The Department may, at its discretion, publish part or all of the information pro the submission. All personal contact details will be removed prior to publishing. Yes, I consent to my identified submission being published tion provided in your submission on the Department's website or in related documents. If information from your submission is published, the Department may identify you and/or your organisation as the author What is your name? Brendan Shaw Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice What is the name of your organisation? - My organisation is called: - Text

Shawview Consulting

Are you making feedback on behalf or your organisation?

Futureproofing Australia's systems and processes

Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA

1.1. Transparency and communication of HTA pathways, processes and decision

ease select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment path 1. Streamlining and aligning HTA pathways and advisory committees

Please select the topics within the chapter(s) you would like to provide feedback on. 3. Methods for HTA for Australian government subsidy (technical methods) 3.3. Economic evaluation

Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions 4.1. Approaches to funding or purchasing new health technologies

Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes

5.5. Capacity and capability of the HTA system

21

Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them? ddress some but not most of the issue(s)

If you would like to expand on your answer above you can do so below:

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 Moreover: the risk of competing policy, budgetary and administrative priorities to influence a decision and recommendation on funding a medical tech 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.

23 1

Positive

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard

Taking all Options within this section: 2.1. Streamlining and aligning HTA pathways and advisory committees into account

Overall, to what extent could the options (if implemented) address the issues that relate to them?

dress little or none of the issue(s)

If you would like to expand on your answer above you can do so below:

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 supporting HTA evaluations in Australia. 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 where better coordination and collaboration between Commonwealth and state/territory health systems is required. 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 the 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. See attached paper for more discussion.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))

48.2

if implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine pathy Positive

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC

Neutral

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Unified HTA pathway for all health technologies with Commonwealth funding

Positive

If you would like to expand on your answer above you can do so below. Vaccine pathway
In recent years, Shawiew 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 Shawiew Consulting also examined was the role of the Australian Technical Advisory Group on Immunisation (ATAGI) vis. A vis the PBAC in evaluating vaccines for funding under the NIP. Our analysis found that the valuating vaccines for funding under the NIP. Our analysis found that the valuating vaccines for funding under the NIP. Our analysis found that the valuating vaccines for funding under the NIP. Our analysis found that the valuating vaccines for funding under the NIP. Our analysis found that the valuation of the NIP. Our analysis found that the valuation of the NIP. Advisory (NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Paper (Insee South NIPAGI) as produced in the Outlook Pap 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. See attachment for more discussion.

Tyou would like to expand on your answer above you can do so below -Unified HTA pathway for all health technologies with Commonwealth funding

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. See attached paper for more discussion

96 Taking all Options within this section: 3.3. Economic evaluation into account

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Address some but not most of the issue(s)

98.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Valuing of long-term benefits

101

101 If you would like to expand on your answer above you can do so below -Valuing of long-term benefits

The recognition of the issue of the discount rate used in 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 accessine 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. See attached paper for

103

Taking all Options within this section: 4.1. Approaches to funding or purchasing new health technologies into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them? Address some but not most of the issue(s) 105.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Negative 105.2

Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit Neutral

107

If you would like to expand on your answer above you can do so below -Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

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 albenetis Scheme operate. Over many years, the P88 has sevolved and changed based on the concept of 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. See attached paper for more discussion.

157

Taking all Options within this section: 5.5. Capacity and capability of the HTA system into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

If you would like to expand on your answer above you can do so below:

There is certainly a need to expand and deepen the skills, scope and diversity in Australia's health economics discipline. Most experts in health technology assessment are either funded by the pharmaceutical industry or funded by government and existing PBAC processes. Arguably, both funding options present conflicts of interest. Conflicts of interest, if well managed, can add value to deliberations and consultations processes. Moreover, there is a need for a more independent view of health economics in Australia.

1293.1

Fin implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improve HTA capacity and workforce in Australia Positive

167

In summary, considering all the draft reform options together:

How confident are you that the reform options (if implemented) will make health technology assessments better overall? Not very confident

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

See attached paper

238.1 Under the subject 'æRecognising competition between new health technologies that deliver similar outcomes', there are two options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit
To a limited extent

238.2

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit.

To a limited extent

239
What comments do you have about the relative strengths and weaknesses of these alternative potential reform options?
What comments do you have about the relative strengths and weaknesses of these alternative potential reform options? Requiring lower price offers runs a real risk of reducing competition and supply chain diversity/security, and is at odds with broad PBS policy frameworks. Incentivising lower price offers all depends on how it is structured, but carries similar risks.

Which of the proposed reform options do you think offers greatest scope to address the issues identified in consultation to date?

Neither of these

242

Why did you select that response above?

It is unclear how the proposed reforms will help achieve the Government's policy objective of keeping Australia as a 'first launch' country for new medicines. Such reforms are likely to achieve the opposite of this and could reduce competition and the number of suppliers in the market to