

**Response**

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**The Department may, at its discretion, publish part or all of the information 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 of the submission. All personal contact details will be removed prior to publishing.**  
Yes, I consent to my identified submission being published

3  
**What is your name?**  
Sarah Greenbaum

7  
**Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice**  
Pharmaceutical / Medical technology company

8.1  
**What is the name of your organisation? - My organisation is called: - Text**  
Pfizer

9  
**Are you making feedback on behalf of your organisation?**  
Your organisation

13  
**Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish.**  
1. Transparency, communication, and stakeholder involvement in HTA,2. Health technology funding and assessment pathways,3. Methods for HTA for Australian government subsidy (technical methods),4. Health technology funding and purchasing approaches and managing uncertainty,5. Futureproofing Australia's systems and processes

14  
**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 decisions,1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA,1.3. First Nations people involvement and consideration in HTA,1.4. State and territory government collaboration in HTA

15  
**Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways**  
2.1. Streamlining and aligning HTA pathways and advisory committees,2.2. Proportionate appraisal pathways

16  
**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)**  
3.1. Determination of the Population, Intervention, Comparator, Outcome,3.2. Clinical Evaluation Methods,3.3. Economic evaluation

17  
**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,4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR),4.3. Understanding the performance of health technologies in practice

18  
**Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes**  
5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS,5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system,5.3. Consideration of environmental impacts in the HTA,5.4. Mechanisms for continuous review and improvement,5.5. Capacity and capability of the HTA system,5.6. Strengthen international partnerships and work-sharing

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?**  
Mostly address the issue(s)

22  
**If you would like to expand on your answer above you can do so below:**  
We support initiatives that improve patient and clinician engagement in the process while ensuring time to access is not increased through the implementation of this initiative. A key caveat to this is that information that is considered confidential under the status quo remains confidential in any new transparency arrangement. A particular concern is that special pricing arrangements continue to be a policy option in any future arrangement and that confidentiality around special pricing arrangements is preserved in any future model. Further, the ongoing issues with redactions in PSDs must be addressed.

23.1  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries**  
Neutral

23.2  
**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**  
Neutral

25  
**If you would like to expand on your answer above you can do so below -Publish plain language summaries**  
We support initiatives that improve patient and clinician engagement in the process while ensuring time to access is not increased through the implementation of this initiative. A key caveat to this is that information that is considered confidential under the status quo remains confidential in any new transparency arrangement. A particular concern is that special pricing arrangements continue to be a policy option in any future arrangement and that confidentiality around special pricing arrangements is preserved in any future model. Further, the ongoing issues with redactions in PSDs must be addressed.

26  
**If you would like to expand on your answer above you can do so below -Improvements to the HTA webpage including development of a dashboard**  
We support initiatives that improve patient and clinician engagement in the process while ensuring time to access is not increased through the implementation of this initiative. A key caveat to this is that information that is considered confidential under the status quo remains confidential in any new transparency arrangement. A particular concern is that special pricing arrangements continue to be a policy option in any future arrangement and that confidentiality around special pricing arrangements is preserved in any future model. Further, the ongoing issues with redactions in PSDs must be addressed.

27  
**Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA 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)

29.1  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework**  
Positive

29.2  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence**  
Positive

31  
**If you would like to expand on your answer above you can do so below -Develop an engagement framework**  
Consumer consultation will be required to ensure the creation of an engagement framework which meets stakeholder expectations.

32  
**If you would like to expand on your answer above you can do so below -Strengthen consumer evidence**  
Consumer consultation is essential to ensure the creation of a consumer evidence base meets consumer expectations especially with respect to data privacy. The same is true for the creation of a centralised data sharing system for utilisation and outcomes data for HSTs. Consideration of who can access this information is also important to ensure the new data created supports the goals of the review in achieving faster access.

33  
**Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.**  
**Overall, to what extent could the options (if implemented) address the issues that relate to them?**  
Mostly address the issue(s)

34  
**If you would like to expand on your answer above you can do so below:**  
We are highly supportive of initiatives to increase the involvement of First Nations people in HTA and the aim of improving access to Health Technologies for areas of unmet need for First Nations peoples. Consistent with the proposals for horizon scanning, a clear framework is essential to ensure that Sponsors are clear on the process and expectations for proactive submission requests for First Nations people.

35.1  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making**  
Positive

35.2  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education**  
Positive

37  
**If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making**  
We are highly supportive of initiatives to increase the involvement of First Nations people in HTA and the aim of improving access to Health Technologies for areas of unmet need for First Nations peoples. Consistent with the proposals for horizon scanning, a clear framework is essential to ensure that Sponsors are clear on the process and expectations for proactive submission requests for First Nations people.

38  
**If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submissions and education**  
We are highly supportive of initiatives to increase the involvement of First Nations people in HTA and the aim of improving access to Health Technologies for areas of unmet need for First Nations peoples. Consistent with the proposals for horizon scanning, a clear framework is essential to ensure that Sponsors are clear on the process and expectations for proactive submission requests for First Nations people.

39  
**Taking all Options within this section: 1.4. State and territory government collaboration in HTA into account.**  
**Overall, to what extent could the options (if implemented) address the issues that relate to them?**  
Mostly address the issue(s)

41.1  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of central standardised data sharing system for utilisation and outcome data**  
Neutral

41.2  
**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increase opportunities for consultation and work sharing**  
Neutral

41.3

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)**

Neutral

43

**If you would like to expand on your answer above you can do so below -Development of central standardised data sharing system for utilisation and outcome data**

This initiative will need careful consideration with respect to data privacy. It is also critical to ensure the new data created supports the goals of the review in achieving faster access.

46

**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?**

Address some but not most of the issue(s)

48.1

**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))**

Neutral

48.2

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine pathway**

Positive

48.3

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

Positive

48.4

**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

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**Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))**

This initiative can deliver faster access by removing the need for negative PBAC recommendation on a cost effectiveness basis before a therapy is considered for inclusion on the LSDP. However, it isn't clear how this pathway will be funded. It is important that therapies for vulnerable patients with ultra-rare diseases continued to be funded without the need to demonstrate cost-effectiveness and that new pathways are adequately funded.

60

**If you would like to expand on your answer above you can do so below -Vaccine pathway**

This initiative will likely achieve much needed faster access to vaccines by removing the need for separate ATAGI advice before making a PBAC submission. It is important in developing this pathway that opportunities to seek expert advice from ATAGI remain available when needed during the process of submission development (prior to PBAC submission) to ensure important considerations such as modelling assumptions can be incorporated in the initial submission, rather than only during the evaluation process which may result in additional re-submissions to PBAC being required. Flexibility is essential, given some vaccine submissions are complex and will require detailed expert advice to align on clinical considerations for an immunisation program and PICO elements, while more simple submissions may require only limited pre-submission advice.

61

**If you would like to expand on your answer above you can do so below -Expanding role of PBAC**

This initiative aligns with previous proposals from industry, seeking to achieve a centralised and unified approach. To achieve these objectives, the central HTA body for all health technologies receiving Commonwealth and joint Commonwealth and State funding would need to be arm's length from government, not have a savings imperative and be empowered to engage experts relevant to the technology and submission type. This initiative has the potential to achieve improvements in time to access for codependent diagnostics and therapies. It will be important that the consistency and predictability of the current PBAC pathway in terms of reporting and timelines is maintained with the unified pathway.

62

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

This initiative aligns with previous proposals from industry, seeking to achieve a centralised and unified approach. To achieve these objectives, the central HTA body for all health technologies receiving Commonwealth and joint Commonwealth and State funding would need to be arm's length from government, not have a savings imperative and be empowered to engage experts relevant to the technology and submission type. This initiative has the potential to achieve improvements in time to access for codependent diagnostics and therapies. It will be important that the consistency and predictability of the current PBAC pathway in terms of reporting and timelines is maintained with the unified pathway.

63

**Taking all Options within this section: 2.2. Proportionate appraisal pathways into account**

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

Address little or none of the issue(s)

65.1

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager**

Don't know