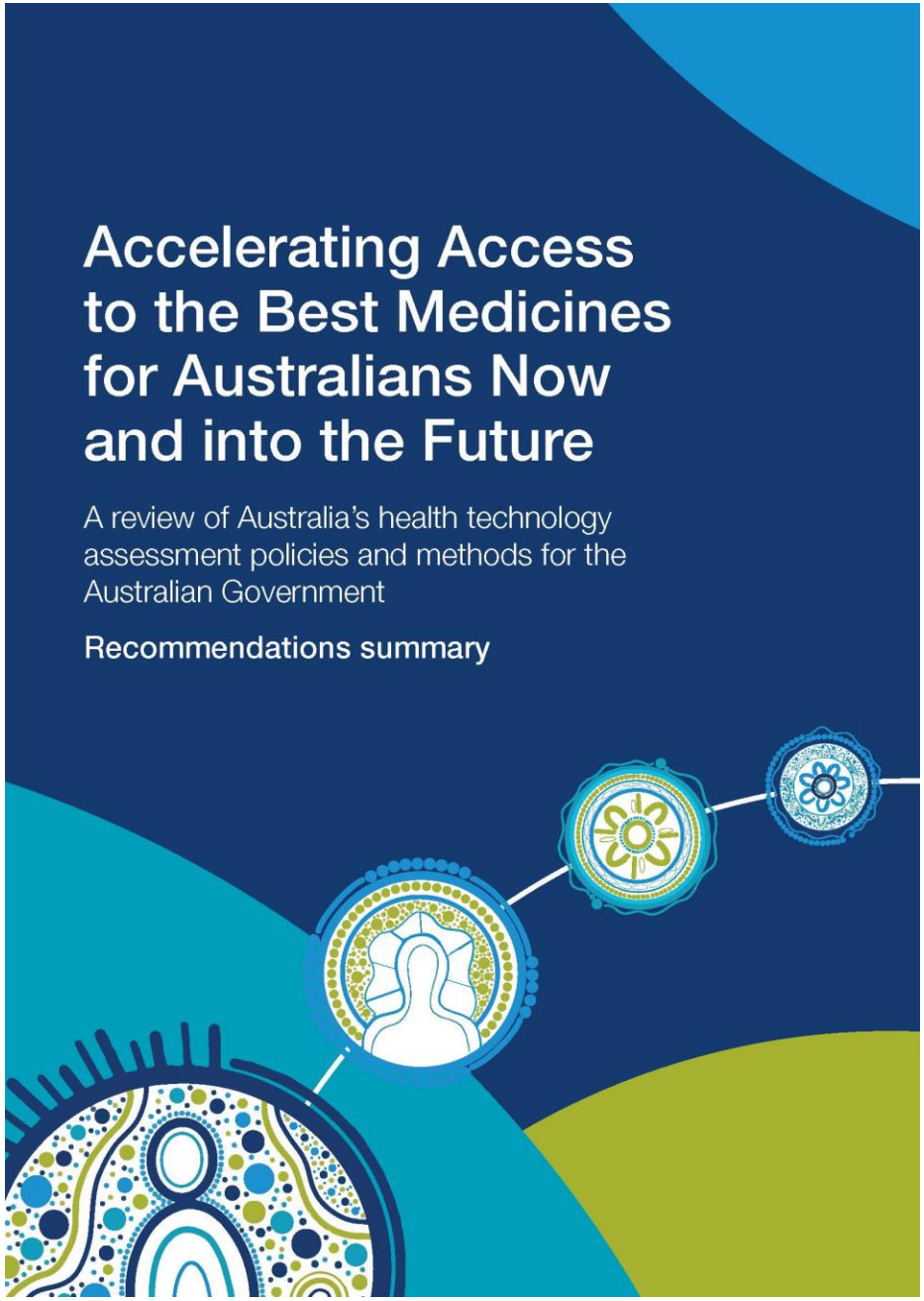
House of Representative Committee Reviews

- 2020 The New Frontier - Delivering better health for all Australians
- 32 recommendations including specific matters for the HTA policy and methods review
- Other inquiries:
  - Obesity and diabetes
  - Rare diseases
  - Rare cancers
  - Childhood arthritis
  - Mental health

Australian Government-Medicine Australia Strategic Agreement 2022-27

- Aims :
  - Provide timely access to new medicines and vaccines.
  - Ensure patients have greater involvement in decision making for medicines access.
  - Modernise processes to keep pace with advancing science and innovative technologies.
  - Address the changing international policy environment on access.
  - Keep Australia as a global priority for the launch of new and innovative medical treatments.

- Key measures for the MA Strategic Agreement include:
  - An independent review of HTA processes will ensure Australia's HTA system evolves to keep pace with advancements in medical technologies.
  - Development of an enhanced Patient Engagement Process will be created to incorporate patient views early in the PBAC system.



Artwork:

Jacinta Anderson 2025 Noongar Yorga.

Health Technology Assessment Policy and Methods Review

Objectives

To identify features that:

1. are working effectively
2. may act as current or future barriers to earliest possible access
3. may act as current or future barriers to equitable access
4. detract from person-centredness
5. may be creating perverse incentives.
6. are implementable and sustainable for both health funders (Commonwealth, state, and territory) and the health technology industry.
7. deliver Australians equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines for all Australians.
8. adopt a person-centred approach in HTA
9. deliver the outcomes sought by recommendations from the Inquiry that are agreed in principle in the Government Response.
10. further the objectives of the new NMP.
11. ensure HTA policy and methods are well adapted to and capable of assessing new technologies that are emerging or are expected to emerge in the coming years.
12. do not compromise assessment of patient safety, effectiveness and cost, or advice to Government on subsidy of health technologies.

Health Technology Assessment Policy and Methods Review

Policies and Methods

1. identification of place of a technology in care and selection of comparators
2. identification of patient relevant outcomes
3. augmentation of primary clinical evidence with data designed to capture the value of health technologies from the perspective of patients and their communities (such as qualitative research, patient preference studies, patient reported outcome measures and patient reported experience measures)
4. evaluations (including how the value of medicines is captured)
5. incorporation and use of direct input from patients, clinicians and other stakeholders with professional or lived expertise, into HTA evaluations and deliberations
6. approaches to increasing transparency in HTA decision-making and communicating this
7. new technologies, or expanded indications, that provide a substantial improvement in health outcomes compared to relevant alternative therapies
8. new technologies, or expanded indications, that do not provide a substantial improvement in health outcomes compared to relevant alternative therapies
9. managing clinical, economic, financial, and other uncertainty throughout the lifecycle of a technology including better capture of necessary data on duration of effectiveness and safety events and
10. assessment of technologies (such as those for rare and ultra-rare diseases) that would be used for conditions where there is high unmet clinical need that have clinical and economic uncertainty including:
    a. use of evidence from relevant sources other than randomised controlled trials where such trials are not feasible and
    b. arrangements for post market assessment and decision making.

Health Technology Assessment Policy and Methods Review

Funding and Approval Pathways

1. approaches that incentivise launch of first in class technologies or first major extension of indication that deliver a substantial improvement in health outcomes compared to relevant alternative therapies
2. equitable distribution and efficient use of limited HTA resources to meet the health and wellbeing needs of the Australian population
3. implications of any recommendations for assessment of other health technologies and hospital funding
4. management of future advances in health care including:
    a. adaptability of HTA approaches
    b. flexibility of advisory committee decision making
    c. avoiding unnecessary complexity or duplication in HTA.
5. the feasibility of international work sharing for evaluation of technologies in scope for the HTA Review
6. purchasing practices used by comparable international jurisdictions.

Health Technology Assessment Policy and Methods Review

Funding and Approval Pathways

Consideration of equity of access in HTA decision making including for the following groups:

a. First Nations people
b. people from culturally and linguistically diverse backgrounds
c. children and older people
d. people with disability
e. people living in rural and remote areas
f. people of low socioeconomic status
g. people living with rare and under-recognised diseasespeople with mental illness
h. lesbian, gay, bisexual, transgender, queer or questioning, intersex and/or other sexuality and gender diverse people (LGBTQI+)
i. other populations in circumstances and at life stages that give rise to vulnerability.

The Review Process

- **2 Public consultation rounds:**
  - 1st - closed in June 2023 - 114 submissions which included responses to an online survey, emailed submissions and online video forums with the Reference Committee.
  - 2nd - feedback on options for reform and closed in February 2024. 139 written submissions and additional feedback through 3 online workshops and one in-person workshop.

- **26 Deep dives with stakeholders**
  - Explored specific complex topics, issues, challenges, and opportunities for HTA involving 116 participants from industry, consumers and patients, clinicians, First Nations Peoples, and state and territory governments.

The Review Process

Commissioned Expert Analysis

Adelaide Health Technology Assessment (AHTA)

- Paper 1. International health technology market approval, funding and assessment pathways
- Paper 2. Horizon scanning and Early Assessment
- Paper 3. HTA Methods: Determination of Population Intervention Comparator Outcome (PICO)
- Paper 4. HTA Methods: Clinical Evaluation

Centre for Health Economics Research and Evaluation (CHERE)

- Paper 5. HTA Methods: Economic evaluation
- Paper 6. Funding and purchasing decisions and Managing Uncertainty

Centre of Research Excellence in Medicines Intelligence (MI-CRE)

- Paper 7. Optimising the availability and use of real world data and real world evidence to support health technology assessment in Australia

The Department of Health and Aged Care

- Paper 8. Australian market authorisation, funding and assessment pathways and timelines
- Paper 9. Emerging Health Technologies

Recommendation Themes
50 Recommendations

- **Streamlining Processes**: Simplify and speed up the HTA process, reducing the time taken for assessments and making it more flexible to accommodate innovations and evolving technologies.
- **Improved Stakeholder Engagement**: Enhance collaboration and engagement with stakeholders, including patients, clinicians, industry representatives, and researchers, to ensure a more inclusive and transparent process.
- **Adapting to Emerging Technologies**: Develop more adaptive frameworks to better assess novel and rapidly evolving technologies, including digital health solutions and gene therapies, which may not fit within traditional models.
- **Value-Based Assessment**: Shift towards a more comprehensive, value-based approach to assessment, considering broader health system benefits and patient outcomes beyond just cost-effectiveness.
- **Efficiency and Coordination**: Improve coordination between the various bodies involved in HTA, such as the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC), to reduce duplication and overlap.
- **Use of Real-World Data**: Increase the use of real-world data (RWD) to supplement clinical trial data, providing a more complete picture of the effectiveness and safety of technologies once they are in use.
- **Capacity Building**: Invest in the development of capabilities, skills, and resources to ensure that the HTA process is supported by high-quality evidence and expertise.

Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment

- Provide **transparent communications and timely notifications** to enhance the clarity of HTA processes and enable timely consumer engagement.
- Coordinate **centralised and expanded consumer support** to facilitate engagement across the health technology pathway.
- Develop a process for **consumer identification** to expand the diversity of consumers engaged in HTA processes.
- Provide accessible **resources and training** to support equitable consumer engagement in HTA.
- **Elevate consumer evidence and input** for consideration in HTA deliberations and decision-making.
- Establish guidance to enable **early and continuous collaboration** between stakeholders.
- Further develop processes to enable **consumer-identified items for HTA Committees' considerations**.
- Establish a **consumer feedback loop following HTA Committee recommendations** to provide insight into how consumer input has been used to inform the assessment of health technologies.
- Develop a **consumer digital portal** to connect consumers with information and resources required for consumer engagement.
- Ensure consumer engagement is informed by **consumer-focused horizon scanning** processes and opportunities.

IAG Terms of Reference Role and Functions

- The IAG is an advisory body comprising of senior leaders and representatives from across the sector.

- It is established for 12 months to adopt a collaborative and co-design approach in developing implementation options for consideration by the Government in the formulation of its response to the HTA Review.

- The role of the IAG is to provide advice to Government. This advice is subject to further government consideration and processes including where funding or othe government decision is required.

- The IAG will:
  - be an expert advisory group on reform implementation design
  - provide advice on the prioritisation of recommendations
  - provide advice on developing a roadmap for sequencing the Government's response to the recommendations of the HTA review.

- In performing the above functions, the IAG will also have regard to the recommendations of the inquiry report 'The New Frontier – Delivering better heath for all Australians' and the more recent consumer engagement Enhance HTA report.

Other Important Aspects of ToR

The Minister will provide to the IAG an initial list of recommendations from the HTA Review for priority consideration and may direct the IAG on its work plan from time to time.

A range of existing and newly established committees and reviews will inform the work of the IAG including:

- Health Technology and Genomics Collaboration (HTGC), a subcommittee of the Health Chief Executives Forum
- National Aboriginal Community Controlled Health Organisation
- National Health, Sustainability and Climate Unit.

Members of the IAG will ensure advice provided to the Government:

- is evidence-based
- reflects the views and opinions of the organisations they are representing
- is in the best interests of the health of Australians and the Australian health system
- considers equity of access for Australians
- considers the aims and objectives of the HTA review
- focuses on the delivery of patient centred outcomes.

IAG Deliverables

- The IAG will be responsible for interim reports to the Secretary and Minister, outlining advice, decisions, and activities undertaken by the IAG.

- The IAG will also be responsible for the delivery of a co-designed draft Government response to the HTA review and a final report on the work of the Group to the Minister.

Membership

Member	Role on the Implementation Advisory Group
Prof Andrew Wilson	Chair
Dr Richard Mitchell	Clinical Representative
Dr Lorraine Anderson	Clinical/Indigenous Representative
Ms Nicole Millis	Consumer Representative
Ms Kirsten Pilatti	Consumer Representative
Ms Elizabeth de Somer	Industry Representative
Ms Anne Harris	Industry Representative
Prof Emily Lancsar	Health Economist/Commonwealth
Mr Duncan McIntyre	Commonwealth
Dr Olivia Hibbitt	Jurisdictional representative

Minister Butler's Letter: Context and Priorities

'No one group can implement reforms in response to the findings and recommendations of the HTA Review Report on its own. Implementation will require the ideas, expertise and commitment of all.'

'I have established an IAG of broad membership with a diverse mix of representatives from patient groups, clinical practice, industry and government. This diversity of voice ensures all views are heard. It also will support consensus building across stakeholders for the implementation of key reforms to deliver better health outcomes for all Australians.'

'In line with Australia's National Medicines Policy and the Australian Government's priority to Strengthen Medicare, I ask the IAG prioritise the development of its advice on implementation of recommendations from the HTA Review Report relating to:

1. More equitable access for patients
2. Process changes to support more streamlined HTA
3. Improved stakeholder engagement in HTA'

'I also ask the IAG consider the expected benefits, responsibilities for, and cost implications of reform implementation in its advice to government. This advice should make a clear case for why additional Commonwealth funding is needed and provide a strong evidence-base for the merits of implementing relevant reforms. This should include consideration of the expected benefits for patients and better service provision for sponsors.'

IAG Processes

- Monthly meetings
- Supported by DoHAC secretariat and Allen and Clarke, consultants.
- Additional meetings including additional consultations as required or requested.
- Envisaged that as we unpack different recommendations there will be recommendations where:
  - IAG can add little more to in terms of implementation ie requires costing and Government decision and implementation by Dept or PBAC.
  - IAG will identify potential options for implementation and will want to further consult.
  - IAG will identify pathway(s) for further development before there is clarity on implementation.
  - IAG will identify sequential interdependency of decisions ie Government may need to provide advice on preference for one step before the IAG can advice on next step.
- Co-ordinate responses with other working groups.

IAG and Implementation Timeframes

- IAG Appointments end January 2026

- Terms of Reference specify a '**co-designed draft Government response to the HTA review and a final report on the work of the Group to the Minister**'.

- ToR allow for interim reports and IAG intends to use these to bring potential early opportunities to Minister's attention.

- IAG recognises that there are some recommendations will take 1-2 years to implement if approved eg
  - changes in submission evaluation process require adequate lead time for sponsors.
  - Establishing better capacity for real world evidence generation 2-3 years.
  - If recommendations require changes to legislation - ?