The Department may, at its discretion, publish part or all of the information provided in your sub as the author of the submission. All personal contact details will be removed prior to publishing. esite or in related documents. If information from your submission is published, the Department may identify you and/or your orga

ously (personal and organisation ease publish my submission anor nal names will be removed and the submission will be marked as "Name withheld") (Note: if you select this option and your submission contains identifying information, your submission may not be published).

What is your na 

ease 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

Are you making feedback on behalf or your organisation?

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

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

ration in HTA,1.3. First Nations people involvement and consideration in HTA 1.1. Transparency and communication of HTA pathways, processes and decisions, 1.2. Consumer, clinician and other stakeholder engagement and consider

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

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 the ddress little or none of the issue(s)

22

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

There appears to be a disconnect between what is discussed in the meeting and what is reported to the applicant. While a report is provided, the applicant has no idea what additional issues may have been discussed and reflect the values/biases of the common the common that is discussed and reflect the values of the common t Insert appears to be a disconnect netween what is a locationsed in the meeting and what is reported to the applicant. The major are a report to provided, the applicant mas no use what a disconnect netween what is a locational information provided have affected the assessment. It is also unclear if the consumer representative on the MSAC committee actually represents the people who would be most affected by this decision. I commend the inclusion of consumers on the MSAC committee, however it is not clear that the 'exconsumer' is the most appropriate person to be providing comment. For example, if this is a technology aiming to improve health outcomes for either a specific population such as indigenous people, or persons with a particular illness such as Hepatitis C, then the consumer talking to the MSAC committee should be a patient or community representative who actually is acutely aware of the issues for that specific population. While letters of support may be provided, it is not the same as a providing the opportunity for a person who will be directly impacted by the decision to be part of the committee discussion. person who will be directly impacted by the decision to be part of the comm 23.1

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

If imple ented, 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: 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 little or none of the issue(s)

18 fry ou would like to expand on your answer above you can do so below:

There appears to be a disconnect between what is discussed in the meeting and what is reported to the applicant. While a report is provided, the applicant has no idea what additional issues may have been discussed and reflect the values/biases of the committee . For example, an applicant may specifically request health equity be considered. Or alternatively, MSAC may ask and be given additional information. From my experience there is no acknowledgement of whether any of the requested considerations or additional information provided have affected the assessment. It is also unclear if the consumer representative on the MSAC committee actually represents the people who would be most affected by this decision. While I commend the inclusion of consumers on the MSAC committee, currently it is not clear that the 'exconsumer' is the most appropriate person to be providing comment. For example, if this is a technology aiming to improve health outcomes for either a specific population such as Indigenous people, or persons with a particular illness such as Hepatitis C, then the consumer talking to the MSAC committee should be a patient or community representative who actually is acutely aware of the issues for that specific population. While it is the norm for letters of support to be provided, it is not the same as a providing the opportunity for a person who will be directly impacted by the decision to be part of the MSAC committee discussion.

Positive

29.2 ated, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen cons

If imple Positive 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? Address some but not most of the issue(s)

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

While I commend the inclusion of consumers on the MSAC committee, currently it is not clear that the 'exconsumer' is the most appropriate person to be providing comment. For example, if this is a technology aiming to improve health outcomes for either a specific population such as Indigenous people, then the consumer talking to the MSAC committee should be a patient or community representative who actually is acutely aware of the issues for that specific population. While it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to be provided, it is the norm for letters of support to the sup not the same as a providing the opportunity for a person who will be directly impacted by the decision to be part of the MSAC committee discussion. Along with this, there should be an opportunity for the applicant to present their application, raise important issues and also participate in discussions. Currently the process feels very inefficient and one-sided.

35.1

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

If impler Positive 35.2

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

37

If you would like to expand on your answer above you can do so below-First Nations peoples partnership in decision making Should be the norm

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)

47

If you would like to expand on your answer above you can do so below: There is benefit in have better alignment of processes for PBAC and MSAC.

Timplemented, 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 Don't know

tf imple mented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC Don't know

fly ou would like to expand on your answers above you can do so below:

The current MSAC review process does not allow for consultation between applicant and assessor following the submission. This is an adversarial process with the 'ceassessor' justifying their role by being as critical as possible. If an assessor makes an incorrect assumption which becomes part of the submission response it is difficult for the applicant to challenge this once presented to ESC and carried through to MSAC. The assumption made by the government is that the view in the assessment is correct. However, it is likely that there may be misunderstandings or mistakes made and contentious issues will be highlighted during the assessment process. There should be an opportunity for review the assessment and update the application if required to provide during the assessment process. There should be an opportunity to respond. This step could be documented and included in the application. An opportunity for review prior to review by ESC would make the process more efficient and save a lot of time spent by the applicant trying to clarify or correct statements in subsequent reports.

Currently while the assessor may provide a written response (limited to two pages), it is common that the same 'ceweaknesses' from the original assessment are presented to the applicant at each review cycle.

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

Don't know If implement Positive uld these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions

65.2

ented, overall would these Options have a positive or negative impact on you [/your organisation]? - Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity) If imple

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Positive

65.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for subr

Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Don't know

65.6
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised

65.8 If implement Don't know nented, overall would these Options have a positive or negative impact on you [/your organisation]? - Development of a disease specific common model (reference case) for disease areas with high active product development

65.9 If implemen Don't know 67

nented, overall would these Options have a positive or negative impact on you (/your organisation)? - Decouple the requirement for the TGA Delegate's overview to support PBAC advice

If you would like to expand on your answer above you can do so below -Triaging submissions

An opportunity for engagement would be beneficial. Currently while the assessor may provide a written response (limited to two pages), it is common that the same 'ceweaknesses' from the original assessment are presented to the applicant at each revi if this is a result of responses not being read or if they are disregarded, but the general feeling is that there is no opportunity to challenge errors or contentious issues from the original assessment.

In summary, considering all the draft reform options together:

onfident are you that the reform options (if implemented) will make health technology assessments better overall?

Not very confident

## HTA some thoughts

## Transparency of process and time of evaluation

The current MSAC review process does not allow for consultation between applicant and assessor following the submission. This is an adversarial process with the "assessor" justifying their role by being as critical as possible. If an assessor makes an incorrect assumption which becomes part of the submission response it is difficult for the applicant to challenge this once presented to ESC and carried through to MSAC. The assumption made by the government is that the view in the assessment is correct. However, it is likely that there may be misunderstandings or mistakes made and contentious issues will be highlighted during the assessment process. There should be an opportunity for the applicant to review the assessment and update the application if required to provide clarification or rebuttal to the assessor if it is considered mistakes have been made in the assessment. The assessor would also have the opportunity to respond. This step could be documented and included in the application. An opportunity for review prior to review by ESC would make the process more efficient and save a lot of time spent by the applicant trying to clarify or correct statements in subsequent reports.

Currently while the assessor may provide a written response (limited to two pages), it is common that the same "weaknesses" from the original assessment are presented to the applicant at each review cycle. It is unclear if this is a result of responses not being read or if they are disregarded, but the general feeling is that there is no opportunity to challenge errors or contentious issues from the original assessment.

## Transparency of process

There appears to be a disconnect between what is discussed in the meeting and what is reported to the applicant. While a report is provided, the applicant has no idea what additional issues may have been discussed and reflect the values/biases of the committee. For example, an applicant may specifically request health equity be considered. Or alternatively, MSAC may ask and be given additional information. From my experience there is no acknowledgement of whether any of the requested considerations or additional information provided have affected the assessment. It is also unclear if the consumer representative on the MSAC committee actually represents the people who would be most affected by this decision. While I commend the inclusion of consumers on the MSAC committee, currently it is not clear that the "consumer" is the most appropriate person to be providing comment. For example, if this is a technology aiming to improve health outcomes for either a specific population such as Indigenous people, or persons with a particular illness such as Hepatitis C, then the consumer talking to the MSAC committee should be a patient or community representative who actually is acutely aware of the issues for that specific population.

While it is the norm for letters of support to be provided, it is not the same as a providing the opportunity for a person who will be directly impacted by the decision to be part of the MSAC committee discussion. Along with this, there should be an opportunity for the applicant to present their application, raise important issues and also participate in discussions. Currently the process feels very inefficient and one-sided.

## Different types of evaluation and funding pathways

Currently MBS covers "tests and examinations by doctors needing to diagnose and treat illnesses". This does not include rebates for activities related to secondary prevention such as full skin examination for melanoma or conducting a screening or diagnostic test using POC testing technologies in the clinic – if these procedures were to be listed under the current model they could theoretically be considered as laboratory items and incur a laboratory test rebate but there would no recognition for the services conducted in the clinic. Whether these activities are part of "usual" GP consultation needs further discussion given both require skills that are outside "usual" general practice clinical activities. A full skin examination may be seen as a specialised activity and operating a PCR machine required to analyse a point of care test requires training and takes up considerable staff time each time the test is processed and in addition may include reporting responsibilities. As new technologies, such as point of care tests and AI technologies, will likely be introduced for use in general practice there needs to be provision for MSAC to evaluate changing models of care and consider new types of items numbers to reflect changing practices for clinicians and nurses. Currently item numbers for clinical practice are stuck in the old paradigm with entrenched political interests. New funding pathways may help, but services provided within general practice should still be eligible to be listed on the MBS. GPs need assurances that investments in training and quality assurance for example are worthwhile and can be embedded with certainty into practice. Short term funded schemes are not a solution.