

Response
2 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? Ruchi Kanojia
7 Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Consulting
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
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,4.3. 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 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system,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: The proposed option and solutions need to fully capture the pre-submission, HTA process and post HTA process (eg Post PBAC/ or decision making stage) fully and with more granularity. Currently the medicines update webpage doesn't capture this in detail and in real time. Updates are often delayed whilst listings and certain milestones have been achieved by the sponsor. The transparency of process milestones, timeliness and submission churn should also be made available however, it should be done in a constructive way so the systems in place are able derive key KPI statistics. This data should be made available in a monthly or quarterly report so that it is transparent and clear to all stakeholders and community how the system tracking against envisaged policy intent. Make key word searches or simple search of PSDs easier and in one platform. It is a difficult process and information is generally buried. If PSDs can be searched for outcomes, comparators, key clinically accepted outcomes and more generally around key uncertainties and how this has been addressed in past then it would allow stakeholders have guidance around a particular therapy area/ drug class and decision making process and companies which are small and in start up phases with limited resources an easier way to navigate decision making. Pricing information such as Therapeutic relativity, RSAs and SPA, where possible should be shared with respect to it's nature and structure. Keeping commercial info hidden
23.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries Very positive
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 Very positive
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? Mostly address the issue(s)
28 If you would like to expand on your answer above you can do so below: Clinician engagement needs to be expanded, while it is very important to have consumer's input the paper lack measurable ways in which clinician input can be sought. This is paramount when assessing new technologies in rare conditions, or in large population where clinical advancements have been limited and data is also limited. It is also critical to get input in areas where performance of technology is being discussed when it is an early adoption or driver change in the therapy area. This can be done by establishing clinician advisory groups who then advise the committee on various aspect of the submissions/ technology and it's performance including ways generate RWD if none exist. equally it is unclear how patient input will be weighted and assessed in decision making clear steps in where input from both clinician's and patients will be sought during various stages of HTA process. What will their remit and how will their responses add to the submissions before the decision making HTA committee. how will this be share with the evaluation groups and how will impact the evaluation process.
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 Strengthen the framework for Clinician input.
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)
47 If you would like to expand on your answer above you can do so below: The options paper addresses some issues with LSDP however, the value of money approach is confusing. Does the department intend to apply a predefined ICER to rare conditions seeking listing through LSDP? PBAC as a sole committee will need to be supplemented with expert and clinical advisory groups as at times the PBAC lacks the clinical knowledge for these areas (and others). Expanding PBAC role will partially resolve co-dependent technology issues considering funding via PBS or other pathways is not clear. Also, the PBACs capability in diagnostics and various MBS item codes and hospital systems can be limited and it is unclear whether this will have the indented policy outcome. Single entry and one HTA committee is troublesome as this can be a long process with increased up-skilling and resources within the DoH. This will need to be fit for purpose and will require establishment of many subcommittees with therapeutic expertise to advice the committee. It is recommended that a more collaborative approach is adopted instead. PBAC should be advised by Clinical advisory groups, States, and territories as well as consumers. Provide a simpler triage process for Me too's with therapeutical advancements and breakthrough technologies. This can be done via expanding PBAC executive committee's role and remit and providing decision making powers so that certain funding decisions can be made by it or supported. This can work to relieve PBAC's capacity for more complex submission.
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 Neutral
48.3 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC Negative
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 Very negative
61 If you would like to expand on your answer above you can do so below -Expanding role of PBAC Timelines, methodologies, and guidance should be aligned with the MSAC to be able to assess co-dependent technologies in more streamlined or Parallel way. This could require legislative changes and hard to implement. This can also be done in conjunction with improving MSAC timelines to align with PBACs .
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 difficult implementation and legislatively unclear/ cumbersome.
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? Mostly address the issue(s)
64 If you would like to expand on your answers above you can do so below: unclear exactly how the risk, levels of uncertainty and fiscal cost would inform the triaging. There could be issues in implementation if developed tools and criteria form subjective views on risks and uncertainty.
65.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager Positive
65.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions Positive

If implemented, 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)

Very positive

65.3

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 1: Introducing an optional resolution step before HTA committee consideration

Very positive

65.4

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

Positive

65.5

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 3: Early Price negotiation

Positive

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

Neutral

65.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding resolution step to all relevant cost effectiveness submissions

Neutral

65.8

If implemented, 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

Positive

65.9

If implemented, 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

Neutral

77

Taking all Options within this section: 3.1. Determination of the Population, Intervention, Comparator, Outcome into account.

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

Mostly address the issue(s)

78

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

PICO would need to have input from clinicians and Patients, while the options papers suggest this, it is unclear how this would be achieved and the timelines required of this process once it is implemented. what is also unclear is how this would be evaluated or if at all. What would be assessment from the evaluators and how this would add to the PBAC's decision making process. it is likely to extend the timelines of full HTA assessment so thought should be given to the of PICO and pros of going through this process.

79.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased early stakeholder input

Very positive

79.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased transparency for stakeholders

Very positive

79.3

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

Very positive

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?

Mostly address the issue(s)

98.1