HTA Review Options Paper feedback

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Thank you for the opportunity to provide feedback on the HTA Review Options Paper. The HTA Review presents a unique opportunity to assess the way that Australia undertakes health technology assessment of medicines.

Goals of the HTA Review

One concern is whether the stated goals in the HTA Review Options Paper agree with the actual shared goals of the Commonwealth Government and Medicines Australia.

On page 51, the Options paper states:

"*The HTA Review is a commitment in the 2022–2027 Strategic Agreement between the Commonwealth and Medicines Australia*.

The commitment was made in recognition of the shared goals between the Commonwealth and Medicines Australia to:

- *reduce the time for Australians to access new health technologies,*
- *ensure Australia remains an attractive country for new health technologies to be launched, and*
- *build on Australia's status as a world leader in providing access to affordable healthcare*."

Unfortunately, the statement of shared goals in the Options Paper do not agree with the actual shared goals of the Commonwealth and Medicines Australia as stated in the Strategic Agreement. That Agreement states on page 10:

"*5. Health Technology Assessment – A policy and methods review*

5.1 The Commonwealth and Medicines Australia:

5.1.1 have the shared goals of:

(a) reducing time to access for Australian patients so that they can access new health technologies as early as possible; and

(b) maintaining the attractiveness of Australia as a first-launch country to build on 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 barriers to access are minimised" .

The point here is that rather than just reducing the time for Australians to wait for health technologies and ensuring Australia is an attractive country for new health technologies, the stated goals of the Commonwealth government (and Medicines Australia) are that Australia be a 'first-launch country'. This is an explicit policy goal of the Commonwealth Government that Australia be amongst the first countries in the world to enjoy the benefits of new medical technologies when they become available. The recent Covid-19 pandemic demonstrated that Australians want Australia to be such a 'first-launch' country that has early access to the latest new medical technologies. Australians want Australia to be 'first in the queue' in accessing such technologies.

Setting aside the fact that most of the available evidence suggests Australia is not, in fact, a first-launch country, the point here is that the goals reflected in the HTA Review Options Paper do not seem to reflect the goals of the Commonwealth Government, as agreed with Medicines Australia. The goals as stated in the Options Paper seem to be a somewhat diluted version of the aspiration compared to what the Commonwealth Government has previously said it wants to achieve. This general approach seems to be reflected in a somewhat cautious approach to several of the HTA issues canvassed in the Options Paper, such as incorporation of social benefits, discount rates, cost-effectiveness thresholds, administrative reform of the system and the like.

This is incongruence in the policy objectives of the HTA Review should be corrected by (1) correctly reflecting and incorporating what the Commonwealth Government's stated goals for the HTA Review are, (2) prioritising a bolder reform agenda that is focussed primarily on ensuring Australia is a 'first-launch' country for new medicines and other medical technologies, and (3) ensuring that any official metrics developed to measure progress on Australia's HTA and medical funding programs include indicators of the time taken for Australia to fund medical technologies compared to when they are first approved internationally and how Australia compares with other high-income, leading countries.

Broader review of scope and funding level for the Pharmaceutical Benefits Scheme

At various points through the Options Paper, the comment made that any relaxation of the current thresholds, constraints and standards in Australia's HTA system could risk leading to an increase in cost of the Pharmaceutical Benefits Scheme. The implication is that any efforts to improve the speed and availability of new medical technologies and make Australia a 'first-launch' country could have budgetary implications that should be managed or avoided.

Unfortunately, this underlying approach in the HTA Review is disappointing for several reasons. On any measure, the PBS is not seeing major relative growth in expenditure commitments seen

in other parts of government spending, such as the National Disability Insurance Scheme, Medicare, the AUKUS nuclear submarine program and so on. Moreover, once the rebates now paid back to government by pharmaceutical companies each year are considered, the PBS is equal to or *lower* as a share of GDP than it was in 2002 when the first Intergenerational Report came out raising concerns about the financial sustainability of the PBS.

The pharmaceutical industry, through bodies like Medicines Australia, has spent the last two decades working with Australian governments to secure the financial sustainability of the PBS. For all the collaboration, negotiation and occasional open arguments between the parties, this has worked. It is worth remembering that one of the major rationales for all this pricing reform over the last 20 years has been precisely to enable reforms and improvements to allow new medicines to be available to Australians quicker than is currently the case.

To now read the HTA Review Options Paper at various points focus on the risk that any changes in HTA settings could even slightly increase the budgetary cost of the PBS is disappointing. This approach is at odds with what the broader policy objective of government PBS reforms have been over the last two decades. It was precisely to provide the fiscal headroom to undertake HTA and policy reforms to the PBS and improve Australians' earlier access to the newest medicines and therapies that all of the cost-cutting and hard-worn reforms over the last two decades were done. The last two decades of reform where upwards of $30 billion in savings were generated were not done to cross-subsidise the growth of other expenditure areas in health and social policy, but to help ensure Australia is a 'first-launch' country for new medicines. To now see the HTA Review Options Paper on many occasions focus on the need to manage costs and avoid any fiscal implications is disappointing and ignores the opportunity for improvement created by the PBS reform agenda.

I recognise that some of these issues may result from the HTA Review's scope and terms of reference, and that is partly the problem. If the Review is prevented by broader policy directions from entertaining reforms that improve and expand the scope of the PBS, then this suggests that a broader policy discussion about the scope, scale and trajectory of the PBS is necessary alongside this Review of the technical HTA policies, methods and processes used by the PBAC and other HTA committees. In the aftermath of the Covid-19 pandemic, which demonstrated the value of a well-funded health system that leverages new medicines and vaccines at an early stage, having a broader policy discussion about the place of the PBS in the scope of Australia's health and economic system may be timely. This is particularly important if the HTA Review feels constrained in what it can recommend because of overriding broader policy concerns inside government.

Whether it is within the purview of the HTA Review, or alongside the Review as part of a broader policy dialogue, a discussion about the future scope and scale of the PBS in the context of Australia's health, social and economic agenda is probably overdue.

One joint Commonwealth-state/territory HTA evaluation agency

For some years, I have increasingly been coming to the view that the Australian government should reform the structure and administrative arrangements for its HTA system. These issues

had been touched on, or alluded to, in previous reviews (2009 DoHA, DoFA review, 2006 PC review), but were not sufficiently explored or followed up.

Rather than necessarily having one HTA *committee* to make assessments of all HTA technologies (medicines, vaccines, devices, diagnostics, etc), I believe the more important structural reform here is to consider having a new, separate HTA *agency* that perhaps services several HTA committees. The proposal here is that a new public sector agency be created to replace the current administrative structure supporting HTA evaluations in Australia.

As the Options Paper points out, currently there are several separate HTA evaluation committees serviced by secretariats contained within the Department of Health and Aged Care, and supported by evaluation units in various universities around Australia that are contracted by DHAC to undertake the actual evaluations. Moreover, as the complexity and opportunity presented by emerging medical technologies grows, there are a growing number of complex Commonwealth-state/territory funding issues in supplying medical technologies (eg. cell and gene therapies) where better coordination and collaboration between Commonwealth and state/territory health systems is required to ensure these therapies are adequately funded and delivered. While the Commonwealth may fund the acquisition of a therapy, the state and territories fund the delivery and administration of the therapy through their hospital systems. There are several emerging issues with the current administrative arrangements.

First, there are opportunities to improve good governance and public administration in the current system. Currently, the same government agency that is responsible for achieving health budget objectives, delivering Commonwealth government policy objectives, and managing political issues for government – the Department of Health and Aged Care – is the same agency that provides secretariat support, contracts university HTA evaluators, and manages the administration and financing of evaluation committees. While perhaps fit for purpose when the HTA system was first established more than 30 years ago, the growing size, complexity and scale of the HTA system today begs the question whether such 'in-house' arrangements for the administration and delivery of HTA evaluations is still sufficient or appropriate. As well as opportunities for synergies and efficiencies by co-locating all the administration and evaluation functions in-house in a new, dedicated public sector HTA agency, the creation of such an agency will also put public sector HTA evaluation work at arm's length from both the policy and fiscal functions of federal and state governments. It would also separate the academic HTA research and teaching work conducted at universities from the day-to-day evaluation work of governments.

Second, the increasing complexity of medical technologies and accompanying administrative issues across Commonwealth and state/territory jurisdictions, together with growing international collaboration in HTA, recommend a separate, dedicated public agency for HTA evaluations. The three-way coordination increasingly required across different medical technologies (medicines, vaccines, devices, diagnostics, data, etc); federal-state levels of government; and nations in international collaborative exercises, requires a degree of administrative and evaluation coordination that is greater than the current arrangements where the Commonwealth Department of Health and Aged Care and several academic units at selected universities support to the system. For example, state and territory governments are often required to make their funding decisions relying on advice and recommendations coming

out of the Commonwealth health portfolio, but there are questions about the extent to which state and territory governments are serviced and engaged by the current HTA evaluation system.

Some of the problems, delays and stakeholder complaints about the current system stem from a lack of coordination, lack of transparency in evaluation and decision-making responsibility. Be they patients, industry, academics or even public sector officials, the lack of visibility and accountability about who is responsible for decision making in government is one of the growing problems in the current system. Moreover, the risk of competing policy, budgetary and administrative priorities to influence a decision and recommendation on funding a medical technology are not being effectively managed consistent with best practice public administration is increasing. Ultimately, the accountability and transparency of government decisions to decide whether to fund or not to fund a medical technology could be better. The current system might have been appropriate 30 years ago when HTA evaluation was first introduced in Australia, but given the growth in scope, scale, professionalism, and influence of HTA in the health system today, the systems supporting HTA need to change.

For these reasons, consideration should be given to the creation of a new, separate, public sector agency responsible for managing all HTA evaluation in the health system and making health technology assessment recommendations to government. This new body, perhaps operating like the National Institute for Health and Care Excellence (NICE) model in the United Kingdom, or Canada's Health and Technology Agency (CADTH), would be established to provide arm's-length HTA recommendations to Commonwealth and state/territory governments. Importantly, this body would not have the responsibility to make the final funding decision for medical technologies. This, instead, would still be the responsibility of Commonwealth and state/territory governments.

Such an agency could be staffed with full-time dedicated administrative, clinical and economic employees that provide technical and administrative support to the existing HTA committees (eg. PBAC, MSAC, ATAGI, Prostheses List, etc). The point here is that rather than one committee to oversee all HTA evaluation processes, as flagged in the HTA Review Options Paper, rather the important reform would be to have one dedicated HTA agency that provides services and support to the various HTA committees that contain the independent expertise in their respective areas of medical technology. The existing HTA committees would make their recommendations to government – serviced by the new HTA agency – and governments would still undertake the final price negotiation with providers and fund the medical technologies themselves. Unlike the Pharmac model in New Zealand, where the government evaluation agency is also the government funding body with a capped budget and, therefore, operates under a conflicted and compromised policy agenda, under the proposed model here the Australian HTA committees operating over a new separate agency would make recommendations to the Commonwealth and state/territory governments on the clinical and cost-effectiveness of the medical technologies. It would then be the responsibility of those governments to act on and implement those recommendations in a timely and visible manner.

As is so often the case in health funding, the devil is in the detail of how such proposals are implemented and, therefore, in their ultimate success. While potentially an important step change in the way HTA is conducted in Australia, there are several issues and risks with such a proposal:

1. An important factor for success in this proposed reform will be to model the proposed new Australian HTA agencies such as NICE in the UK or CADTH in Canada. Both agencies provide models of independent, considered HTA evaluations making recommendation that are subsequently acted on by the respective funding agencies in their countries. On the other hand, Pharmac in New Zealand is also given the responsibility of funder of medicines and managing budget policy, in addition to HTA evaluation. The growing long-term revelations around Pharmac's political, policy, ethical and administrative problems are now culminating in recent commitments by the new New Zealand government for major reform of that institution and the way medicines are funded in that country. Shawview Consulting recently completed a report on Pharmac's various economic and administrative issues, commissioned by Johnson & Johnson New Zealand, which can be found here. The problems in the Pharmac model stem from mismanagement of administrative conflicts of interest, a lack of transparency in decision-making processes, a capped fiscal budget, and a lack of accountability and political oversight of the agency. To be clear, Australia should not pursue the Pharmac model, which has now been shown to be ineffective, inappropriate and often prioritising political budget objectives ahead of patient welfare. In suggesting a new HTA agency for Australia, models provided in NICE in the UK, CADTH in Canada, and perhaps other dedicated HTA agencies that provide arm's-length recommendations to government could be examined as prototypes.
2. The cost and funding of a new Australian HTA agency is also an issue to consider. Like the operation of the Therapeutic Goods Administration, the current HTA processes for medicines and vaccines under the PBAC and ATGAI are funded out of fees paid by sponsor companies. Similar arrangements are being introduced for MSAC processes. The cost of establishing a new, dedicated HTA agency that replaces the current Department of Health and Aged Care processes, and university-based evaluator network may not be inconsiderable. In developing a properly resourced, independent public sector agency, consideration should be given to whether such an agency should be funded out of industry fees and charges, what the likely cost of such an agency to industry is likely to be, and the impact of the level of those fees on the demand and timing of HTA evaluations because of those fees. Australia already has enough difficulty meeting its stated policy objective of being a 'first launch' country, so the impact of adding additional burdens in the form of potentially higher fees would have to be considered. The size and priority of Australia's health market is not the same as other countries, so this should be a factor in considering the implementation of a new agency.

Discount rate used in Australia

The recognition of the issue of the discount rate used in Australian government HTA systems and the recognition that more should be done to examine the issue is welcome. As documented elsewhere in Medicines Australia's 2022 submission to the PBAC on the topic, which Shawview Consulting contributed to, the 5% discount rate that is used as standard by the PBAC and other government HTA bodies is out of step with international best practice. MA's submission recommended that Australia adopt a 1.5% discount rate consistent with that used in varying degrees countries like Canada, England and the Netherlands. In any event, a 5% discount rate

used by a high-income, developed country like Australia is out of step with other industrialised countries, is at odds with World Health Organization recommendations, and disadvantages Australians in accessing preventative medical technologies like vaccines, genomic screening, other preventative screening programs, and medical cures using one-off treatments with higher up-front costs that provide long-term benefit to patients and the broader community.

There are two issues with the discount rate used in Australian HTA:

1. The 5% discount rate used in Australia is high by international standards. This is a statement of fact. The implications of this are debated, but Medicines Australia's submission argues that this 5% discount rate disadvantages the Australian community and is the result of a lack of regular review and oversight of the discount rate. Australia's benchmark 5% discount rate was set during the 1980s when the discipline of health economics was in its infancy, when community standards about the long-term benefits of interventions was different, and when medical technology, Australia's economic circumstances, and the global health were vastly different from what we see today. While people can argue about the relative merits and impact of a 5% discount rate on HTA decisions (and I am certainly disappointed in the use of such a high rate in this country), the fact is that Australia's 5% discount rate is high by comparison with what most other similar countries use in practice today.

2. The second issue is, then, is what to do about it. The comment in the HTA Review Options paper that "flexibility in discounting approaches and other aspects of economic evaluation enables the PBAC and the MSAC to account for where these variations impact cost-effectiveness estimates" (page 122) is encouraging but is unclear as to its practical impact, as there is no visibility of when or how the PBAC has accepted a lower discount rate below 5% in recommending a medicine or a vaccine for funding in the past. It is not clear where the PBAC has substituted its standard 5% discount rate for a lower discount rate in past recommendations of a medicine or vaccine for funding. Information on examples where this has occurred and/or or how other HTA variables are treated more generously to compensate for Australia's 5% discount rate would be helpful. The revelation in the Options Paper that "the PBAC considered a lower discount rate for the meningococcal B vaccine" is informative, although whether PBAC consideration of a lower discount rate led to a lower discount rate being accepted as part of a positive recommendation for that vaccine is unknown. A better understanding of how this consideration occurred in this case and others would be welcome. Much more common are PBAC public summary documents that routinely cite the PBAC's 5% discount rate as one of the reasons for rejecting submissions for funding medicines and vaccines. Certainly, the PBAC's commentary on the issues in the relevant public summary document of its consideration of the Medicines Australia 2022 discount rate submission is revealing in so far as much of the emphasis of the PBAC's deliberations seemed to be concerns about potential budgetary impact of lowering the standard discount rate, rather than the health, economic and ethical case for reducing the rate.

It is worth noting that the PBAC's advice, repeated in the Options Paper (page 126) that if the government wanted to reduce the discount rate it should be no lower than 3.5% would still put Australia's discount rate at a higher rate than Canada, Indonesia, Japan, Malaysia, the United States, and many European countries,

Besides funding some medicines, vaccines and therapies that may be disadvantaged by the relatively high 5% discount rate, other medical interventions where the cost-effectiveness evaluation is severely adversely affected by using a 5% discount versus, say, a 3% discount rate include population-level genomic screening programs and campaigns for bowel cancer screening programs.

Encouragingly, the Options Paper notes that "there are circumstances where it may be reasonable to have an alternative (lower) discount rate for some therapies" (page 126) and is probably the first recognition in government circles that there may be issues with Australia's current high discount rate. While unfortunately further delaying progress, the Paper's recommendation that the government should model and analyse the impact of changing discount rates is welcome as it would probably be the first visible systematic government review of Australia's 5% discount rate assumption since it was introduced in 1991. Such modelling, however, should equally assess the benefits as well as costs of varying the discount rates. It is disappointing that much of the focus of this exercise in the Options Paper, much like the PBAC's public summary document commentary, is on the budgetary and fiscal risks of any change, rather than the health, economic and social benefits of funding medical technologies and interventions sooner.

Vaccines

In recent years, Shawview Consulting has undertaken significant policy research work on the funding and valuation of vaccines in Australia. Our report, *Valuing Vaccines: Ensuring Australia's access to vaccines today and tomorrow*, commissioned by Sanofi Australia, reviewed the process for funding vaccines in Australia, looked at the evolution of vaccines funding policies and the development of the National Immunisation Program (NIP), the HTA issues in the assessment of vaccines, and compared Australia's system with other models in other countries.

While looking at a range of HTA technical issues affecting vaccines, one area Shawview Consulting also examined was the role of the Australian Technical Advisory Group on Immunisation (ATAGI) vis-à-vis the PBAC in evaluating vaccines for funding under the NIP. Our analysis found that Australia is one of the few countries that uses the HTA body for medicines (PBAC) to evaluate and make recommendations for funding vaccines, rather than its National Immunisation Technical Advisory Group (NITAG). As noted in the Options Paper (page 80), Australia is one of the few countries in the world that does not use its NITAG to recommend vaccines for funding on its national immunisation scheme. Instead, Australia relies on its medicines funding HTA body, the PBAC, to make those recommendations. The vast majority of other countries use their NITAG system to make recommendations to government on funding vaccines, not their medicines HTA body, for valid reasons which the Shawview Consulting report explores.

One issue raised in the Shawview Consulting report is whether the unique Australian experiment of asking the medicines HTA body (PBAC) to recommend vaccines rather than the country's NITAG (ATAGI) has been successful or not. There is a question whether such arrangements have allowed Australians to fully realise the potential value of vaccines and the country's vaccines funding program (NIP). The Shawview Consulting report highlighted that

several of the broader systematic constraints and issues in the Pharmaceutical Benefits Scheme's HTA evaluation system particularly impact on vaccines and are one of the sharper ends of where Australia's HTA processes and assumptions affect access to health care technologies. While not being prescriptive here, given the recurring issues some vaccines seem to be having in securing government funding, there is a question about how well the current system for evaluating vaccines is working. At face value, it would seem to be important to retain ATAGI as an important function in the vaccines assessment process. The question would be whether the HTA evaluation function for vaccines would remain with the remit of the PBAC or should be given to ATAGI – a move that would be more similar to the way many other countries assess the cost-effectiveness of vaccines for their vaccination programs.

Genomics

The discussion in the HTA Review Options on the use of genomic diagnostics and pharmacogenomic therapies (pages 102 – 103) is welcome, although somewhat vague in what it means. The use of genomics in health care is one of the emerging technological platforms in the health sector (along with things like big data, artificial intelligence, cell and gene therapies), where the health system is struggling to keep up with technological progress. Developing guidelines on the use of genomic diagnostics and pharmacogenomic therapies is most likely to be a useful step in developing pathways for the use of these tools.

However, as with many things in HTA, the devil will be in the detail. How other decisions on Australia's HTA framework on things like broader societal benefits, discount rates, cost-effectiveness thresholds and the valuation of preventative health programs, will affect the uptake and use of genomics in the Australian health context.

New price reduction policies, resubmission caps and Australia as a 'first-launch' country

Broadly speaking, the proposals in the HTA Review Options Paper to have required price reductions on listing new molecules in an existing class of medicines, and the suggestion of a capped number of resubmissions to the PBAC, are worrying. The (admittedly limited) data presented in the Options Paper on the sequencing of new medicine launches in Australia vis-à-vis other countries already shows that companies choose to launch medicines in Australia after other countries and regions like the United States and Europe. Other previous data consistently shows that companies bring new medicines to Australia sometime after medicines are launched in these countries and other places such as Japan and, increasingly, places like China. Much of the data that analyses the timing of launches of medicines in Australia compared to other countries shows that Australia is often not, in fact, a 'first-launch' country.

For these reasons, the proposed mandatory and incentivised price reduction measures on listing that have been proposed in the Options Paper are problematic. Firstly, at a time when the policy objective is to ensure Australia is a 'first-launch' country, such measures are likely to work in the opposite direction. It will be important to understand how such policies would help contribute to achieving this goal of the Commonwealth government.

Secondly, such policies, arguably, represent a fundamental change in the way pricing and policy processes of the Pharmaceutical Benefits Scheme operate. Over many years, the PBS has evolved and changed based on the concept of competition between patented medicines in the F1 formulary through health technology assessment on entry and pricing policies on listing. Competition has been achieved separately in the F2 formulary for multiple brand medicines through the operation of price disclosure. Required price reductions for new medicines on entering the PBS on listing, together with caps on resubmissions, could work to reduce this competition in the market that provides treatment options for patients and clinicians while driving efficiency and effectiveness in healthcare. By mandating a constraint on what a cost-effective price could be for listing and imposing further barriers for companies to prioritise Australia as a viable market, the result could be to reduce competition and supply chain security in the market to the point where the policy drivers the PBS is built on stop working. With less companies and less treatment options on the PBS, competition among companies falls and less long-term pressure on medicine prices exists.