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 organisat 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 What is your name? Delaine Smith Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Industry association / Peak body,Other [please specify] Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Other [please specify] - Text national cooperative trial group What is the name of your organisation? - My organisation is called: - Text Australasian Leukaemia & Lymphoma Group and Haematology Society of Australian & New Zealand Are you making feedback on behalf or your organisation? Your organisation 12 se 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 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. 1. Transparency, communication and stakeholder involvement 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 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, 4.3. Understanding the performance of health technologies in pr Please select the topics within the chapter(s) you would like to provide feedback on, 5. Future proofing 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. M 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 ac 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 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 25 If you would like to expand on your answer above you can do so below -Publish plain language summaries Plain Language Statements need to be simplified, visual diagrams infographics may assist 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 Dashboard is a great idea, particularly if horizon scanning is introduced. With the multi interfaces and interaction capabilities it will be good to be able to navigate a targeted query directly from a dashboard rather than a search function. This would need to have all components also explained in plain language and outline integration/application processes with other regulatory bodies. 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) If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework Positive

Positive

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

31

If you would like to expand on your answer above you can do so below -Develop an engagement framework

PICO workshops for clinician and HCP engagement are a good idea.

Opportunities to discuss the 'comparator' selection is very important.

In areas of unmet need and particularly in areas where there is an urgency to therapeutic intervention the comparator does need to be aligned and considered to what is the current Australian practice. This cannot always be termed "standard of care' as there may be

significant variation across Australia. An informed discussion with clinical experts to inform the comparator maybe highly beneficial.

Adopting a framework of continuous improvement and review is strongly supported.

Engagement framework should involve representation from state and federal health jurisdictions to ensure equity of access and to avoid "postcode prescribing".

If you would like to expand on your answer above you can do so below -Strengthen consumer evidence

Point 2 of promoting consumer input into clinical trials and reducing duplication is supported, and mechanisms to assess the effectiveness of consumer input need consideration, particularly in under-represented and rare disease areas i.e. proportionality and opportunity need to be taken in to consideration so as to not disadvantage the review of products and technologies designed to address rare conditions.

Currently there are strong mechanisms to ensure consumer input and co-design for research and clinical trials originating in Australia and funded by Australian funding bodies. The same mechanisms do not apply to trials sponsored by international entities. Proportionality

needs to be considered in this context and clear and accessible pathways to allow consumers to be supported, educated and trained to facilitate this should also be provided. This would need to prioritise training and explanation of the methodologies currently used by decision makers.

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)

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

If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making Solutions to address First Nations peoples effected by rare cancer need to be identified as there is already inequitable access to routine standard of care therapeutics.

If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submis sions and education

The solution proposed is supported and likely to have a significant impact in the assessment of HTA for First Nations peoples. This will need funding to support the implementation of the additional bridging resource. 39

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) 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

Positive

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

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

Some aspects of centralised data sharing are already underway through the ARDC HESANDA program, and this should be considered prior to recommendations on this matter.

Outcome data registries "some incentives to support health care professionals/services to participate and contribute to such data registries would be beneficial in order to enable the resources to better capture data from centre who are delivering the care, and monitoring Outcome data registries the patient outcomes. This program of work would be strengthened through mandatory reporting of highly specialized therapeutics in clinical use.

The ANZTCT Registry (formerly ABMTRR) is a good example of a mandated register to follow CAR T-cell recipients as a national effort federally funded so that all jurisdictions involved in CAR T-cell treatment can report cases for long term clinical outcome.

If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing
Inequity is commonly the result of differences in the implementation across the states and territories. It will be key to develop proposals that can be rapidly funded and equally supported by the states and territories. Rapid and productive engagement to enable increased opportunities will need a wide scale education program and agreement to consistency in the appointment of the workforce to manage this across the states and territories

45

If 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 Implementation of horizon scanning should increase state and territory engagement and overcome barriers between states and territories. Horizon scanning needs to be bidirectional (state to federal/federal to state) but also allow for a co-directional (State/State) for optimal market watch regarding new opportunities and implementation of funded HTA.

It is key for programs like HTA that are federally approved and are adopted quickly and without delay across the states and territories.

The delivery of a nationally cohesive approach to funding needs to be expedited, with agreed timeframes adhered to, ultimately facilitating equity of access to all Australians. The success of this model is highly dependent on state compliance and readiness to adopt federally funded/approved HTA, mechanisms to seek this buy-in early need to be addressed.

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?

Mostly address 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))

Positive

18 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 50

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

The proposal is supported, but will need funds for the resources to enable timely review under the model proposed.

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

Agree to streamlining the process for vaccines to more closely align with other pathways, and re-positioning ATAGI to advise to PBAC.

61

If you would like to expand on your answer above you can do so below-Expanding role of PBAC
Figure 5 is clear. The explanatory notes have not detailed how HTA that crosses over the public inpatient and outpatient setting will be assessed.

It will be important that once a HTA is approved under this proposed model that the jurisdictions adopt the model approved eg medicine approval delivered to public inpatients. It would be good to understand how the co-dependant review will operate to ensure that medicines and services are streamlined. Will it be solely dependent of the sponsor of either to make the request, will horizon scanning be operationalised to search for these alignments in co-dependency etc';

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 proposal if implemented will need to ensure diversity in expertise sourced for the review of speciality areas

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?