



Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 27 January 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 27 January 2023.

All Committee members attended as well as support staff from the Review Secretariat in the Department of Health and Aged Care (Department) and the probity adviser. Representatives from Medicines Australia joined for part of the meeting.

What did the Committee discuss?

Probity

The Chair reminded the Committee members to raise any potential conflicts of interest that arise during the HTA Review with the Chair, Secretariat or probity adviser.

The probity adviser reminded the Committee of the confidentiality arrangements set out in the HTA Review probity plan.

The Committee considered it is important to balance confidentiality and transparency during the HTA Review. The Committee agreed in principle to the publication of documentation related to the HTA Review unless it involved confidential material or working drafts of papers in preparation to be considered by the Committee.

The Committee considered it may be helpful to publish the HTA Review probity principles because they would provide any interested stakeholders visibility of the principles and procedures the Committee has agreed, to support the integrity and transparency of the HTA Review.

Discussion with Medicines Australia

The Committee invited representatives from Medicines Australia to join its meeting for a discussion about the concerns Medicines Australia has raised publicly about consultation on the HTA Review draft terms of reference. The Chair thanked Medicines Australia for its input to the draft terms of reference and acknowledged the concerns Medicines Australia had raised. Medicines Australia expressed that there should be broader transparency and greater communication moving forward. The Committee agreed that it would publish any documentation related to the HTA Review where possible. Medicines Australia requested that the discussion paper for the terms of reference be published. Medicines Australia also enquired about the criteria used to select the HTA expert. The Department advised that the request for tender for the HTA expert (including the criteria) was publicly available, as it was published on AusTender at the beginning of 2022. The Committee advised that it had expressed its view on the expert in HTA based on the tender evaluation process at its previous meeting. The Committee agreed to a request from Medicines Australia to re-publish the criteria used to evaluate the tenderers that was included in the request for tender and a summary for ease of understanding (see Appendix 1). The Committee advised that the outcome of the tender cannot be disclosed until processes to

engage the expert in HTA have been completed. The Chair and Medicines Australia agreed that the discussion was useful and that it was important for both parties to maintain communication throughout the Review. Medicines Australia accepted an invite from the Chair to have regular discussions with the Committee throughout the Review process.

Stakeholder feedback on the draft terms of reference

The Committee received feedback from 32 organisations/individuals on the draft terms of reference. The Committee considered all input it received. The Committee welcomed the input received from additional individuals and organisations who had requested the opportunity to provide input. Based on the input it received, the Committee discussed making a number of changes to the draft terms of reference which include:

- adding further information upfront to make it clear that the HTA Review is a commitment in the 2022-27 [Strategic Agreement between the Commonwealth and Medicines Australia](#) (Strategic Agreement)
- clarifying how consumer engagement and other concurrent HTA reforms will be taken into account
- aligning language to the aims and vision of the National Medicines Policy and the goals set out in the Strategic Agreement, including reducing time to access
- better defining how equity in HTA will be considered as part of the HTA Review and
- summarising the new National Medicines Policy and the Standing Committee on Health, Aged Care and Sport Committee inquiry into approval processes for new drugs and novel medical technologies in Australia in greater detail and linking the HTA Review to the moving parts of those processes and the Strategic Agreement more explicitly.

The Committee considered that the Strategic Agreement should be included as an attachment to the terms of reference as it sets out key areas to be addressed by the Review.

The Committee noted that a significant number of issues that stakeholders considered should be addressed by the Review were within the scope set out in the draft terms of reference without being specifically listed. The Committee agreed that it would develop a work plan that would set out in greater detail the issues to be covered by the HTA Review, including those that had been raised by stakeholders, that fall within the scope of the terms of reference.

The Committee considered that health technologies such as medical devices, digital technologies, or medical services (other than those that are used to improve a medicine, vaccine, cell therapy or gene therapy) should not be within the scope as the HTA Review is a specific commitment between the Government and the medicines industry.

The Committee noted that there are a number of existing arrangements for state and territory governments to work with the federal government. The Committee therefore considered that state and territory arrangements should not be included specifically in the scope.

The Committee agreed to work towards finalising the terms of reference prior to its next meeting. The Committee noted advice from the Department that once it had agreed the final terms of reference, it would be put to Government for approval before being published.

Work to be undertaken by the HTA expert

The Committee considered the scope of the work of the HTA expert given the draft terms of reference so as to enable the Department to commence processes to engage the expert in HTA. The Committee agreed that equity, cultural safety, and consumer evidence and engagement should be considered in the scope of work.

The Department advised that the scope of work may vary depending on discussions with the HTA expert and progress of the Review. The Department advised that once the Committee agreed the proposed scope of work, the Department would commence processes to engage the expert in HTA.

Other business

The Committee noted that it would seek briefings on concurrent consumer engagement work and on the new National Medicines Policy at its next meeting on 13 February 2023.

Who is the Reference Committee?

- Independent Chair: Adjunct Professor Debora Picone AO
- Patient Representatives: Ms Ann Single and Dr Dawn Casey PSM
- Chair of the Pharmaceutical Benefits Advisory Committee (PBAC): Professor Andrew Wilson
- Clinical/Scientific Representative: Professor Andrew Roberts AM
- Member nominated by Medicines Australia: Mr John Young
- Government Nominee: Ms Adriana Platona PSM

Where can I find out more about the HTA Review?

[Health Technology Assessment Policy and Methods Review](#)

Appendix 1 – Statement of Requirement and evaluation criteria in the Request for Tender for the HTA expert published in 2022

Statement of Requirement

The service provider will be required to:

1. Undertake analysis under the guidance of the Reference Committee of current methods used by the PBAC, contemporary research and relevant methodologies and purchasing practices used by comparable international jurisdictions. Analysis of current methods used by other Commonwealth HTA Committees such as the MSAC and implications of the review for linked activities of these Committees may also be required.
2. In undertaking its analysis, the service provider will need to consider relevant broader economic policies and methodologies used to make funding decisions in areas beyond health technology assessment and the outcomes of recent reforms to health technology assessment in comparable jurisdictions such as the United Kingdom.
3. Subject to the guidance of the Reference Committee – the analysis may include, but not be limited to, analysis of contemporary research and methodologies used by comparable jurisdictions including in relation to:
 - selection of comparators
 - methods for evaluating rare diseases for reimbursement and alternative funding pathways if required
 - methods for evaluating new and emerging technologies (including cell and gene therapies, and other precision-based medicines) and the suitability of existing funding pathways as required
 - methods for evaluating all new medicines and vaccines
 - use of real-world evidence for evaluation including use of evidence from sources other than randomised controlled trials
 - managing clinical, economic, financial, and other uncertainty
 - examining the feasibility of international work sharing for reimbursement submissions
 - methods used by MSAC.
4. Perform additional project work on an as needs basis and sometimes in a short timeframe. This may include requests from the Reference Committee for specific types of analysis and summarising submissions to the Review from patients, industry, health practitioners and relevant representative bodies.
5. Provide draft and final reports that detail the findings of the analysis.
6. Attend meetings held by the Reference Committee and discussions with relevant officers in the Department.

Required expertise

The contractor will have ready access to specified personnel with appropriate qualifications and experience who are readily available to perform the roles in the table below. Noting the broad scope of expertise required, consortium or subcontractor tenders will be accepted:

Specified Personnel	Qualifications and experience	Roles
Group leaders/Senior Evaluator	Qualifications and/or experience in critically evaluating clinical trial and related economic information and/or broader economic policies	The Group Leader will:
	Ability to critically review and quality assure the report	<ul style="list-style-type: none"> have overall responsibility for the quality and timeliness of the Contractor's performance of all Service deliverables
	Demonstrated experience in managing projects involving meeting fixed deadlines with high quality deliverables.	<ul style="list-style-type: none"> liaise with the Department's Project Officer and the Reference Committee for the Review in relation to all matters involving the delivery of the services.
	Demonstrated knowledge of the Australian Health System	Senior Evaluators can act in the role of the Group Leader
Evaluators	Appropriate tertiary level qualifications and/or experience in critically appraising clinical trial and related economic information	Writing the reports, and undertaking analyses, including technical economic analyses, to support the report.
Experts	Experts who have advanced training and/or experience in relevant fields including:	Experts may contribute their expertise to:
	<ol style="list-style-type: none"> public policy HTA methods health economics government financing and economic policy medicine clinical epidemiology pharmacology biostatistics 	<ol style="list-style-type: none"> Analyses conducted to support the report Draft and finalise reports

Evaluation Criteria

Technical Evaluation Criteria

Description	Weighting
<p>Criterion One – Tenderer experience</p> <p>The Tenderer’s ability to deliver the Services within the Department’s timeframes, as demonstrated by the Tenderer’s relevant prior experience in providing reliable, high-quality services for projects of a similar nature or undertaking analysis covering similar subject matter to the Services described in the Statement of Requirement.</p>	30%
<p>Criterion Two – Demonstrated understanding of the Department’s requirements for Services as described in Schedule 1</p> <p>The Tenderer’s understanding of the Department’s requirements (as described in the Statement of Requirement).</p>	25%
<p>Criterion Three – The Tenderer’s capacity to deliver the Services</p> <p>The extent to which the Tenderer has readily available Specified Personnel (including back-up Specified Personnel) with appropriate qualifications, skills, and experience in:</p> <ul style="list-style-type: none">• knowledge of fields relevant to delivering the Services, including but not limited to:<ul style="list-style-type: none">• public policy• HTA methods• Australian HTA practices and regulation including for the PBAC and MSAC.• medical and surgical services including diagnostics and therapeutics• health economics• government financing and economic policy• medicine• clinical epidemiology• pharmacology• biostatistics• support personnel to support the Specified Personnel to deliver the Services; and• ability to leverage Specified Personnel to support surge capacity requirements, including at short notice.	25%

Description	Weighting
<p>Criterion Four – Tenderer’s approach in delivering the Services</p> <p>The experience and approach of the Tenderer in delivering similar Services, including, but not limited to:</p> <ul style="list-style-type: none"> • how the Tenderer’s, resources, governance, and operational plans will assist the Tenderer to deliver the Services • ability to work collaboratively with stakeholders • conflicts of interest management strategies • risk management strategies • management and control of the Services • expertise and quality assurance procedures; and • ability to deliver high quality analysis reports in a timely manner. 	20%
Pricing – refer to Schedule 5 of the RFT	Not weighted

Non-Technical Criteria

No.	Evaluation Criteria
1	The degree of financial viability of the Tenderer, including any associated risks to the Department.
2	The degree of the Tenderer's overall compliance with the RFT and Draft Contract and the likelihood of any non-compliance meaning the Department is unable to agree a contractual arrangement with that Tenderer.
3	The extent to which any risks associated with the number and type of any conflicts of interest which have been identified by the Tenderer or which may later arise can be, have been, and/or will be, appropriately managed.
4	The extent to which the Tenderer does or will meet Commonwealth policy requirements.
5	The extent to which the Tenderer does or will meet all security requirements.
6	Any other risks to the Department which are inherent in, or associated with, the Tenderer's offer.
7	<p>The Tenderer’s proposed approach to:</p> <ul style="list-style-type: none"> • using Indigenous enterprises in its supply chain; and • the employment of Indigenous Australians.