INDEPENDENT REVIEW OF HEALTH TECHNOLOGY ASSESSMENT

This paper outlines ideal outcomes from the independent Health Technology Assessment (iHTA) Review to meet the mutual intention and expectations of the Agreement, followed by proposed Terms of Reference which will enable those outcomes.

iHTA Review – Ideal Outcomes

In view of Australia's ambition to be a world leader in providing healthcare, the HTA Review should address the goals and issues outlined in the Strategic Agreement to achieve the following:

1. Place **patients and the community** at the centre of Australia's reimbursement system, so that the real impact and benefits of new medicines, biotherapeutics and vaccines are explicitly taken into account in reimbursement decisions.
2. With reference to the above, seek out and include the views of **more disadvantaged groups** and those who are heavy users of healthcare, such as Aboriginal and Torres Strait Islander peoples, people from culturally and linguistically diverse backgrounds, those with disabilities and those in regional and remote areas.
3. Broaden the criteria for **valuing medicines**, to systematically include the full range of benefits to health, society and the economy.
4. Redesign the reimbursement system to **reduce time to access** for Australian patients so that they can access new health technologies as soon as they are registered by the Therapeutic Goods Administration.
5. Create additional pathways for the reimbursement of emerging technologies such as **cell and gene therapies**, and for **rare diseases** and small patient populations.
6. Ensure HTA is used to evaluate cost-effectiveness only and that budget **decisions are made separately**.
7. Create a **reporting framework** to ensure that the objectives of the HTA Review are achieved via the creation of legislated metrics.

Medicines Australia's Draft Proposed Terms of Reference

Preamble

The Commonwealth of Australia and Medicines Australia entered into a Strategic Agreement on 6 September 2021 (the Agreement). The Agreement contains a commitment that the Commonwealth support a Health Technology Assessment Policy and Methods Review (the HTA Review).

Australia aims to be a world leader in providing healthcare, with patients at the centre of the health system, including more disadvantaged groups and those who are heavy users of healthcare, such as Aboriginal and Torres Strait Islander peoples, people from culturally and linguistically diverse backgrounds, those with disabilities and those in regional and remote areas.

As outlined in the Agreement, the Commonwealth has a shared commitment with Medicines Australia to reduce time to access for Australian patients so that they can access new health technologies as early as possible; and maintain the attractiveness of Australia as a first launch country to build Australia's status as a world leader in providing patients access to affordable healthcare by ensuring that our assessment processes keep pace with rapid advances in health technology, and that barriers to access are minimised.

Scope

The Commonwealth processes in scope for the HTA Review are:

- The expertise, role, remit, functions and methods applied by the Pharmaceutical Benefits Advisory Committee (PBAC), the Medical Services Advisory Committee (MSAC) and the Life Saving Drugs Expert Panel in relation to the assessment of health technology for medicines, vaccines, blood products, cell and gene therapies, and co-dependent technologies in the context of Australian Government subsidy programs.
- The processes which surround the abovementioned HTA bodies including, but not limited to, the capabilities and resourcing within the Department of Health, the role of the Department of Health in pricing negotiations and funding approval (the role of Treasury, Department of Finance and Cabinet).

Terms of Reference

The HTA Review Committee will examine the following matters, and consider them against potential alternative approaches, including international best practice:

1. Examine the feasibility of reforms to ensure patients have subsidised access immediately upon registration, including the reporting of access measures.
2. Identify the best mechanisms for explicit recognition of patient and community interests and benefits in reimbursement decisions, including the outcomes of the decisions.
3. Examine the limitations of current HTA evaluation approaches by the HTA bodies, and identify policy, legislative or guideline improvements that will introduce efficiencies and speed up time to access for existing health technologies in Australia, involving specific consideration of:
    a. selection of comparators
    b. use of real world evidence for evaluation including use of evidence from sources other than randomised controlled trials
    c. managing clinical, economic, financial and other uncertainty.
    d. the feasibility of international work sharing for reimbursement submissions
    e. how the current evaluation approach can be broadened to consistently enable full societal impact
4. Consider the additional challenges to subsidised access for rare diseases and new and emerging health technologies, including but not limited to small data sets, high costs and small patient

populations. Make recommendations on how to address these barriers, including the appropriateness of the existing HTA and funding mechanisms.

5. Make any other recommendations, having regard to the expert report, the public consultation process and other relevant reviews, on improvements that can be made to the HTA process in Australia.

Reporting Timeframe

The final recommendations of the Reference Committee will be provided to the PBAC (and its Technical Subcommittee) and the Commonwealth by June 2023, with implementation of findings from the review by July 2024 subject to Government approval.

Definitions

Existing health technologies: innovative medicines (F1), combination therapies, new presentations, blood products, screening tests, co-dependent technologies and vaccines.

Expert report obtained by the Department of Health which provides an analysis of current methods used by the PBAC (and, where requested, other HTA Committees such as MSAC), contemporary research and relevant methodologies (including broader economic policies and methodologies use to make funding decisions beyond HTA) and purchasing practices used by comparable international jurisdictions such as the United Kingdom.

HTA: HTAs for subsidy purposes analyse evidence of the benefits, harms and costs of a health technology to determine its value. Value involves:

- clinical effectiveness – does the health technology work?
- safety – is it safe to use?
- community benefit – what is the benefit in both social and economic terms?
- costs – how much will it cost to use?
- economic implications – is it good value for money?
- other information – what are the relevant clinical needs, or social or ethical issues?

HTA Bodies means the Pharmaceutical Benefits Advisory Committee (PBAC), the Medical Services Advisory Committee (MSAC) and the Life Saving Drugs Expert Panel.

New and emerging health technologies: orphan drug indications, rare diseases, cell and gene therapies and precision therapies.

Other relevant reviews include the Inquiry into approval processes for new drugs and novel medical technologies in Australia and the Review into Efficient Funding of Chemotherapy.