Australian Government
Department of Health and Aged Care

Health Technology Assessment Policy and Methods Review: Frequently Asked Questions

What is HTA?

Health Technology Assessment (HTA) involves a range of processes to assess the quality, safety, efficacy, effectiveness, and cost effectiveness of health technologies. These processes are used to support Government decisions about health technologies.

Why do we do HTAs?

The purpose of HTA is to provide policymakers, funders, health professionals and health consumers with the necessary information to understand the benefits and risks of health technologies and procedures and how different health technologies compare with one another. This information is then used to inform policy, funding and clinical decisions, and assist with consumer decision-making.

What decisions are HTAs used for?

Market authorisation

Market authorisation is the approval (and listing on the Australian Register of Therapeutic Goods – ARTG) that health technology companies need to sell and supply goods, such as medicines and medical devices, in Australia.

Government subsidy

HTA is used to inform decisions about what health technologies should be subsidised or reimbursed under Australia's health subsidy and funding schemes. HTA is also used to determine under what circumstances a health technology should be subsidised and at what cost to the tax payer.

Who undertakes HTAs?

In Australia, several advisory and regulatory bodies use or undertake HTAs when they prepare advice to government.

Market authorisation

The Therapeutic Goods Administration (TGA; part of the Department of Health and Aged Care) is responsible for market authorisations. It evaluates, assesses and monitors all therapeutic goods.

HTA for Australian Government subsidy.

Two principal health technology advisory committees assess health technologies for Australian Government subsidy:

- Medical Services Advisory Committee (MSAC)
- Pharmaceutical Benefits Advisory Committee (PBAC)

What is the difference between HTA for market authorisation and HTA for government subsidy?

HTA for market authorisation helps decision makers consider whether a health technology should be allowed to be sold or supplied in Australia.

It provides information that helps decision makers understand whether health technologies:

- are safe
- perform as intended
- meet appropriate standards for use in Australia.

HTA for government subsidy helps decision makers consider whether a health technology should be subsidised. It provides information that helps decision makers understand how effective and safe a health technology would be compared

with any alternative health technologies available to patients.

This information helps decision makers understand whether Australians would be better served by a health technology over available alternatives and whether any additional cost for the health technology is worth paying for.

What information is considered in a HTA?

The information considered depends on the decision the HTA is to be used for.

HTA for market authorisation considers evidence about a health technology's:

- clinical effectiveness – does the health technology work as it claims to?
- safety – is it safe to use?
- quality – is it manufactured to acceptable standards?

HTA for government subsidy considers evidence about a health technology's:

- clinical effectiveness and safety compared to alternative technologies – is the health technology more effective or safer than any available alternative health technologies used to treat the same condition?
- costs – how much will it cost the tax payer?
- economic impacts – is it good value for money?
- other information – what are the relevant clinical needs, or social or ethical issues?

What types of health technology do we assess for government subsidy?

We use HTAs to assess:

- pharmaceuticals (including vaccines)
- diagnostic tests
- medical devices
- surgically implanted prostheses
- medical procedures
- public health interventions.

How does the government subsidise or fund access to health technologies?

The government provides funding to support access to health technologies through a number of programs and subsidy schemes. These include:

- Pharmaceutical Benefits Scheme
- Life Saving Drugs Program
- Medicare Benefits Schedule
- National Immunisation Program
- Private Health Insurance Rebate

What is the HTA Policy and Methods Review and why is it important?

The HTA Policy and Methods Review (HTA Review) is a commitment under the 2022-27 Strategic Agreement between the Commonwealth and Medicines Australia. Under the Strategic Agreement, the Commonwealth has committed to supporting and resourcing the HTA Review. The HTA Review is an opportunity to consider reforms to ensure Australia's HTA policy and methods are continuously evaluated and improved.

Who is reviewing?

The HTA Review is being overseen by a Reference Committee. The Reference Committee comprises the following members.

- Independent Chair: Adjunct Professor Debora Picone AO
- Patient Representatives: Ms Ann Single and Dr Dawn Casey PSM
- Chair of the Pharmaceutical Benefits Advisory Committee: Professor Andrew Wilson
- Clinical/Scientific Representative: Professor Andrew Roberts AM
- Industry Representative: Ms Elizabeth de Somer
- Government Nominee: Ms Adriana Platona PSM

What is being reviewed?

The HTA Review will not consider HTA policy and methods for all health products and services.

The HTA Review will consider HTA policy and methods for:

- medicines and vaccines
- highly specialised therapies (such as cell and gene therapies)
- other health technologies that are linked to use of medicines vaccines and highly specialised therapies (such as pathology tests)
- foreseeable changes in health care that may influence the need, accessibility, effectiveness or cost-effectiveness of new health technologies.

The full scope of the HTA Review is set out in the terms of reference which can be accessed via the HTA Review website.

What are the goals of the HTA Review?

The HTA Review will examine HTA policy and methods to identify features that:

- are working effectively
- may act as current or future barriers to earliest possible access
- may act as current or future barriers to equitable access
- detract from person-centredness
- may be creating perverse incentives.

The HTA Review will consider reforms that address identified challenges and present a comprehensive set of recommendations for reforms to Government that:

1. are implementable and sustainable for both health funders (Commonwealth, state, and territory) and the health technology industry
2. deliver Australians equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines for all Australians
3. adopt a person-centred approach in HTA
4. deliver the outcomes sought by recommendations from the Standing Committee on Health, Aged Care and Sport Inquiry into approval processes for new drugs and novel medical technologies in Australia that are agreed in principle in the Government Response
5. further the objectives of the new NMP
6. ensure HTA policy and methods are well adapted to and capable of assessing new technologies that are emerging or are expected to emerge in the coming years and
7. do not compromise assessment of patient safety, effectiveness and cost, or advice to Government on subsidy of health technologies.

How can I participate in the HTA Review?

There will be several opportunities for people and organisations interested in the HTA Review to participate. Please visit the HTA Review web page for detailed information about consultations and subscribe to PBS News so that you are notified of any updates on the HTA Review's progress.