



Australian Government
Department of Health and Aged Care

Probity Plan

Health Technology Assessment Policy and
Methods Review



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Background

The Australian Government assists Australians with the cost of health technologies through a range of different funding arrangements. Health technology assessment (HTA) is a key tool in ensuring the Government enables Australians to gain subsidised access to the most effective health technologies for the prevention, management and treatment of medical conditions.

HTA provides a means by which health technologies can be assessed, including against existing health technologies, based on the most robust estimates of the health outcomes delivered. Decisions to subsidise new health technologies are informed by advice from independent, expert advisory committees such as the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC). When deciding their advice, expert advisory committees consider an evaluation which summarises relevant information including clinical safety, effectiveness and cost of health technologies compared to alternatives and a range of other factors. HTA enables recommendations to Government that synthesise these elements.

HTA is used for medicines, vaccines, highly specialised therapies (such as cell and gene therapies), other health technologies (such as pathology tests or imaging technology).

The Government is supporting and resourcing a HTA Policy and Methods Review (the Review) under Clause 5.3 of the 2022-27 Strategic Agreement Between the Commonwealth and Medicines Australia (Strategic Agreement). The HTA Review is being undertaken in recognition of the shared goals set out at clause 5.1 of the Strategic Agreement of:

- reducing time to access for Australians so that they can access new health technologies as early as possible, and
- maintaining the attractiveness of Australia as a first-launch country to build on Australia's status as a world leader in providing access to affordable healthcare,
- by ensuring that Australia's assessment processes keep pace with rapid advances in health technology and barriers to access are minimised.

The Review will be overseen by a Reference Committee which is independently chaired. The Reference Committee includes the Chair of the Pharmaceutical Benefits Advisory Committee, a government nominee, a member nominated by Medicines Australia, two patient representatives and a clinical/scientific representative.

The delivery of the Review will involve review activities and consultations with a broad range of stakeholders, many of whom will have a financial, business, or professional interest in the outcome of the Review. Further, the Review may have implications for the expenditure of considerable government funds. The Review is anticipated to be high profile in the context of the involved sectors as well as the community, and may attract scrutiny from the Parliament, accountability authorities such as the Australian National Audit Office, along with the media and the public.

On the basis of the complexity of relationships and interests associated with the Review, the probity¹ risk associated with the delivery of the project is considered to be Medium-High.

The approach to probity in this context is to have a Probity Plan that is principle-based, and an independent Probity Adviser on hand at all stages of the Review to provide guidance, support, and advice for all Review Participants, consistent with the Plan's purpose and the probity principles. This approach reflects the complex and dynamic nature of the Review and provides scope to tailor probity controls or interventions to the specific probity risks that may emerge through the process. This approach also recognises that the Review is being supported by senior and experienced public servants and advisers, who are familiar with the business of government and public expectations for high standards of probity in such significant processes.

¹ **Probity** means that decisions are made with integrity, honesty and fairness while observing due process as necessary elements in the pursuit of value for money.

Purpose

The purpose of this Probity Plan is to outline probity principles and processes that are expected to be applied in all aspects and activities related to the Review.

This Probity Plan is designed to support the integrity and transparency of the Review and its associated processes, and to maintain the highest levels of probity and public accountability throughout the process. This Probity Plan commenced with the appointment of the Reference Committee that is in place at the date of the approval of the Probity Plan.

The objectives of this Probity Plan are to:

- ensure prescribed processes have been identified and can be followed or adhered to
- ensure the processes designed are equitable and conducted with integrity
- clarify accountability
- preserve public and stakeholders' confidence in Government processes; and
- improve defensibility of the Review to potential legal challenge or other external scrutiny.

This Probity Plan applies to all members of the Reference Committee, all Department of Health and Aged Care (the Department) officials involved in the Review as well as relevant consultants, service providers and stakeholders participating in, or contributing to, the Review (collectively referred to as the "Review Participants").

It is understood by the Department and the Reference Committee that the Minister for Health and Aged Care (the Minister) and the office of the Minister should be aware of and will apply the principles set out in this Probity Plan.

Certain requirements in the Probity Plan may be waived for specific Review Participants, with the agreement of the Probity Adviser or the Reference Committee Chair, where other controls can be relied upon or where meeting the requirement is not practical.

All Review Participants will be required to positively acknowledge that they have read, understood, and will comply with this Probity Plan.

Probity principles

The following probity principles apply to the conduct of the Review activities:

- demonstrating the achievement of a Review outcome that meets public expectations for transparency and accountability
- treating all stakeholders and Review Participants equitably and in an impartial manner
- conducting all Review activities with unimpeachable fairness and integrity
- securing sensitive, personal and confidential information
- identifying relevant interests and appropriately managing those which may create an actual, perceived or potential conflict of interest
- appropriately managing communications with Review Participants and stakeholders
- maintaining the integrity of procurement and administrative decision making; and
- maintaining a suitable audit trail.

Review Participants are accountable for ensuring that the activities, actions, and decisions related to the Review are undertaken in a manner consistent with these probity principles.

The probity principles are intended to complement (not replace) the obligations and expectations applying to Review Participants, including requirements (as applicable) under the:

- *Public Service Act 1999*
- *Crimes Act 1914*
- *Privacy Act 1988*
- *Archives Act 1983*
- *Public Governance, Performance and Accountability Act 2013* (PGPA Act)
- Guidelines on Ethics and Probity
- Guidelines on Official Conduct of Commonwealth Public Servants
- Commonwealth Procurement Rules
- Accountable Authority Instructions of the Department or applicable policies
- Protective Security Policy Framework.

This Probity Plan has been designed to support the management of the key probity risks facing the Review.

Integrity of Review outcomes

Review Participants should ensure that the activities of the Review, including the actions and decisions taken in the Review process, represent the best outcome in terms of achieving the stated objectives.

Role of the Review probity adviser

An independent Probity Adviser, Sententia Consulting, has been appointed to provide oversight and advice to Review Participants as appropriate during the Review. This is intended to provide Review Participants and the public with a level of comfort that the Review is conducted in a manner that is fair, objective, and defensible.

The Probity Adviser reports directly to the Department Executive and to the Reference Committee Chair and will raise probity concerns or risks as appropriate. The Probity Adviser will be objective and equitable in its engagement and is available for advice to all Review Participants.

The Probity Adviser will provide advice in real-time to support compliance with this Plan and the achievement of the Review objectives. This will include briefing Review Participants on probity requirements and any associated protocols, monitoring the decision making in the Review, identifying areas of probity risk to the Reference Committee, and investigating any probity concerns (such as conflicts of interest or breaches of confidentiality). At the conclusion of the project, the Probity Adviser will produce a probity report or sign-off letter on the project to the Department and the Reference Committee.

The Probity Adviser will be involved through all stages of the Review and will be given full access to all Review documentation, personnel, meetings, and premises to the extent required to perform their scope of services.

The Probity Adviser will perform specific roles in managing Conflicts of Interest, Confidentiality, Probity Issues and Queries and Probity Breaches, as set out in the Probity Plan.

Governance

The Reference Committee and the Department team responsible for supporting the Review will have joint responsibility to ensure adequate consideration of probity issues raised by the Probity Adviser, including the approval of mitigations and/or the acceptance of probity risks.

The Reference Committee and the Department will also be jointly responsible for managing and implementing the requirements of the Probity Plan in consultation with the Probity Adviser, as well as approving any deviation or changes made to the Plan.

The Probity Adviser does not have any decision-making authority with respect to the Review and operates in an advisory capacity only. This role does not remove the Reference Committee's accountability for the Review process.

Conflict of interest

A conflict of interest arises where there is an interest that conflicts, has the potential to conflict, or could be perceived to conflict, with the interests of the agreed terms of reference of the Review and the intended outcomes of the Review.

Actual, potential, and perceived conflicts of interest may arise at any time and have the potential to seriously undermine the integrity of the Review and the achievement of the Review objectives. Such conflicts of interest must therefore be identified and appropriately addressed as soon as possible. Advice on such conflicts should be sought from the Probity Adviser without delay.

All Review Participants must, upon involvement in the Review, declare any interests (personal, financial, or professional) relevant to the Review activities and complete, as applicable:

- Conflict of Interest Declaration and Confidentiality Deed (for APS Employees and Employees of Commonwealth Entities, or
- Conflict of Interest Declaration and Confidentiality Deed (for Personnel who are not APS Employees and Employees of Commonwealth Entities.

The requirement to complete the Deed may be waived by the Probity Adviser or Reference Committee Chair where a previous, relevant conflict of interest declaration can be relied upon, or where the completion of the declaration is not practical.

The Probity Adviser will review all completed interests declarations. If upon consideration of a declaration of relevant interests the Probity Adviser identifies a perceived, potential, or actual conflict of interest, the Probity Adviser will advise the Reference Committee and the individual on steps to manage that risk including necessary controls to manage the conflict.

Understanding the relevant stakeholder groups involved in the Review is key to determining interests relevant to the Review activities.

Contracted organisations (or any of their subcontractors) who are providing services or advice to the Review must, at an organisational level, have declared to the Reference Committee or the Department (depending on the engagement process) prior to the commencement of their engagement, whether or not they have any interests relevant to the Review activities.

All Review Participants have a continuing obligation to regularly review their declarations and update them as required to reflect the conduct of the Review activities. Review Participants will be periodically reminded of the need to keep their declarations up to date for changing circumstances. In addition, all Review Participants will be able to complete a new declaration at any point in time.

The Probity Adviser will keep and maintain a register of Review Participants' interest declarations, and record any advice given, updated declarations, actions taken and any mitigation arrangements that are put in place.

Confidentiality

Improper distribution or disclosure of information relating to Review activities has the potential to compromise the integrity of the Review and may breach obligations placed on the Commonwealth and its representatives regarding the treatment of confidential information.

All Review Participants must, upon involvement in the Review, complete a Confidentiality Deed Poll prior to accessing any confidential Review information. This requirement may be waived by the Probity Adviser or Reference Committee Chair where a Review Participant is already bound by an appropriately binding confidentiality arrangement, or where the completion of the Deed Poll is not practical. The Probity Adviser will maintain a register that records each individual who has completed a relevant confidentiality undertaking.

Information handled and maintained by Review Participants in connection with Review activities will be sensitive to Government, departments and third-party stakeholders. Review information may also be confidential² and subject to restrictive non-disclosure, confidentiality and use requirements.

As a result of these sensitivities, all Review Participants should treat, as the default position, non-public Review information as confidential. Review information should only be disclosed and/or communicated to those individuals with a clear 'need to know' who have signed a confidentiality undertaking or are subject to their organisation's confidentiality obligations and with prior written consent from the Department or Reference Committee Chair.

Where confidentiality arrangements are entered into with Review Participants or other parties, Review Participants should ensure they strictly adhere to those arrangements. This applies not only to officers assigned to the Review, but also to all employees, contractors, and consultants in their organisations.

All commercially (or otherwise) confidential information (including drafts) identified during the Review, in whatever form, must be stored securely at all times on departmental systems (including emails and GovTeams) or the systems of contracted consultants/advisers, and should have access controls in place to limit access to only authorised Review Participants and relevant advisers.

When providing access to or communicating Review information not in the public, Review Participants should clearly identify the information as confidential and ensure the recipient is notified of the restrictions placed on the information, including that:

- the information must be maintained in strict confidence;
- recipients shall not disclose to any third party, all confidential information observed by or disclosed to it by the Review, the Department or contracted suppliers;
- recipients shall not use or disclose the confidential information for any other purpose other than for the purpose of the Review;
- recipients shall use all reasonable endeavours to ensure that all persons receiving the information keep it confidential and are informed of the above restrictions; and

² For the purposes of this Plan, **confidential information** is considered to be information that is marked confidential, is advised by the party providing the information as being confidential or is information that would not have otherwise been accessible by Review Participants if not through the Review - and is not public information. If unsure whether information is confidential, advice should be sought from the Probity Adviser.

- recipients shall not further disclose the information to any other person without seeking the prior consent of the Department.

Review interactions

A review protocol³ will be developed by the Commonwealth (with support from the Probity Adviser) and agreed with each of the Review Participants prior to commencing Review processes. At the commencement of each Review engagement or meeting, the Review Team or Probity Adviser will reinforce the expectations of the review protocols to those attending the meeting.

Prior to commencement of the Review, the Assistant Secretary of the team responsible for supporting the Review will provide a briefing to staff of the Office of Health Technology Assessment and to the Senior Executive of the Technology Assessment and Access Division. The briefing will highlight expectations regarding communicating with staff and stakeholders on the Review, in particular, maintaining confidentiality and probity for the Review processes.

All formal meetings held with Review Participants in relation to the Review activities, must adhere to the following requirements (unless otherwise agreed or pre-approved):

- meetings must be structured around an agenda
- there must be a written record of the meeting; and
- the Probity Adviser must be in attendance at all meetings and consultation activities and review minutes of the meetings.

At the end of each meeting the Reference Committee will agree on content for a communique to be published on the Department of Health and Aged Care website. This will be a standing item on each agenda.

In general, any approaches to Reference Committee members from stakeholders should be referred to the Review Secretariat for formal receipt and management. This will support good record keeping, ensuring complete consideration of sources of input to the Committee, as well as to protect the Committee and its members from unnecessary impositions on their time. In certain instances, the Chair of the Reference Committee may authorise or recommend certain instances where Committee members should bilaterally engage with stakeholders.

In addition, Reference Committee members should refrain from accepting any form of entertainment, catering, or in-kind support from stakeholders during the course of the Review.

Probity briefings

A key control in managing the probity risks related to the Review is that all Review Participants must receive a probity briefing from the Probity Adviser to ensure that they are

³ A review protocol sets out the expectations, processes and behaviours for the Review discussions and engagements.

informed of their probity obligations in connection with this Plan. Briefings must be held before a Review Participant's involvement in the Review commences, or at such other times as may be appropriate.

It is an important safeguard for both the Department and Review Participants that individuals are aware of their personal obligations with regard to the Probity Plan. The probity briefing will set out the key probity principles that apply to the Review activities and outline the measures to manage probity risks that may arise, such as with respect to confidentiality, conflicts of interest and demonstrating value for money (in relation to Review-related procurement).

In instances where it is not practical for a Review Participant to attend a probity briefing, the Probity Adviser may inform them of their probity obligations through written briefing material. The Probity Adviser will maintain a record of each Review Participant who receives a probity briefing in connection with the Review.

Probity issues and queries

During any process, it is possible that probity issues will arise. In these circumstances, Review Participants should bring the issue to the attention of the Reference Committee Chair, the Department's team responsible for supporting the Review and/or the Probity Adviser for timely advice and resolution.

The Probity Adviser is available to all Review Participants to discuss any probity issues or concerns in relation to the Review. In the event of probity issues arising, the Probity Adviser will assist in the management of the issue in accordance with the Probity Plan. Dealings with the Probity Adviser on a probity issue are done so on the understanding that any such matter will be treated in confidence.

Probity issues will be documented in the Probity Register, and a record of individuals involved, and actions undertaken to resolve the issue will be reported to the Department team responsible for supporting the Review and the Reference Committee Chair to enable appropriate visibility and action.

Probity breaches

Any breach of the principles or requirements included in this Plan, or any activity that is inconsistent with generally accepted principles of probity, will be considered a "probity breach".

If a probity breach occurs, it is essential that the breach is identified, reported, documented, and investigated. A breach does not necessarily lead to a compromise of

the Review; however, all breaches must be managed according to their risk to the Review.

Where appropriate, reliance is placed on legal advice where enabling legislation exists.

In the event of a breach of probity principles, the Probity Adviser will report this to the Department team responsible for supporting the Review and/or the Reference Committee Chair for resolution.

Records management

Records will be maintained throughout the Review to provide sufficient information to enable independent review, and in a manner consistent with the requirements of the records management policy of the Department and the Archives Act 1983.

Consistent and thorough record keeping is vital in supporting the transparency and accountability of Review outcomes. Review Participants must ensure that their record-keeping of all material evidence, considerations and decisions of the Review, and the reasons for them, is sufficient to provide a clear audit trail and meet accountability expectations.

In this regard, the following are essential:

- all significant phone calls, emails, meetings, and other correspondence related to the Review must be documented with records maintained; and
- all key internal meetings of Review Participants that relate to the Review must be documented with records maintained.

Gifts and hospitality

Gifts and hospitality, including attendance at sponsored industry events, have the potential to give rise to perceptions of conflict. As much as possible, these are to be avoided by the Reference Committee and all staff or consultants supporting the Review for the duration of the Review. If there are legitimate policy requirements for attending such events, this should first be discussed with the Probity Adviser.

Plan review period

This Probity Plan will be reviewed annually, or when changes in circumstances for the Review and its probity risk profile warrant a review or change. A review may be triggered by advice from the Reference Committee, the Department team supporting the Review, or the Probity Adviser.

Following any advice from the Reference Committee or the Department, the Probity Adviser will make suggested changes for consideration by the Reference Committee and the Department.