Australian Government
Department of Health and Aged Care

Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 24 July 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 24 July 2023.

Representatives of Medicines Australia, the pharmaceutical industry, Adelaide Health Technology Assessment (AHTA), the Department of Health and Aged Care (Department), and the Chair of the Medical Services Advisory Committee (MSAC) were invited to speak with the Committee in deep dive sessions and discussions regarding draft papers, as outlined below. Support staff from the Review Secretariat in the Department also attended.

What did the Committee discuss?

Deep Dive with Cell and Gene Industry Representatives

The Committee discussed with several pharmaceutical industry representatives, including members and non-members of Medicines Australia. Staff from Medicines Australia and Departmental officials who engage with Highly Specialised Therapies, including cell and gene therapies, were also present.

The Committee heard industry perspectives on various issues and potential opportunities relating to the HTA and subsidy of cell and gene therapies, including exploring matters raised through submissions to Consultation 1 of the Review, including those presented in the Medicines Australia submission. Industry representatives conveyed that the current funding and HTA pathways for cell and gene therapies lacked clarity and certainty for their industry and indicated their preference for a more streamlined pathway.

Issues around equity of access for Highly Specialised Therapies, delivered in public hospitals and jointly funded by the Commonwealth and State and Territory governments, were discussed. The Committee heard that following an MSAC recommendation, companies are required to negotiate with each State and Territory government separately to agree on supply arrangements for the Highly Specialised Therapy, contributing to differences in the timing of implementation and availability of these therapies across jurisdictions. Industry representatives emphasised the need to standardise the delivery of these therapies, noting that a limited number of centres across Australia are certified for delivery, with each State and Territory having a different, sometimes lengthy certification process.

The Committee thanked the representatives for the time and effort taken to discuss these issues and said that it would welcome further consultation once draft options for reform have been developed for Consultation 2.

Update on Papers from Adelaide Health Technology Assessment

Three expert academic groups, including AHTA, have been contracted to undertake research and analysis of contemporary research and HTA methodologies to support the deliberations of the Review.

Research leads from AHTA provided the Committee with an update on the progress of the papers under development and a high-level overview of initial findings. The leads informed the Committee that the *International health technology market approval, funding and assessment* paper and the *HTA Methods: Clinical evaluation* paper were partly drafted given the broad range of topics to be covered under these papers. The leads informed the Committee that greater progress had been made on the *HTA Methods: Determination of Population Intervention Comparator Outcome (PICO)* paper and the *Early identification of emerging technologies (horizon scanning) and early value assessment* paper. The Committee noted that AHTA has obtained information from international HTA networks, international HTA agencies, industry and various subject experts in addition to peer-reviewed literature.

The leads informed the Committee that AHTA's initial research for the *International health technology market approval, funding and assessment* paper has found that in most countries that provide reporting, HTA to inform reimbursement of medicines is done reactively, meaning that the assessment takes place after a submission has been received. Furthermore, the assessment of HTA is typically carried out internally within government or conducted by national independent agencies with a relationship to the government. The Committee heard that the timeline to funding decision from submission is comparable across all countries studied, however, time taken for patients to have funded access to medicines varies considerably, with many countries reporting that they have no fixed timeline for patient access. Germany and France are exceptions with funding from market access. Four countries (including Australia) permit parallel submissions for HTA assessment and market authorisation, to allow faster access to medicine. The Committee reflected on the impact of resubmissions to the Pharmaceutical Benefits Advisory Committee (PBAC) on the Australian timeline, including recently implemented re-entry processes, reasons for resubmissions, which medicines are more likely to be subject to multiple submissions and the need to have transparency about the causes to guide the development of potential options for improvement.

It was also noted that equity was an important consideration across many jurisdictions and stakeholder engagement was widespread across HTA processes. The Committee also heard initial findings regarding the existence of alternative pathways used in some jurisdictions.

The leads informed the Committee that AHTA's initial research into horizon scanning has found that a small number of HTA agencies undertake it, and several horizon scanning collaborations across jurisdictions. The leads also noted that horizon scanning is mostly used for planning and preparedness, especially relating to new innovative technologies. The leads provided an overview of the Early Value Assessment process recently initiated in the UK. The Committee requested that AHTA also look into horizon scanning methods used by patient organisations and the benefits of early scientific advice.

The leads informed the Committee that for the PICO paper, AHTA's early research has found some agencies have a separate scoping phase to determine the PICO criteria. The Committee also noted that the role of PICO criteria in jurisdictions where funding is provided

before full evaluation differs from traditional HTA, as it may inform the development of primary evidence as well as what secondary evidence should be collated. Also, in some jurisdictions, input is incorporated from patients, which may help determine relevant outcomes and from clinical experts, which may help determine the relevant comparators.

The Committee heard an overview from the AHTA paper leads on their initial research into Clinical Evaluation Methods in HTA, including methods used in other countries that differ from typical methods used for randomised controlled trials. The Committee heard about some of the nuances of the reporting of different international methodologies that create challenges for the synthesis of the information.

Deep Dive on Medical Services Advisory Committee Processes and Methods

The Committee had a discussion with the Chair of MSAC, Professor Robyn Ward, regarding MSAC processes including synergies and differences with PBAC processes and opportunities and challenges. Representatives from the Department's MSAC support team were also present for the discussion. The Committee heard about the evolution of MSAC processes over recent years, including greater alignment with PBAC processes, changes to streamline codependent submissions, and establishing the Highly Specialised Therapies pathway. The Committee noted that many of the submissions MSAC now receives are for programs (for example, newborn bloodspot screening) that require a national implementation approach rather than medical services which can be implemented as a single Medicare Benefits Schedule (MBS) item. The Committee also noted that the implementation of positive MSAC decisions is often complex due to the involvement of multiple disparate providers and payers with differing needs and expectations. The Committee heard about the broad membership and expertise of MSAC that enables it to assess a range of health technologies. The Committee noted that the main reason MSAC recommendations often take longer to implement is due to the disparate funding programs for which MSAC provides advice, with each having its unique process for implementation. In the case of listing items on the MBS, unlike the PBS, the Minister for Health and Aged Care does not have a funding delegation for listing new MBS items and the Department must then provide advice to the Minister on MSAC deliberations and seek authority to put forward the new policy proposals through Budget processes which can impact time to access. The Committee agreed that it would need to consider potential options for reform relating to the discussion at a subsequent meeting.