Health Technology Assessment Review –

Implementation Advisory Group

Interim Report

6 August 2025

CONTENTS

1.0 EXECUTIVE SUMMARY

The Health Technology Assessment (HTA) Review Implementation Advisory Group (IAG) was established to provide the Government with advice on the prioritisation of the HTA review recommendations, and develop a roadmap for HTA reform. This Interim Report outlines the IAG's progress, early insights and next steps toward delivering a final report and roadmap by January 2026.

Since February 2025, the IAG has held monthly meetings to develop a phased work plan that includes the analysis of HTA review recommendations, development of the roadmap and the delivery of the final report.

Early insights have been consolidated into the following five focus areas, along with opportunities that could be progressed in the short-term:

1. **Improved access and equity** –
    - co-develop Terms of Reference for a HTA First Nations Advisory Committee with relevant stakeholders
    - establish a targeted working group to identify priority paediatric conditions that may warrant consideration for applying an age-agnostic PBS listing approach
    - develop potential definitions for high unmet clinical need (HUCN) and high added therapeutic value (HATV) in consultation with relevant stakeholders for government consideration
2. **Greater transparency and engagement** –
    - develop a stakeholder engagement framework with the guidance of the Consumer Consultative Committee and in consultation with relevant stakeholders
    - progress priority updates to the Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines, including in relation to comparator selection
3. **Modernised assessment pathways** –
    - develop pilot pathways for the streamlined assessment of medicines for inclusion on the Life Saving Drugs Program (LSDP) and some co-dependent health technologies
    - design new cost-minimisation pathways for piloting in consultation with industry stakeholders
4. **Better data use and enhanced evidence** –
    - map existing datasets and access to understand the opportunities and gaps for using RWD to inform HTA
5. **HTA workforce capacity and capability** –
    - assess current workforce gaps and future needs to develop a sustained HTA workforce plan.

The IAG will begin prioritisation of recommendations and the development of the roadmap in August 2025, and will undertake further stakeholder consultation to inform this work. The IAG will provide its final report with more detailed implementation advice for HTA reform in January 2026.

2.0 BACKGROUND

The Health Technology Assessment (HTA) Review examined Australia's HTA system, and involved substantial engagement with stakeholders to identify features that were working effectively and those that are potentially acting as barriers to access. The **Final Report** of the Review was published in September 2024, and provides 50 recommendations to improve access to new health technologies, tackle inequity, and make HTA processes simpler and easier for consumers and clinicians to participate in.

The Health Technology Assessment Review Implementation Advisory Group (the IAG) was established to provide advice to Government on the prioritisation of recommendations from the HTA Review and develop a roadmap to sequence the Government's response. In providing its advice, the IAG will also consider the recommendations of the inquiry report *The New Frontier – Delivering better heath for all Australian*s and the consumer engagement *Enhance HTA report*, which was developed alongside the HTA Review.

The **Terms of Reference** for the IAG define the IAG role and expected outcomes. As an advisory body, the IAG comprises of senior leaders and representatives from across the health sector. Membership includes representatives from consumer organisations, industry, clinicians, health economics experts, a jurisdictional representative and the Australian Government. The group adopts a collaborative and co-design approach in developing advice for consideration by the Government.

In February 2025 the then-Minister for Health and Aged Care, the Hon. Mark Butler, asked that IAG members prioritise advice on implementation of actions relating to:

1. more equitable access for patients
2. process changes to support more streamlined HTA
3. improved stakeholder engagement in HTA.

This Interim Report provides an update on activities and approach undertaken by the IAG since its establishment and outlines some early insights. A Final Report and Roadmap are expected to be provided for Government consideration in January 2026.

3.0 UPDATE ON IAG ACTIVITIES AND APPROACH

Since February 2025, the IAG has had monthly formal meetings, supplemented with several out-of-session meetings. Through these meetings the IAG has discussed options for reform implementation design, the prioritisation of recommendations and development of a Roadmap for sequencing the Government's response to the recommendations of the HTA Review. To ensure their advice is well informed the IAG members are also actively seeking insights and consulting with their relevant sectors.

The IAG has also met with the Chairs of Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) to discuss the reform priorities of those committees and the ongoing work that aligns with HTA Review recommendations. The Chair of the IAG has also met with industry and consumer groups and presented at relevant industry meetings. Additionally, the IAG is considering work underway in comparable overseas jurisdictions to gain insights into the value, costs and feasibility of implementation in Australia.

The IAG has a phased workplan to develop a HTA Review Roadmap and accompanying implementation advice to Government. The IAG approach consists of three stages, outlined below.

3.1 Stage One: Recommendation analysis (March – August 2025)

During this stage the IAG are working through each of the HTA Review's 50 recommendations. In analysing each of the recommendations, the IAG evaluate a series of considerations which will inform the development of the Roadmap. This ensures a consistent approach is taken to each recommendation (see Table 1 for the eight analytical considerations). To further support the analysis of the recommendations, the IAG developed criteria for assessing value and impact, as shown in Table 2.

The objective is that the final advice by the IAG to the Government will provide a strong evidence-base for the merits of prioritising relevant reforms, including the expected benefits for patients and sponsors.

At the time of writing this report, the implementation group is nearing completion of this recommendation analysis stage.

Table 1: Analytical framework for recommendation analysis

Analytical element	Key questions to consider
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?

Table 2: Value criteria

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.

3.2 Stage Two: Implementation analysis and Roadmap development (August – October 2025)

During this stage, the IAG will develop advice on prioritisation and sequencing implementation of the HTA Review's recommendations. To inform subsequent planning, implementation actions will be identified, and members will seek to highlight relevant dependencies, resource requirements and potential risks.

To inform the prioritisation and development of the implementation Roadmap, IAG members will continue to actively seek insights and consult with their relevant sectors.

3.3 Stage Three: Final report and Roadmap (October 2025 – January 2026)

In the final stage, the IAG will conduct further analysis and incorporate additional insights to refine the Roadmap for Government consideration, consulting with stakeholders to ensure the Roadmap is robust and fit-for-purpose. The Final Report and Roadmap will outline the IAG's advice on priority areas for HTA reform implementation, sequencing and interdependencies, and key responsibilities.

4.0 EARLY INSIGHTS

This section includes early insights from the IAG, and an update on progress towards development of a Roadmap. This analysis is being shaped by the three priorities outlined by the Minister for Health, Disability and Ageing – more equitable access for patients, more streamlined HTA, and improved stakeholder engagement.

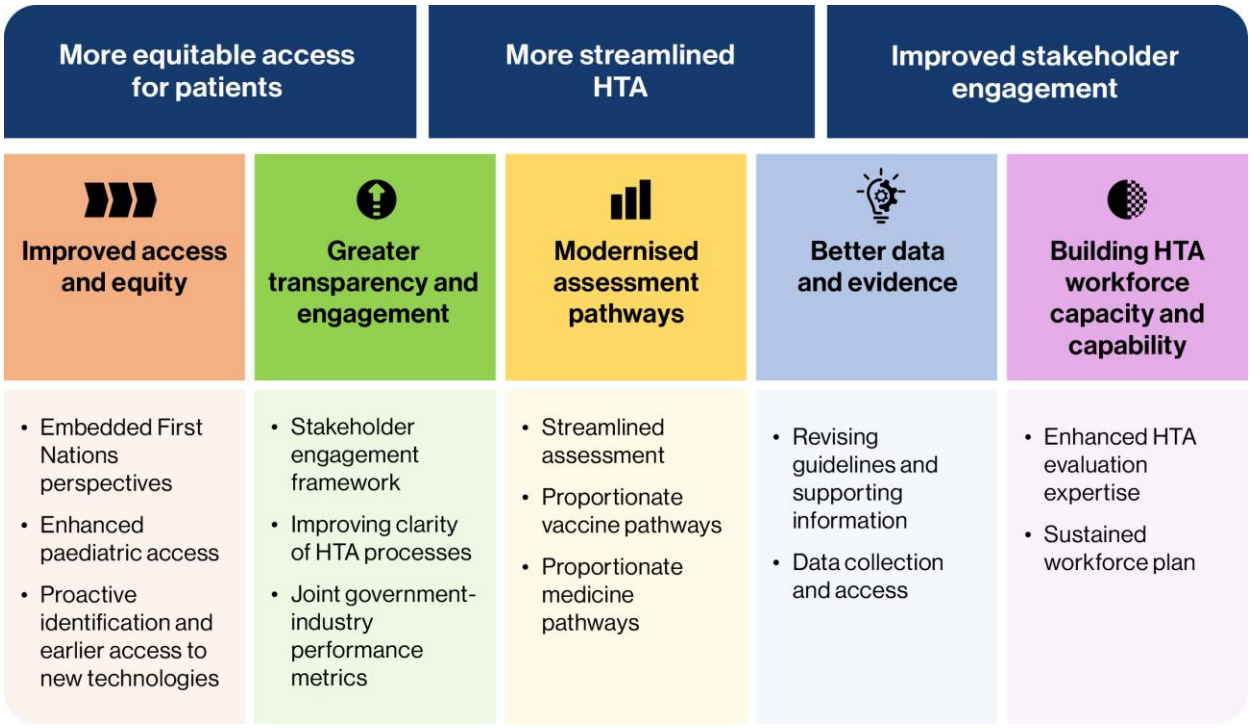
Through this analysis, IAG members have identified the need to consolidate their advice into focus areas for implementation. This consolidation recognises the many linkages across the HTA Review recommendations and is intended to provide clarity and transparency in monitoring progress towards the key desired outcomes.

As outlined in Figure 1, the proposed focus areas include:

- improved access and equity
- greater transparency and engagement
- modernised assessment pathways
- better data and evidence
- building HTA workforce capacity and capability

In the analysis undertaken by the IAG, the group has identified several priority actions that it expects will be key to successful implementation of each focus area. Members have, in some cases, additionally identified 'first steps' for implementation of these actions, to provide Government with clear insight into how and when these actions will be considered in its Roadmap.

Figure 1: Focus areas and priority implementation actions



4.1 Improved access and equity

The HTA Review recognised the critical importance of improving equitable access to health technologies for high priority and under-served population groups. These groups include First Nations people, paediatric patients, and others facing inequities in healthcare access and outcomes.

Embedding First Nations perspectives into HTA decision-making

The HTA Review identified that there is a lack of formal and routine involvement of First Nations people in HTA decision-making. The Review made recommendations aimed at improving First Nations involvement in HTA decision-making and reducing health inequities including establishment of a First Nations Advisory Committee to contribute to HTA assessment and decision-making.

IAG members considered that initial establishment of a committee and development of supporting Terms of Reference would not be complex. Members noted however that it will be important to engage with stakeholder groups and align with both existing engagement mechanisms and new processes to be established through the broader reform package. IAG members also agreed that an important principle in establishing a new committee will be to ensure that no delays are created in decision-making and assessment processes.

As an initial action the IAG has identified that Government should work with relevant stakeholders to develop Terms of Reference for a HTA First Nations Advisory Committee. Drafting of this document would help define the anticipated role, scope and timeframes of the committee and determine the most appropriate reporting structures.

The IAG identified that the initial role of the committee could include providing advice on the prioritisation and implementation of other recommendations from the HTA Review relating to First Nations health and engagement. This would include for example consideration of how to ensure that sponsors include appropriate consideration/assessment of the impact on health outcomes for First Nations people in submissions.

In developing its Roadmap for Government consideration, the IAG intends to consider this advice further in consultation with key stakeholder groups.

Enhanced paediatric access

The HTA Review found that access to PBS-listed medicines for children and young people could be increased, including by PBAC adopting an approach of being age-agnostic with its restriction unless there are specific reasons to limit use. In considering this area of need, IAG members acknowledged both the challenges in developing the necessary data to support paediatric use and potential risks of Government endorsing age-agnostic listings, including potential legal limitations.

IAG members agreed that a cautious staged approach was required in exploring the initial steps that could support increased paediatric access. The IAG noted that there were issues for both the sponsor and the TGA which would need to be considered. The IAG is aware that the PBAC has commenced work on this issue. As an initial action, the IAG has identified that Government (in consultation with PBAC) should consider establishing a targeted working group to identify priority paediatric conditions that may warrant consideration for applying an age-agnostic approach, noting the work PBAC has previously undertaken on drugs for inflammatory arthritis in children.

Proactive identification and earlier access to new technologies including therapies to address high unmet clinical need

The HTA Review found that the adoption of a more proactive approach to identifying therapies that address HUCN could improve health equity, including for paediatric and First Nations populations. The IAG noted that there is no definition of HUCN even though the terminology already forms part of the criteria for some PBAC pathways.

The IAG agreed that reforms to first define and then address areas of HUCN should be a priority. Members suggested that as an initial action the Government could consider establishing a research project to summarise the approaches used to define and identify HUCN in international jurisdictions and consult with key stakeholders to develop Australian criteria for HUCN. Members also acknowledged the potential risks with establishing a definition of HUCN – including the perception that this may deprioritise other areas of need, or inadvertently limit the current flexibility that HTA committees have in considering applications and thereby constrain decision-making.

Members also noted that specific processes would need to be developed to effectively consider technologies to address an identified HUCN and carefully consider the potential risks. To this effect, the IAG identified that following the development of an appropriate definition for HUCN, the Government should consider developing, piloting and evaluating a modified pathway for medicines that meet the definition which would be more proactive than the current solely sponsor submission-based approach.

The IAG considered the recommendations relating to an expedited access or bridging funding programs for medicines with HATV where there is an HUCN. The IAG noted that the concept of HATV is also undefined, even though it is commonly used, and indicated that future research could include a process to define HATV. The IAG agreed that progressing actions to address areas of HUCN, and changes that improved the overall access times, would be more equitable and should be the highest priority. The IAG identified that as an initial action, potential definitions for HUCN and HATV should be developed in consultation with relevant stakeholders for government consideration.

4.2 Greater transparency and engagement

A central focus of the HTA Review was the need to improve transparency and stakeholder engagement in HTA. Robust and effective engagement with stakeholders is essential throughout the HTA process. Enhanced stakeholder participation and understanding of HTA decisions will have a range of benefits for Government, individuals and society.

The Chairs of the PBAC and the MSAC have advised the IAG that both committees have progressed initiatives to increase transparency of assessment processes and enhance stakeholder engagement. For example, the MSAC provides decision summaries for consumers, and the PBAC has increased engagement with sponsors to allow for more tailored discussions. IAG members have also noted the work of the Consumer Consultative Committee in bringing consumer views into HTA processes.

In the analysis undertaken to date by the IAG, the following priority actions have been identified.

Developing a stakeholder engagement framework

IAG members agreed that the development of a stakeholder engagement framework is an important first step to ensuring that stakeholders, including consumers and clinicians, are empowered to more effectively engage at the relevant time in HTA processes. Development of this framework would be guided by the Enhance HTA Report and the HTA Review. The IAG also identified that the framework development would require supporting actions to be undertaken including updates to guidelines and development of supporting educational material and training.

To commence work on this action, the IAG identified that the Government could consider resourcing the Department of Health, Disability and Ageing to progress the stakeholder engagement framework, under the guidance of the Consumer Consultative Committee and in consultation with all stakeholders.

Revising guidelines and developing supporting information to increase transparency

Initial analysis by the IAG has identified a range of processes and methods used within HTA that could be more clearly explained to stakeholders. In some instances, this may be sufficient in addressing concerns, and in others would allow for better analysis of the issues and gaps that should be addressed.

While the IAG will undertake further mapping of potential updates, two areas have been identified for initial priority updates in the guidelines:

- Managed entry agreements (MEA) – identifying barriers to MEA uptake and ensuring that the MEA framework is clearly understood by stakeholders.
- Comparator selection – building on the recent work by the PBAC, which highlights the existing flexibilities, to provide further clarity on the factors that guide comparator selection.

In addition to updating guidelines, there is also an opportunity to publish documents regarding HTA funding mechanisms and current pricing processes. The IAG identified that a challenge in providing further transparency in relation to these processes will be ensuring that flexibility is maintained so that the system can respond appropriately to new technologies and needs as they arise.

Improving transparency of the joint government-industry performance statistics and information

Since the HTA Review, there has been considerable progress on the development of joint performance metrics by government and industry stakeholders, through the Access to Medicines Working Group (AMWG). If feasible within the lifespan of the IAG, members will liaise with the AMWG and review the proposed statistics and information to be published to consider if additional work, either by the AMWG or separately, should be considered by Government to meet the intention of the HTA recommendations. This could include linkages with other recommendations relating to transparency and improving access to information.

4.3 Modernised assessment pathways

Australia has several pathways for assessing health technologies for Australian Government funding. The HTA Review noted that these pathways and their component processes form a complex ecosystem, with numerous interdependencies and interactions between the different pathways. The Review sought to identify improvements to the HTA pathways and processes which would enable the system to keep providing Australians with world-class access to medicines while meeting the needs of Australians into the future.

The interdependencies between pathways and the evolving technology landscape will make implementation of new streamlined pathways challenging. To ensure a robust design and practical implementation, the IAG identified that Government should take a staged implementation approach in considering any proposed new pathways to ensure that they will operate as intended. This could include further scoping in consultation with stakeholders and introduction of pilot pathways for further evaluation in the first instance.

The IAG has identified three initial sets of actions which could be considered for piloting by Government in the short term to improve HTA processes. These proposed pilots focus on providing streamlined processes which will make more efficient use of time, data and resources.

Enhancements to streamline the assessment pathway

Expanding the advisory role of the PBAC could support improvements in the appropriateness and timeliness of some submission pathways. The IAG has identified that, as an initial action, Government could empower PBAC, as a pilot in the first instance, to directly make recommendations to the Minister for Health, Ageing and Disability, in relation to:

- medicines for inclusion on the Life Saving Drugs Program (LSPD)
- co-dependent health technologies funded through both the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), where MSAC has already considered and recommended similar uses of technologies.

Establishing more proportionate vaccine pathways

The Australian Technical Advisory Group on Immunisation (ATAGI) provides a wide range of advice for government and the public, including contributing to public health recommendations on the use of vaccines. However, unlike many other international jurisdictions, recommendations for the inclusion of vaccines in the National Immunisation Program (NIP) do not come directly from ATAGI, and they must be reviewed by the PBAC.

To be considered for listing on the NIP, sponsors must seek ATAGI advice before making a PBAC submission. The HTA Review found that ATAGI's processes add approximately 31 weeks to the 17-week PBAC HTA cycle, resulting in approximately a 48-week HTA pathway for vaccines for NIP listing.

The IAG has identified that Government could consider development of a more proportionate appraisal pathway for vaccine submissions consistent with already approved classes of vaccines, by removing the need for PBAC consideration of subsequent similar vaccines. The implementation of this pathway could have significant benefits in terms of increasing system efficiency.

Establishing more proportionate medicine pathways

The IAG has discussed the merits of commencing consultation regarding the criteria and rationale to pilot a streamlined pathway for submissions using cost-minimisation analysis. This pilot would focus on ensuring that the funding and assessment mechanisms and effort are proportionate to the complexity, risk and benefit of the submission. This would optimise the time and effort that sponsors, the department, evaluators and the PBAC spend on submissions.

The IAG has identified that the Government could consider developing new cost-minimisation pathways for piloting in consultation with industry stakeholders to ensure that they are transparent and practical. Initially this could apply to submissions for medicines in the same class and for the same condition where there are no claims of increased benefit over existing listed therapies.

4.4 Better data use and enhanced evidence

It is important that HTA guidelines are updated to reflect evolving best practice, stakeholder expectations and emerging challenges. While the IAG is continuing its analysis of the recommendations relevant to this focus area, two key actions have been identified.

Updating HTA Guidelines and publishing supporting information provide more clarity on HTA methods

The HTA Review found that existing guidelines do not give participants enough clarity on the HTA process for presenting, using and assessing emerging evidence, and evidence for emerging technologies. Updates to the PBAC and MSAC guidelines would ensure Australia's HTA processes remain fit for purpose in a rapidly evolving health landscape. To achieve this, updates should be informed by research and consultation with a wide variety of stakeholders, including Government agencies, clinicians, industry, consumer representatives, and patient groups.

The IAG notes that a comprehensive review of the PBAC Guidelines is overdue, and that a number of the HTA review recommendations refer to updating the Guidelines. The IAG noted that the review could be commenced prior to the IAG's final report, focussing on some priority areas including comparator selection and discount rate.

Supporting data collection and access for HTA

As Australian Governments continue to champion digital health across the healthcare system, there is a growing opportunity to harness the wealth of data being generated to drive improved health outcomes for all Australians. The HTA Review highlights several opportunities to take full advantage of this data. The IAG heard from the PBAC about constraints on access to existing information held by AIHW.

The HTA Review's recommendations aim to enhance timely access to relevant, quality real-world data (RWD) and real-world evidence (RWE) (generated by analysing RWD) to support decision making. RWD and RWE play an important role in supporting the evidentiary needs of decision-makers across the health technology assessment process. This includes informing subsidy approvals, post market reviews and PICO (Population, Intervention, Comparison, and Outcome) in HTA evaluations, and serving as an input for cost-effectiveness modelling and usage. The IAG also highlighted that RWE can be particularly beneficial in supporting assessment for smaller patient populations, including First Nations People.

While this focus area is still being explored, the IAG recognises that significant work is already being undertaken in relation to the effective utilisation of health data in Australia. It will be important to maximise the work that is already underway and assess how it can be accessed and effectively utilised to support HTA decision making. In parallel, assessing the existing information gaps across the health system will provide the foundation for the potential development of a more comprehensive approach for how RWD and RWE could more consistently and effectively be captured, accessed and utilised.

Through early discussions the IAG has noted the many linkages this work has to the New Frontier Report and the Enhance HTA report, which highlight the clinical- and consumer-focussed opportunities to create cross-system linkages and enhance existing data infrastructure. Members also discussed the digital health and data initiatives currently being progressed including the Australian Digital Health Agency's Health Connect Australia and the Commonwealth Scientific and Industrial Research Organisation (CSIRO)'s Sparked program, which are building the national capabilities needed to support the secure, real-time sharing of health data. Members noted the potential, with appropriate data governance and health systems interoperability, to harness this work to support RWE generation for HTA. Interjurisdictional support and engagement on initiatives to enhance sharing of health data was also confirmed.

The IAG Roadmap will provide further advice on how this national capacity can be progressively built through a collaboration between Government, industry and researchers. This may be similar to the type of capacity building Government has funded through the MRFF research translations missions or cooperative research centres.

4.5 HTA workforce capacity and capability

Implementing reform in the above HTA focus areas will require enhanced workforce skillsets and greater capacity. Without a deliberate workforce uplift, these reforms cannot be implemented effectively or sustainably.

The HTA Review highlighted a steady rise in HTA submissions, with a corresponding increase in complex and innovative therapies including cell and gene therapies, genomics and new vaccines. New health technologies are also changing rapidly. Evaluation experts must be capable of understanding and assessing cutting-edge modalities, such as advanced therapeutics, novel diagnostics, and therapies built on RWD and emerging evidence types. Expertise in these methods is essential to make timely, evidence-based recommendations.

As submissions continue to increase in complexity and volume, the department will need to continue developing the skills of its evaluation workforce. This capability uplift is required across multiple parts of the HTA process – from those involved in research supporting HTA processes, to those involved in submitting and assessing HTA submissions.

A sustained workforce plan that seeks to identify future challenges and build relevant skills to meet these needs is required because the HTA Review found that the capabilities that underpin the HTA processes are unique, in-demand and not easily accessible. The IAG considers that as a first step the Government should undertake a study of existing workforce capacity and gaps, including new expertise that may be required for new health technologies.

5.0 NEXT STEPS

With the framework for recommendation analysis now established, the IAG is working towards rapidly completing the recommendation analysis phase. This background work has helped to establish a common understanding among members and will provide a solid foundation for moving into the prioritisation phase of work.

The IAG will continue to consider the identified focus areas and the prioritisation of early actions to develop a clear HTA reform Roadmap for Government consideration. It is expected that the IAG will complete its initial prioritisation work by October 2025. This should allow for further consultation and feedback to be provided by key stakeholders ahead of the IAG providing its final advice in January 2026.