. Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Pharmaceutical / Medical technology company hat is the name of your organisation? - My organisation is called: - Text UCB Australia Pty Ltd Are you making feedback on behalf or your organisation? Your 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 Streamlining and aligning HTA pathways and advisory committees, 2.2. Proportionate appraisal part 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. 3. Methods for HTA for Australian government subsidy (technical methods) 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
18 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, 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 Strongthen 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 the If you would like to expand on your answer above you can do so below:

Clarification should be provided on how stakeholders would be incentivised to participate in HTA processes. 23.1 nted, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language sum 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 Neutral 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 rela ostly address the issue(s) If you would like to expand on your answer above you can do so below The pharmaceutical industry should be participant in the development of the framework. 29.1 ed, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engage If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence Positive 31 Tyou would like to expand on your answer above you can do so below -Develop an engagement framework
We support the development of a consumer engagement framework to ensure that the voices of those directly impacted by the technology are part of the decision-making process. We hope this will lead to health technology assessments that reflect real-world needs and priorities, and equitable outcomes. Consumer input can also reveal practical considerations of considerations of her missed by technical experts, such as usability, accessibility, and potential social impacts. In the final options paper, the pharmaceutical industry should be identified as a stakeholder who should an active role in the co-design of this framework as we have many insights to share from our technical experience in clinical trials and compassionate access programs. 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) If you would like to expand on your answer above you can do so below:

We strongly support equitable outcomes as a pillar of the Options paper with the inclusion of First Nations people's involvement in HTA. We would have also liked a stronger call-out to other marginalised groups including those with rare or ultra rare conditions.

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 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. 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) We fully support a nationally cohesive approach to HTA for technologies. While the proposed options seem to work towards this goal, the proposals could be strengthened by removing the Federal/State Government co-funded model to have sole Commonwealth funding, with centralised HTA. This would ensure equity between Australia's States and Territories, rather than 'expostcode lotteries'. Collaboration with states and territories will continue to be important for these products in order to ensure timely and coordinated implementation. 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 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 If implemented, overall wo public hospital inpatients) d, 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 Negative 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? ddress some but not most of the issue(s) 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)) Don't know 48.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine path Positive If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC

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

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 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? Penny Lovell

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Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))
The impact of this option is unclear due to the lack of specific information. While this option is welcomed in principle, more clarity on the key requirements needed to access this pathway and on the expected value for money of these therapies is needed. Similarly, the option should not change the current approach to ultra rare disease funding in terms of expected data requirements. A clarification that these drugs are not supposed to meet any predetermined cost-effectiveness thresholds should be included.

60
If you would like to expand on your answer above you can do so below -Vaccine pathway
While streamlining the pathway should be a positive approach, the final proposal needs to ensure that the future value of the vaccines is appropriately captured (i.e. reducing the discounting rate).

63
Takking all Options within this continue 2 approach approach approach and a second.

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

65.1

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

Positive
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions
Positive
65.2
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)
Don't know
65.3
If implemented overall would the cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)
If implemented overall would the cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)
If implemented overall would the cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)

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

FOSITIVE
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