Use of Artificial Intelligence in PBAC Submissions

Landscape

The Pharmaceutical Benefits Advisory Committee (PBAC) recognises that artificial intelligence (AI) technologies are being adopted in drug development and clinical research as well as in activities associated with the preparation and assessment of submissions for regulatory and health technology assessment (HTA). Given the widespread adoption of AI this document seeks to establish common principles for their responsible use in HTA processes.

The use of AI must be accompanied by appropriate transparency, accountability, governance and human oversight. These expectations are intended to support confidence in the evidence considered by the PBAC and maintain trust in PBS decision-making processes.

PBAC expectations

The use of AI in the preparation or evaluation of submissions is not prohibited. However, sponsors remain fully responsible for the accuracy, completeness, reliability and integrity of all information provided to the PBAC, regardless of whether AI has been used in its preparation.

The safe and responsible use of AI in the PBAC process is a shared responsibility involving sponsors, evaluators, and the Secretariat. AI should support and enhance expert judgement and should not replace scientific assessment, critical appraisal, independent evaluation or decision-making.

Sponsors and evaluator groups using AI should have an appropriate understanding of the capabilities, limitations and risks of AI tools and remain responsible for reviewing and validating all AI generated outputs prior to their use in submissions or evaluations. Given that AI generated outputs may contain errors, omissions, biases or unsupported conclusions, appropriate human review and quality assurance should be applied. AI generated outputs do not constitute evidence in themselves and do not replace the evidentiary requirements of a PBAC submission.

Sponsors should ensure that AI content remains traceable to the underlying evidence, data and analyses on which it is based. Sponsors should clearly distinguish AI-generated content from primary evidence sources, including clinical study reports, trial datasets and other evidence, so that the origin of information remains transparent and independently verifiable.

The Secretariat and evaluators may use approved AI tools to support administrative, information-management and analytical support activities associated with the assessment of submissions. This may include document review, information extraction, summarisation, drafting support and quality assurance activities. Such tools are intended to support efficiency and consistency and do not replace expert assessment or decision-making.

Any use of AI by the Secretariat and evaluators will be undertaken in accordance with applicable privacy, information security and confidentiality requirements governing PBAC submissions. More information is published on the Department of Health, Disability and Ageing website[1].

Evaluators remain responsible for the accuracy, appropriateness and verification of any AI assisted commentary prepared as part of an evaluation. All evaluation findings, recommendations and advice provided to the PBAC remain subject to human review, expert judgement and accountability.

AI is not used to make explicit recommendations to the PBAC, determine PBAC advice, or replace committee deliberations and decision making.

[1] Artificial intelligence (AI) in health care - https://www.health.gov.au/topics/health-technologies-and-digital-health/what-we-do/artificial-intelligence-ai-in-health-care

Disclosure of AI use

Sponsors, evaluators and the Secretariat are expected to disclose any material use[2] of AI in the preparation of a submission. This disclosure should include:

- the AI tool or platform used;
- the purpose for which AI was used;
- the component(s) of the submission affected; and
- the processes undertaken to review and validate AI-generated outputs.

The disclosure may be provided in the submission main body or another clearly identifiable section of the submission.

Privacy, confidentiality and governance

Sponsors and evaluators are responsible for ensuring that the use of AI complies with applicable privacy, confidentiality, contractual and legislative obligations. The use of AI should not compromise the protection of confidential, commercially sensitive or personal information contained within submissions.

Future development

As AI technologies continue to evolve, the PBAC may periodically review and update these expectations to reflect emerging evidence, best practice and compliance with Australian Government policy.

Further information

The PBAC encourages sponsors, evaluators and the Secretariat to remain informed of evolving guidance on the responsible use of AI in research and scientific publishing, including guidance published by scientific journals, academic organisations and research institutions[3].

[2] Material use generally refers to circumstances where AI has contributed substantively to the generation, synthesis, interpretation, analysis or drafting of content included in a submission. Routine administrative functions, such as spelling or grammar assistance, would not ordinarily require disclosure.

[3] One recent example being Flanagin A, Perlis RH, Bibbins-Domingo K. Updated Guidance for Author Use of AI in Medical Publication. *JAMA. 2026;336(11):926-928*