

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? Dean Whiting
7 Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Industry association / Peak body
8.1 What is the name of your organisation? - My organisation is called: - Text Pathology Technology Australia
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
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
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
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? Address some but not most of the issue(s)
22 If you would like to expand on your answer above you can do so below: We generally support initiatives to improve public engagement in the HTA process and would support further application of these improvements across HTA for the full IVD sector.
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 Positive
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 The options paper mentions the concept of a processing time clock. It may be possible to model the device used by the USA FDA "our member base report this system is largely working well.
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 Neutral
29.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence Neutral
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 little or none of the issue(s)
47 If you would like to expand on your answer above you can do so below: we cannot understand how the suggested single access gateway approach can efficiently accelerate the HTA process and shorten assessment times. The vast diversity in complexity of technologies and services mitigate against such a strategy. A single gateway model would further extend meeting duration - PBAC meetings take ~3-4 days, similarly for MSAC meetings - which leads to the question, what is the planned meeting duration to cover both PBAC and MSAC through a single gateway? Lack of relevant technical/clinical expertise is already an issue with our current MSAC pathway - this will be compounded if combining HTA committees across the different technologies. Consolidation of committees could lead to an increase in evidentiary requirements for IVDs to align with that applied to pharmaceutical products in a streamlined assessment protocol. Given the vastly lower risk factors and completely different cost and price structures for IVDs this would not be justified and would reduce the number of technologies receiving MBS reimbursement and further delay time to reimbursement.
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
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 The current expansion of IVD technology into genomics proteomics, biomarkers, point of care technology, and the associated digital enablers, is further evidence against the single gateway concept. It will become exceptionally challenging for a single committee, no matter how competent, to be expert enough to complete even an initial triage of potential high-medical need technology. While coordination and collaboration across HTA systems is a desirable goal, especially in so far as getting better coordinated implementation between federal and state/territory governments, we suggest this may be achieved through better resourcing processes, rather than trying to consolidate consideration of the variety of expert advisory committees into one committee and, thereby, diluting the evaluative expertise that comes from different HTA committees. We strongly suggest a single front door concept be abandoned in favour of sector specific multi-stakeholder, expert advisory groups of related healthcare professionals, service providers, patient advocacy representatives, and the industry.
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? Don't know
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? Address some but not most of the issue(s)
140 Taking all Options within this section: 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system 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)
141 If you would like to expand on your answer above you can do so below: We suggest the scope for review of the impact of HTA for access to health technologies be extended to include the full spectrum of diagnostic tools and supporting technology, not just those within the narrow use of medicines. Restricting horizon scanning to technologies that impact the PBS leaves much of the impact of other IVD technologies outside the reach of our healthcare system.
142.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Horizon scanning for advanced therapies (including high cost, HSTs funded through the NHRA) and other potentially disruptive technologies Neutral
142.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Horizon Scanning to meet priority areas (including addressing equity and HUCN) Neutral
142.3 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Horizon Scanning to help operational and capacity planning for HTA and health systems Neutral
145 If you would like to expand on your answer above you can do so below -Horizon Scanning to meet priority areas (including addressing equity and HUCN)

Horizon scanning activities should include the full scope of the IVD sector, not just those technologies within the narrow scope of medicines.

146
If you would like to expand on your answer above you can do so below -Horizon Scanning to help operational and capacity planning for HTA and health systems

Horizon scanning activities should include the full scope of the IVD sector, not just those technologies within the narrow scope of medicines.

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

168
If you would like to expand on your answer above you can do so below:
please see additional document.

231
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.

PICO should be agile enough to consider weighted evaluation of each component. For example, when considering an IVD comparator for a point of care test (POCT), it may not be suitable to choose a laboratory test, when in many cases across Australia the real alternative to POCTs is no test at all, as even if a laboratory test could be accessed, results are not timely enough to be effective. We believe the Outcome of PICO needs to be context based. The outcome for difficult to reach populations might be very different to the outcome for populations that can readily access traditional health services.

252
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.
Sector specific multi-stakeholder, expert advisory groups of related healthcare professionals, service providers, patient advocacy representatives, and the industry should be established on a permanent basis. The EAGs can complete horizon scanning and identify technologies that address unmet healthcare need or improve current outcomes.