



Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 14 August 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 14 August 2023.

Representatives of from the Centre for Health Economics Research and Evaluation (CHERE) and Adelaide Health Technology Assessment (AHTA) gave presentations. Support staff from the Review Secretariat in the Department of Health and Aged Care (Department) attended.

What did the Committee discuss?

Update on action items from previous meeting

The Committee heard that most of the Consultation 1 submissions have now been published on the Office of Health Technology Assessment Consultation Hub. The Committee noted that the Secretariat is continuing to work with some stakeholders on their publishing preferences in relation to anonymity.

Paper on Funding and purchasing decisions and Managing Uncertainty by CHERE (interim update continued)

Research leads from CHERE continued their interim update from the previous meeting on the progress of their paper on funding and purchasing decisions and managing uncertainty, which included a summary of their interim findings.

The Committee noted that the paper will cover approaches to funding and purchasing new health technologies, including associated pricing and price negotiation processes and strategies for health technologies that provide (or do not provide) a substantial improvement in efficacy or reduction in toxicity compared to alternatives, are for rare diseases and small populations where there is high unmet clinical need, may address equity concerns, are codependent technologies and that have limited evidence of long-term outcomes. The Committee noted that Australia is aligned with the majority of comparative jurisdictions in listing treatments after a price is negotiated.

The Committee heard CHERE's preliminary findings on equity concerns, including that prominent areas of focus in the literature include rare diseases, children, and First Nations people. The Committee heard that internationally, there are diverse processes aimed at ensuring access to drugs for rare diseases, including various funding and purchasing approaches. The different approaches noted included funding sources specifically allocated to funding treatments for rare diseases, alternative HTA pathways and processes, and pricing mechanisms. The Committee spoke about the need for the paper to include evidence specific to First Nations people and heard that, in many cases, there is a void of relevant

literature. The Committee and CHERE engaged in a discussion of options to address this literature gap and agreed to expand on this area in the paper.

The Committee heard an overview of CHERE's interim findings on HTA processes for codependent technologies. The Committee noted that having a single submission for codependent technologies and two advisory committees to consider codependent technologies, appears to be unique to Australia. The Committee discussed that there is different terminology for this type of process internationally including some companies referring to the term 'companion' rather than codependent and provided guidance to CHERE on terminology that may assist to broaden their literature findings.

The Committee discussed CHERE's interim findings on various approaches for managing risk and uncertainty internationally and in Australia and advised CHERE of areas to focus further research on. The Committee noted that financial managed entry agreements which are characterised by confidential discounts or rebates, population level price-volume agreements and cost-sharing or capping agreements are more commonly used across jurisdictions than performance managed entry agreements which are characterised by coverage with evidence development. The Committee noted that the availability of data from registries has been crucial to informing performance managed entry agreements in a number of jurisdictions. The Committee spoke to additional information it would like to see incorporated into the paper including further context around the health systems in other jurisdictions and how these differ to the Australian health system. The Committee requested CHERE liaise with the international HTA bodies to ensure currency of the information; CHERE indicated this may not be possible for all countries in the current timeline, the Committee noted the timing pressures for the papers.

Presentation by AHTA on HTA Methods: Determination of Population Intervention Comparator Outcome (PICO)

Research leads from AHTA provided the Committee with a briefing on the early draft of their paper on determination of Population, Intervention, Comparator, Outcome (PICO). The briefing included an overview of the scoping review approach AHTA used to examine the available information on the paper topic. The Committee heard about processes used to determine PICO for different health technologies in Australia as well as the processes used to determine PICO in comparable international jurisdictions. The Committee noted that applications for consideration by the Medical Services Advisory Committee (MSAC) have a separate process for determining the PICO criteria whereas there is no formal confirmation process for the PICO criteria to be used in most medicine submissions considered by the Pharmaceutical Benefits Advisory Committee. The Committee heard that the proposed PICO confirmation for applications considered by MSAC may be put forward for public consultation and/or targeted consultation with key stakeholders. The Committee heard that across international jurisdictions, the PICO is developed mostly by sponsors and input from health care professionals is commonly sought. The Committee heard that the amount of guidance from HTA agencies on equity considerations varies across jurisdictions and noted that the Institute for Clinical and Economic Review in the US has extensive guidance on improving equity within HTA methods. Research leads from AHTA provided an overview of their findings on the selection of the comparator across jurisdictions including that comparators are consistently based on the standard of care in clinical practice (i.e. the treatment most likely to be replaced), though there are nuances with how this is applied in practice across jurisdictions (for e.g. some jurisdictions are also explicit that the comparator should be a

treatment which is already reimbursed). The Committee heard that with respect to determining the outcome of interest, all jurisdictions studied were consistent in requesting morbidity, mortality, and quality of life. However, the Committee heard that evidence required to validate surrogate outcomes was varied considerably across jurisdictions.

The Committee heard about recent international reforms to HTA processes which have implications for the determination of the PICO criteria to varying degrees. For example, a recent change in Canada has resulted in sponsors preparing their own submissions where previously the Canadian Agency for Drugs and Technologies in Health would conduct a systematic review as part of the appraisal for new medicines, this has placed the responsibility of developing and justifying the PICO criteria onto sponsors.