Rolling review of PBAC Guidelines

Landscape

The Department of Health, Disability and Ageing (the department) and the Pharmaceutical Benefits Advisory Committee (PBAC) have established an ongoing process for maintaining and improving the PBAC (Guidelines), ensuring they remain current, clear and fit-for-purpose, while preserving existing governance and decision-making arrangements.

PBAC has stewardship over the Guidelines, and its ongoing maintenance and improvement are a business-as-usual responsibility of the Committee.

The Guidelines are a substantial and technically detailed document that has historically been updated through periodic reviews. As the volume and complexity of guidance has increased over time, a rolling review process provides a more practical and efficient approach to maintaining the currency, clarity and usability of the Guidelines.

Broader policy, legislative and other substantive reform matters will continue to be considered through appropriate government and HTA reform governance processes.

This approach ensures that complex or contentious issues do not delay improvements that are being progressed through the rolling review process, while maintaining transparency on matters that require longer-term consideration.

More information on HTA improvements that address the HTA Policy and Methods Review can be found at HTA improvements | Australian Government Department of Health, Disability and Ageing.

Any HTA improvements that require changes to the PBAC Guidelines will be coordinated with the rolling review process.

Principles for communication

The following principles will guide the rolling review process:

Principle 1 – The rolling review will focus on continuous improvement of the PBAC Guidelines

The Guidelines are a key source of guidance for sponsors and other stakeholders on the evidence, information and processes that support PBAC consideration of medicines and vaccines.

The rolling review provides an ongoing mechanism to maintain the currency, clarity and usability of the Guidelines. This includes regular review of guideline content, administrative updates, technical clarifications and incorporation of agreed changes that affect the Guidelines.

The rolling review is intended to support continuous improvement of the Guidelines. It is not designed to resolve all issues identified through broader health technology assessment reform processes or stakeholder engagement activities.

How this principle will be demonstrated

The department regularly reviews and prioritises opportunities to improve the Guidelines and will communicate how proposed changes are assessed and progressed through the rolling review process.

Stakeholders will be informed about the scope of the rolling review, the matters being considered and how updates to the Guidelines will be implemented.

Principle 2 – Transparency in issue identification and decision-making

The department is committed to being transparent about:

Issue identification and prioritisation

- how stakeholders can raise issues and suggestions for improvement;
- issues raised through the rolling review process;
- how issues are assessed and prioritised; and
- the status of issues under consideration.

Guideline development and implementation

- how proposed changes are developed and tested;
- opportunities for stakeholder input and consultation;
- how decisions are made; and
- progress in implementing approved changes to the PBAC Guidelines.

How this principle will be demonstrated

The department will provide clear pathways for stakeholders, including the HTA committees, assessment and evaluation groups, industry, consultants, clinicians, consumers and other interested parties, to raise issues and suggestions for improvement.

These may include but are not limited to:

- an online submission form on the PBAC Guidelines webpage,
- correspondence through the PBAC inbox, and
- feedback provided through stakeholder engagement forums[1], workshops, consultation processes and routine meetings with stakeholder representative or reference groups.

Regardless of how an issue is raised, it will be recorded, assessed and managed through a consistent rolling review process.

Progress reports will identify completed updates, updates currently under development and emerging priorities being considered through the rolling review process, demonstrating the continuous maintenance of the Guidelines over time.

To support transparency, the department will communicate progress through:

- PBS news items updates; and
- a dedicated section on the PBAC Guidelines webpage summarising recent updates, current work and upcoming activities; and
- relevant HTA Review webpages, HTA webinars and stakeholder communications streams,

ensuring stakeholders have clear and accessible sources of information on the status of the rolling review.

To further support transparency, issues and guideline changes will be assigned a status that reflects their stage in the rolling review process. This will provide visibility of both issues under consideration and changes being progressed for implementation.

Status	**Meaning**
Identified	Issue raised
Under Review	Being assessed
In Development	Draft solution being developed

[1] HTA improvements | Australian Government Department of Health, Disability and Ageing

Consultation	Stakeholder input occurring, including under consideration by ESC/DUSC/PBAC
Approved	Endorsed by ESC/DUSC/PBAC, ready to be implemented / published
Completed	Implemented and/or published on website/ updated on PBAC Guidelines
Deferred	Not proceeding currently
Referred	Being handled through another process (i.e. part of the Strategic Agreement discussion)

Where appropriate, the PBAC Chair's Communiqué could indicate significant Guidelines matters proposed for consideration at future PBAC meetings, providing stakeholders with greater visibility of emerging priorities and upcoming opportunities for engagement.