

Medical Services Advisory Committee (MSAC)

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The Hon Mark Butler MP
Minister for Health and Aged Care
PO Box 6022
House of Representatives
Parliament House
Canberra ACT 2600

Dear Minister

Health Technology Assessment Policy and Methods Review Final Report

Thank you for your letter of 8 July 2024 providing an early opportunity for the Medical Services Advisory Committee (MSAC) to consider the final report of the Health Technology Assessment (HTA) Policy and Methods Review and provide its initial high-level reflections on the recommendations.

The MSAC acknowledges that completion of the Review was the result of substantial effort invested by the Review Reference Committee, Department, academic researchers as well as extensive engagement across a diverse range of stakeholders.

The MSAC notes that the final report of the Review primarily focused on assessment and funding of medicines, given it arose from a key commitment in the 2022-27 Strategic Agreement between the Commonwealth and Medicines Australia. Notwithstanding this focus on medicines, the MSAC appreciates that several of the recommendations are likely to directly or indirectly impact assessment and subsidy of health services listed on the Medicare Benefits Schedule (MBS) and other health technologies considered by the MSAC such as products funded through the National Health Reform Agreement and National Blood Arrangements.

The MSAC will therefore be keen to engage in the process of implementing reforms and provide a more comprehensive response to the recommendations at the appropriate time. Given the potential impact of the Review recommendations on the assessment and funding of non-medicine health technologies (such as gene modified cell therapies, pathology diagnostics and devices), the MSAC considers it would also be important to engage with industry and health professionals beyond the pharmaceutical sector, during the process of implementing reforms.

Reflections on the Review's findings

The MSAC welcomes the Review. It is timely given the current era of accelerated development and marketing of health technologies. It is clear from the Review's findings that Australia has a world class HTA and health technology funding system but that improvements are needed to ensure Australians have timely and equitable access to health technologies into the future. The MSAC supports the Review's objectives of addressing inequity, improving timeliness, improving engagement with people impacted by HTAs, and investing in data infrastructure and in HTA capability.

As is set out in this letter, the MSAC supports several of the Review's recommendations and advises a more careful approach for others. The MSAC supports recommendations to ensure that HTA is person-centred and to elevate the consumer voice through broader and more meaningful inclusion in the HTA process. It also supports recommendations that are in favour of a clearer pathway for the assessment of highly specialised therapies, and developing national health data infrastructure to monitor the performance of new health technologies.

The MSAC would also like to take this opportunity to highlight positive outcomes from changes it has implemented in recent years that the Review recommends for the PBAC. The MSAC has implemented plain language summaries of committee outcomes and guidance around qualitative elements which are considered by the HTA advisory committee in decision-making. The MSAC also established an early and transparent explicit population, intervention, comparator and outcomes (PICO) confirmation process overseen by MSAC's PICO Advisory Sub-committee. These reforms have provided greater transparency for stakeholders and improved their understanding and engagement in the HTA process. They have also helped to ensure that patients who could benefit from health technologies are identified and that access is not restricted to overly narrow clinical populations.

Engagement and representation from First Nations people

The MSAC acknowledges the gap in health outcomes between First Nations people and non-Indigenous Australians. It recognises that challenges obtaining equitable access to healthcare contributes to this disparity. The MSAC strongly supports recommendations from the Review aimed at reducing health inequity and improving engagement of First Nations people and their voice into the HTA system.

A unified approach to HTA

The MSAC supports a unified approach to HTA that maintains the expertise required to assess the full range of health technologies and services considered by both PBAC and MSAC. Indeed, the HTA methods used by these two HTA advisory committees already have much in common. The MSAC acknowledges that more could be done to reduce timeframes for assessment and funding of co-dependent technologies and note that it has already implemented initiatives to streamline the development of MBS items for co-dependent tests to alleviate the growing burden on the HTA system.

However, as you are aware, the MSAC has a broad role, providing advice to you and the Department on matters related to the funding of a range of health technologies including highly specialised therapies (such as cell and gene therapies), medical services listed on the MBS, implantable medical devices on the Prescribed List, blood products, and health programs. The broad range of health technologies that the MSAC appraises necessitates that its membership comprises a broad set of expertise, as different approaches and types of evidence are involved depending on the health technology being assessed. The MSAC believes that maintaining its current expertise is crucial, and an important consideration if the Government decides to proceed with reforms to create a unified approach to HTA.

Accelerating access

The MSAC notes the Review found patient and clinician expectations for access to new health technologies are increasing. The MSAC notes the pace at which new health technologies are entering the market means there is now more uncertainty about how effective, safe, and cost-effective new health technologies are compared to the existing standard of care. The MSAC considers that timely access to health technologies is important, but achieving this should not be at the expense of robust assessment and equitable access. The MSAC emphasises that

careful consideration will be required to balance meeting expectations and reducing important risks associated with early access to health technologies with uncertain benefits and harms. The MSAC is of the view that any reforms to support accelerated access should be balanced by reforms that facilitate disinvestment in technologies which do not live up to their promise. Post-HTA data collection will be integral to achieving these twin aims of accelerated access and timely disinvestment, when warranted.

The MSAC supports recommendations to streamline funding of health technologies and address issues that delay implementation. The MSAC notes that Australia assesses health technologies quickly by global standards but that delays occur when applications are not adequately justified and require resubmission or where extended negotiations are required between suppliers, payers and service deliverers. The MSAC supports the HTA Review recommendations in their aim to reduce the extent to which these issues contribute to the time it takes to fund health technologies, and increase transparency around timeframes.

Data collection to meet HTA needs

The number of health technologies being approved that are claimed to have life-long benefits but supported by short term trial data is increasing the need for post-HTA data collection. Such arrangements need to be set up carefully so that data collected is sufficiently robust and fit-for-purpose to support decision making. To date, privately funded arrangements to measure the performance of certain health technologies supported by MSAC have not been adequate to address uncertainty about clinical outcomes in the original applications for funding.

The MSAC therefore considers that post-HTA data collection infrastructure should be Government funded so that it can be standardised, nationally harmonised, integrated with existing clinical workflows, accessible to relevant parties and scheduled for future review to assess utility. Establishing such infrastructure will be essential should the government proceed with reforms to facilitate earlier access to health technologies that promise high added therapeutic value, so that their performance can be reliably assessed after they are funded.

Horizon scanning

The MSAC is supportive of the recommendation to establish a horizon scanning function to enable those involved in the delivery of healthcare to be better informed about the benefits, risks and operational implications of new health technologies. The MSAC considers that if Government proceeds with reforms to establish a horizon scanning function in Australia, it should be led by the Department and engage impacted groups including consumers, clinicians, state and territory governments, and industry. There may also be benefit in engaging with international HTA partners to explore information exchange and work-sharing opportunities, noting that many comparable healthcare systems have similar horizon scanning needs.

Evidentiary standards in HTA

The MSAC notes that several recommendations in the final report aim to develop and clarify guidance on assessment methods used in HTAs for decision-making. The MSAC believes it is important for evidentiary standards in HTA to be maintained. The MSAC considers that strong evidentiary standards that are consistent with international practice play a crucial role in the rigour of Australia's HTA system, which is a key factor in its overall success. HTA advisory committees and decision-makers can only be as confident in the safety, effectiveness and cost-effectiveness of health technologies, as the evidence allows.

The MSAC recognises that it is not always possible for the most robust types of studies, such as randomised controlled trials, to be conducted for certain health technologies. As is set out in

its current guidelines, the MSAC accepts other study designs where randomised controlled trials are not available or sufficient, as well as evidence informed by consumer engagement. The MSAC notes that the information it has received from the public has also been informative to its considerations of certain health technologies.

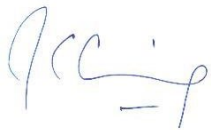
However, it is important that HTA advisory committees maintain their preference for the best possible study designs. The MSAC already sees applications where the level of evidence is too low to provide any confidence about how well health technologies might perform. It is important that standards are maintained so that sponsors are incentivised to undertake and present studies that allow HTA advisory committees and decision-makers to be confident that funding them will improve health outcomes for patients and the wellbeing of the community.

Progressing reforms

The MSAC appreciates that progressing reforms from this Review will be a substantial undertaking, and that reforms will take a significant amount of time and effort to design, consult on and implement. The MSAC is strongly of the view that additional Departmental resourcing would be critical to complete this work effectively noting that existing resources are already stretched by the existing HTA workload.

The MSAC appreciates the HTA Policy and Methods Review as part of the Government's reform agenda to help ensure new medicines and technologies are approved and subsidised safely and effectively. The MSAC would like to thank you again for this early opportunity to provide feedback on the report. The MSAC hopes this will assist you and the Australian Government to respond to the Review's recommendations.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Jonathan Craig', with a stylized flourish at the end.

Professor Jonathan Craig
Chair
Medical Services Advisory Committee
October 2024