Stakeholder Update August 2025

HTA Policy and Process Review – Implementation Advisory Group.

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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

IAG Terms of Reference Role and Functions

- 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.

- Established for 12 months.

- Role: Provide **advice** to Government

- **Advice is subject to further government consideration and processes including where funding or other government decision is required**.

- 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.

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.

HTA Review 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.

Minister Butler's Letter: Context and Priorities

'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.'

The Challenges

- Government has not endorsed specific recommendations from the HTA policy and process review – working assumptions then is that all will be considered for implementation.
- There is a high level of inter-dependency among the 50 recommendations.
- Concerns from both Government and Pharma about the costs of any reforms and who pays.
- Timeframes for change on top of an already lengthy review process is frustrating for all.
- How much collaboration and codesign is possible given timeframe and the nature of some of the negotiations?
- The scene is not static – recommendations made more than 12 months ago.

Framework for Recommendation Analysis

SCOPE	Are the actions required to implement this recommendation clear? Are there any ambiguities that need clarification? Are both the objectives and the outcomes for the recommendation captured?
VALUE/IMPACT	What are the anticipated benefits/value/impact of the actions, assessed against: patient outcomes, timely access, equity, system efficiency and Australian market attractiveness?
DEPENDENCIES/ SEQUENCING	How does this link with the Enhance HTA report recommendations and/or New Frontier report? How does this recommendation integrate with other work underway and with other recommendations? Are there any dependencies or prerequisites that need to be considered?
IMPLEMENTATION COMPLEXITY	What are the potential risks associated with implementing this recommendation? Anticipated difficulty with implementation?
WHO	Who is involved/required to deliver the implementation? Who is impacted by the recommendation? What are the views of consumers, and other stakeholders, including industry and clinicians. In what ways will stakeholders be impacted?
COST	Estimated costs to implement? If new funding is required where could the funding potentially come from?
RESOURCES	What human, financial and technological resources are needed to implement this recommendation?
IMPLEMENTATION TIMING	Can this recommendation be implemented in the short term, medium term, or long term?
MEASUREMENT	Once implemented how will we know it has been successful? Are there any expected key performance indicators/success factors?

Defining Value

Criteria	LOW	MEDIUM	HIGH
• **Patient outcomes** **Considers the impact of the recommendation on patients' health and wellbeing.**	• Minimal improvement in health outcomes.	• Moderate improvement in health outcomes, such as better management of symptoms or modest enhancement of quality of life; or significantly improved outcomes for a moderately sized patient population.	• Significant and measurable improvement in patient health, including reduced morbidity/mortality, enhanced quality of life, or other substantial clinical benefits. A large patient population likely experiences improved outcomes.
• **Timely access** **Considers the impact of the recommendation on expected timeframes to listing for subsidised patient access.**	• Minimal impact on the time taken for patients to access new medicines.	• Streamlines processes or removes minor barriers, resulting in moderate improvements in the time to access.	• Potentially significant improvements in access by reducing the number of days between registration and reimbursement or encouraging the consideration of heath technologies that would otherwise not have been brought forward.
• **Equity** **Considers the recommendation's ability to address disparities and improve access for underserved populations.**	• Limited impact on reducing inequities; benefits are concentrated among already well-served populations.	• Some contribution to addressing inequities, such as targeted interventions for specific underserved groups.	• Substantial reduction in inequities through improved access, outcomes, and inclusion of underserved or high-need populations.
• **System efficiency** **Considers how well the recommendation optimises resource use and improves healthcare processes.**	• Minimal noticeable improvement in resource allocation or operational efficiency; may even increase system burden.	• Some improvements in efficiency, such as reduced wait times or better utilisation of resources, but with limited scalability.	• Major enhancements to system efficiency, including cost-effectiveness, streamlined workflows, or significant reductions in resource waste. Also positions HTA processes to respond to rapid advances in medical science and the increasing complexity and diversity of new health technologies.
• **Australian market attractiveness** **Considers whether the recommendation supports the goal of maintaining Australia as a first choice destination.**	• Minimal impact on Australia's attractiveness as a country to launch new health technologies.	• Somewhat improves Australia's attractiveness as a first launch country.	• Positions Australia as a country where new health technologies are launched early.

Implementation Complexity

Simple	Moderate	Complex
Minimal barriers; implementation is straightforward and requires little effort.	Some challenges exist, but implementation is achievable with reasonable adjustments.	Significant barriers; requires substantial changes or resources to implement.

When considering the complexity levels consider the following:

- number of stakeholders involved (and level of support for the activity)
- level of resources required (time, funding, workforce)
- scalability of solution/actions and can it be expanded effectively
- sustainability of solution/actions
- compatibility with existing systems
- organisational changes needed
- risk of resistance or disruption

Recommendation Specific Advice

- Recommendation either/or/and
  - can be implemented without further development.
  - dependent on decision regarding other recommendations.
  - implementation at a later stage as requires prior steps following implementation of other recommendations.
  - requires further design phases/inputs.

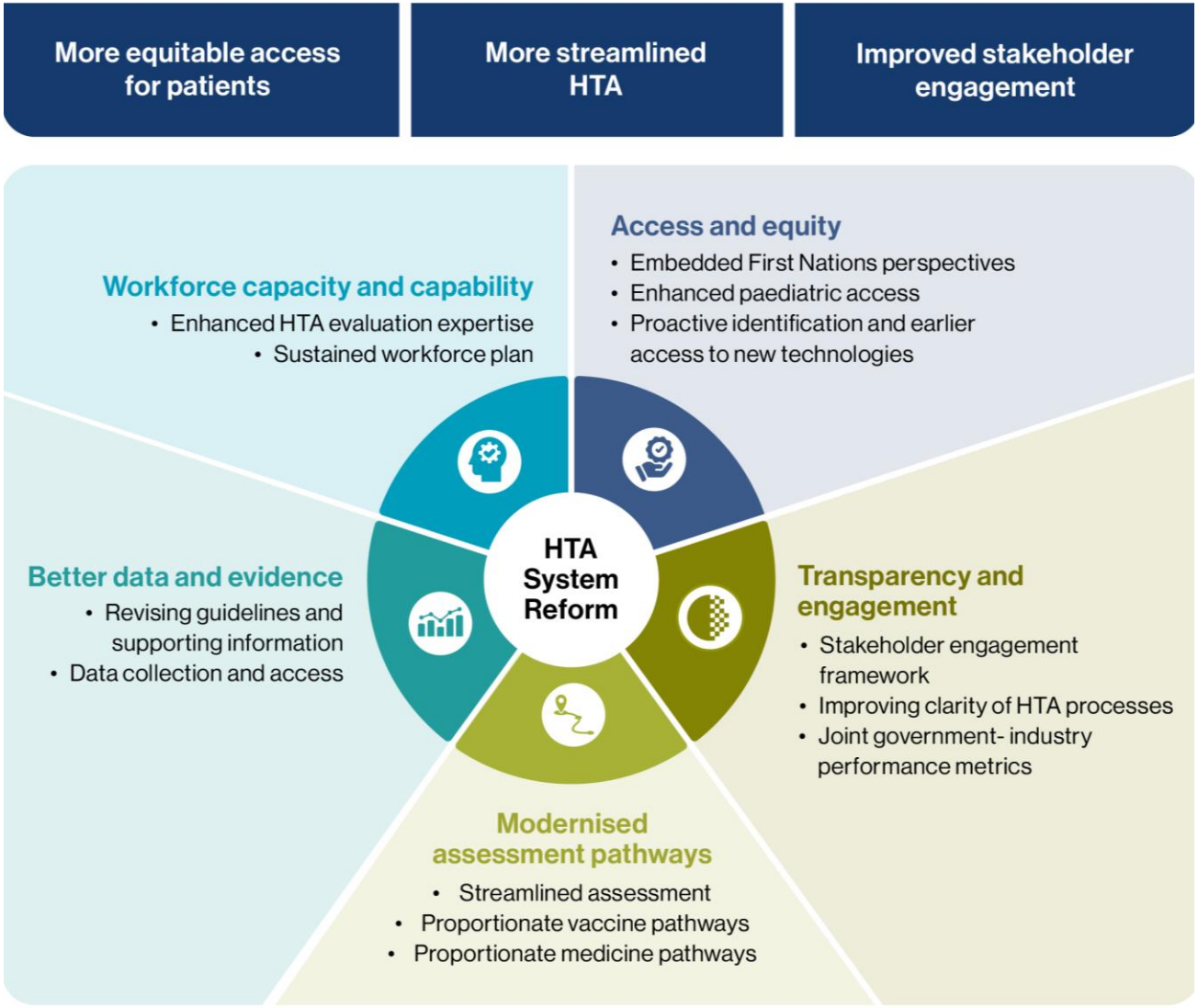
- Who should be responsible for implementation?
- Likely impact in terms of Minister's priorities?
- Priority overall
- Likely timeframe

Progress

42 recommendations considered, with draft advice on 32, 8 to go.

R!: Creating a more equitable system for First Nations peoples
R2: Equitable access to medicines for paediatric patients
R3:Overarching recommendations for all HTA funding and assessment
R4: Unified HTA pathway and committee approach for all health technologies
R5: Triaging submissions
R6: Expanding the advisory role of the PBAC beyond the PBS
R7: Streamlined pathway cost-minimisation submissions
R8: Improve the pathways and processes for listing therapies with high added therapeutic value for unmet clinical needs
R9: Therapies with added therapeutic value
R10: To be considered next week
R11: Proportionate appraisal pathway for vaccines
R12: Proactive vaccine assessment pathway
R13: To be considered next week
R14: Improving time to access life-saving drugs for patients with ultra-rare diseases
R15: Jointly owned performance targets
R16: Addressing the implications of high-cost/high-impact health technologies
R17: Pricing offer framework
R18: Updated post-review framework
R19: Managed entry agreements
R20: Bridging funding program
R21: Incentivise the development of health technologies that address antimicrobial resistance
R22: Publishing plain language summaries
R23: Improving the HTA webpage including developing a dashboard
R24: Developing an engagement framework
R25: Improving involvement of consumers in HTAs
R26: Developing an explicit qualitative values framework
R27: Advice being finalised next week
R28: Advice being finalised next week
R29: Advice being finalised next week
R29: Advice being finalised next week
R30: Advice being finalised next week
R31: Advice being finalised next week
R32: Advice being finalised next week
R33: Advice being finalised next week
R34: To be considered next week
R35: To be considered next week
R36: To be considered next week
R37: To be considered next week
R38: To be considered next week
R39: Discount rate
R40: Comparator selection – ongoing
R41: Advice being finalised next week
R42: Valuing and pricing
R43: Environmental impact reporting
R44: Identifying therapeutic areas of high unmet clinical need
R45: Identifying therapies to address therapeutic areas of high unmet clinical need
R46: Proactive pre-HTA processes supporting the introduction of identified health technologies for high unmet clinical need
R47: To be considered next week
R48: Mechanisms for continuous review and improvement
R49: HTA evaluation workforce
R50: Supporting architecture resourcing

Roadmapping – The Framework



Examples of Early-Stage Advice in the Implementation Roadmap

Improved access programs and equity

- Develop terms of reference for and establish a HTA First Nations Advisory Committee as part of PBAC and MSAC processes.
- Establishing a working group to identify priority paediatric conditions that may warrant consideration for applying an age-agnostic approach.
- Undertake work to define High Unmet Clinical Need and High Added Therapeutic Value.

Greater transparency and engagement

- Prioritize areas for PBAC and MSAC guidelines reviews including those where there is the highest need for clarification for non-technical stakeholders such as comparators and managed entry agreements.
- Resource the Consumer Evidence and Engagement Unit to progress the stakeholder engagement framework under the guidance of the Consumer Consultative Committee.

Modernised assessment pathways

- Pilot the PBAC directly making recommendations to the Minister for Health in relation to medicines for inclusion on the Life Saving Drugs Program and codependent diagnostics.
- Pilot proportionate appraisal pathway for vaccine submissions consistent with already approved classes of vaccines.
- Co-develop and pilot new cost-minimisation pathways in consultation with industry stakeholders.

Better data use and enhanced evidence

- Build on and add to current Australian government programs on health information system to commence progressing work of better real world data.

HTA workforce capacity and capability

- Undertake a study of existing workforce capacity and gaps.

What's next?

- Interim report to Minister in next week.
- Finalisation of Recommendation-specific implementation advice by end of August 2025.
- Draft Roadmap for Implementation based on Framework by mid-late September 2025.
- Consultation on Roadmap October 2025.
- Review and Finalisation of Report due January 2026.