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AMA Submission to Health Technology Assessment Policy and Methods Review – Consultation 1

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The AMA supports the aims and the purpose of the Health Technology Assessment Policy and Methods Review (the Review). The AMA actively contributed to the review of the National Medicines Policy (NMP) and was generally supportive of the final product.[1] It is important that the Review aligns with the aims of the NMP which are to ensure:

- Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians.
- Medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care.
- Support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research, and the successful development of medicines and medicines-related services in Australia.[2]

While the AMA is not involved in any stages of the review process, the outcomes of HTA reviews – the listings of medicines on the PBS and addition of MBS items that accompany the use of therapeutics and devices – are central to the tasks of medical practitioners. The AMA supports safe and affordable access to essential treatments. As such, the outcomes of this review are important for the AMA.

As this is the first consultation we offer principals which we feel strongly the Review must focus on. Specifically, Australia's HTA process must:

- Allow medical practitioners to feel confident in the safety, efficacy and accessibility when prescribing of medicines and therapeutic treatments for any patient
- Provide, within reason, for industry to support Australian specialists in their use of specific therapeutics
- Ensure that patients do not face excessive out of pocket costs for essential and lifesaving therapeutics.

[1] AMA (2022) AMA submission to the National Medicines Policy Consultation.
[2] Department of Health and Aged Care (2022) National Medicines Policy

Components of the HTA process we support

The AMA strongly supports the involvement of medical practitioners in the decision-making processes of HTA. Both the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) have good clinical representation. The following paragraphs from the AMA Position Statement on Doctors' Role in Stewardship of Healthcare Resources 2023 outline why this is important:

> 4.6.3 A role in clinical stewardship of healthcare financing is required to ensure the perspective of doctors is put forward and taken into account in decisions about the performance of current healthcare arrangements and services, proposed changes to existing financing of healthcare services or implementation of new healthcare services or arrangements. Without the clinical stewardship perspective, there is a significant risk that decisions will be driven primarily by government, financing and political perspectives.
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> 4.6.4 Major decisions affecting healthcare taken without clinical involvement may lead to inappropriate resource allocation or incentives. Doctors can provide a practical and informed perspective of clinical practice to healthcare financing and funding decisions. This includes advising on the distinction between high-value care and low value care (including whether interventions are evidence-based) and what such decisions will mean for clinical care in practice.[3]

The AMA has observed both PBAC and MSAC meet these standards, operating as high-functioning committees that provide expert independent advice to the Minister. The AMA strongly supports the ongoing roles of these committees in the HTA process, with improvements to the processes to be made around the composition and working arrangements of them.

We understand the review will examine the role of MSAC specifically on co-dependent technologies which we see is an appropriate scope.

Components of the HTA process we have observed could be improved

As AMA members are at the end of the HTA process, the only relevant experiences we can relay to the Reviewers come from our members' experiences in challenges supporting patients to access medicines which have not yet been approved by an HTA process.

A recent example that was raised by AMA members and members of the public was the lack of public funding for Shingrix, the shingles vaccine. While Zostavax was subsidised, Shingrix was not and cost up to $600 per vaccine. Zostavax is contraindicated for immunocompromised people, leaving these patients with no option but to pay significant out of pocket costs for Shingrix. Shingrix had been approved in 2018 for adults over 50, with an update to make it available to all immunocompromised patients over 18 in March 2022. However, it did not receive a PBS listing until the 2023-24 Federal Budget, more than a year after it was clear there was a genuine need for the subsidy and a solid body of evidence to support it.

[3] AMA Position Statement on Doctors' Role in Stewardship of Healthcare Resources 2023

The rigid structures of the current HTA process were a cause for this delay. Once there was a much stronger body of international evidence that demonstrated its efficacy and need for a population group there should have been a process for immediately reviewing and updating for public funding.

The AMA would expect that relevant international HTA processes are reviewed. We note that the Review is aware of efforts to align with international organisations, and we welcome the funding in the 2023-24 budget for the TGA to expand international collaboration and improve alignment with other regulators.

We are aware of positive models that have a much faster time from registration to public subsidies being made available, such as the German model.[4] Under this model immediate reimbursement of pharmaceuticals is provided following regulatory approval. The formal HTA process and pricing negotiations are conducted simultaneously. This allows immediate access for patients while the more detailed economic considerations are worked through. This may be appropriate for some pharmaceuticals in Australia.

General comment

The experience of Covid-19 demonstrates that we can speed up the process while maintaining high safety and quality standards. We note that this was challenging for the TGA and involved more resources than a business as usual approach, but it did identify that efficiencies can be found in the regulatory components. We look forward to further engagement with the Review to advise on the most appropriate options to achieve this.

The AMA notes that there will be two further consultations as part of the Review. We would welcome the opportunity to participate in a deep dive and invite the Reviewers to engage with relevant AMA Committees.

JUNE 2023

[4] OECD (2018) Pharmaceutical Reimbursement and Pricing in Germany.