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 ation 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 What is your name? Christopher Steer Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Clinician (or representative 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 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 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 pathwa 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 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 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 a Overall, to what extent could the options (if implemented) address the issues that relate to them? Mostly address the issue(s) 23.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including develop Very positive 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? lostly address the issue(s) If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework 29.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence to expand on your answer above you can do so below -Develop an engagement framework a formal engagement framework with organisations such as MOGA (slightly more than what is currently done) would be an option to improve expert input in key priority areas such as oncology drugs and tests 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)

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 Dociribus 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 Taking all Options within this section: 1.4. State and territory government collaboration in HTA into account what extent could the options (if implemented) address the issues that relate to them? Address some but not most of 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 Very positive 41.2 nted, overall would these Options have a positive or negative impact on you (/your organisation)? - Increase opportunities for consultation and work sharing 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) Positive or you would like to expand on your answer above you can do so below. 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)

Recognition that HTA applies to patients regardless of where they live and regardless of which funding source is utilised (State vs Federal) is very important.

Early engagement with state and territory authorities in collaboration with the federal funding pathways and recognition of the overall health economy as it pertains to an individual patient is an important step to assessing the relative value of new treatments.

Recognition that funding of highly specialised therapies is particularly schedial enterpies is particularly challenging when there is overlap between Commonwealth and state and territory government systems (and the ability to shift responsibilities) in both the private and public sectors.

The situation where a new health technology is approved by the PBAC or MSAC but not able to be provided by a State health service needs to be particularly addressed. In addition, the funding of treatments by State health services where potentially they should be funded by the PBAC and/or Federal funding bodies is also an issue worthy of reform. Consideration of moving all funding to a centralised model... avoiding the duplication and game playing around cost shifting would assist in streamlining the HTA process 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))

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

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

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

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

On the surface the incorporation of the pathway for drugs for ultra rare diseases (life saving drugs program LSDP) into the PBAC remit may present advantages however clinicians would not want to see this process disadvantage patients in any way or slow access to life saving drugs. This system may have been set up as an alternative pathway for a reason?¹ eg due to inadequacies in the PBAC process. Clinicians would need to be reassured that these issues were addressed as part of this reform. This may include acceptance that the treatment will not be supported by the same evidence as more common conditions and recognition that the therapy may not be cost effective... and meet different criteria for funding.

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

Expanding the role (and power) of the PBAC would need to be done in a careful manner. The creation of a unified HTA pathway for all health technologies with Commonwealth funding would in theory reduce the time taken for approval of new health technologies and would certainly require legislative reform. Careful thought would be needed in this regard.

Anything that improves the overall timeliness of access to new treatment technologies would be supported by clinicians and their patients.

Care needs to be taken not to shift too much power to the one body without careful checks and balances.

Consultation with expert needs to be done with mutual understanding of the worth of that engagement.

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

Clinicians would support the streamlining of the PBAC/MSAC into a unified HTA pathway on the proviso that appropriate funding follows this approval process. Anything that reduces the time to approval, reduces duplication and bottlenecks is welcome. Anything that slows the process down is not acceptable to clinicians or their patients.

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 some but not most of the issue(s) 65.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager

Neutral If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions Positive

65.2

Positive 65.3

Alternative option 1: Introducing an optional resolution step before HTA committee consideration

Neutral
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:

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

Neutral

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 Neutral 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:

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

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

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

Negative 65.9 If implem Positive 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

Clinicians and their patients would support triaging only if it leads to improvements in timeliness of decision making and not delays. The danger lies in adding complexity and unintended consequence of subsequent delays....despite the intent of speeding access to medicines of higher clinical value.

Clinicians support improving timely access to medicines for all patients.... triaging will work with the appropriate framework and enhanced transparency.