Response

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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

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What is your name?

Ross McLeod

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Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice

Pharmaceutical / Medical technology company

8.1

What is the name of your organisation? - My organisation is called: - Text

AstraZeneca

9

Are you making feedback on behalf or your organisation?

Your organisation

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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

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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

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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

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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

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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

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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 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 AZ Consultation 1 Submission highlighted that enhancing opportunities for stakeholders to become involved in the assessment process with the aim of reaching consensus on modelling structure, assumptions, addressing uncertainty and managing risk during the evaluation process would increase the chance of a positive PBAC recommendation first time, and reduce the patient access gap. This would increase the efficiency of the HTA process. An improvement in process transparency, co-ordination, and engagement with sponsors during the post-PBAC PBS listing process would also increase speed to patient access.

Stakeholder feedback during HTA Review Consultation 1 stressed that consumer occurs late in the process, involves specific consumer representatives on Committees and the process has not been co'designed with consumers. AZ believes implementation of HTA Committee proposed Options to improve transparency, communication, and stakeholder involvement in HTA would be very positive in achieving HTA review outcomes and have limited unintended outcomes. Any changes should retain current positive facets of the HTA process such as confidential pricing and special agreements that permits Australians access to innovative medicines

23.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries

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

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)

29.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework

Very positive

29.2

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

Very positive

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

Very 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

Very positive

39

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?

Mostly address 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

Positive

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)

Positive

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)

The AZ Consultation 1 submission highlighted that treatments like cell and gene therapies and COVID-19 treatments require multiple levels of government funding to support uptake and current processes are inefficient. AZ concurs with the HTA Committee that coordinated horizon scanning would help the Commonwealth and State and Territory governments plan for disruptive technologies, central standardized data sharing systems need to be developed and road maps could be prepared to support the implementation of high-cost therapies requiring state and federal funding. Case managers could be established in DoHA who specialise in cooperation across multi-jurisdictional pathways. They could be made available during pre-submission meetings, and at other points of the HTA process to help shepherd complex submissions and ensure timely access. They would work with Sponsors to facilitate meetings with the relevant state authorities to coordinate funding mechanisms. Further detail about the nature of all stakeholder access (outside of government) to centralised databases is required

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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:

Delays due to complex assessment pathways are a major constraint on HTA assessment efficiency, particularly for co-dependent technologies and rare diseases which require review by multiple committees. PBAC and ATAGI processes could also be streamlined to improve the time to vaccines access and a consolidated pathway could be developed for cell and gene therapies. The Options paper noted that some stakeholders felt new medicines that are non-inferior to alternatives do not require a full HTA and could be assessed over a shorter timeframe.

AZ concurs and believes the outlined options mostly address these issues. AZ supports the view that the level of appraisal should be risk calibrated and be flexible and that early resolution of PBAC identified issues in submissions offers a solution to reduce the number of resubmissions. AZ believe that all submissions should be able to seek early resolution and establishing restrictions around entry to this pathway would unnecessarily limit the potential positive impact of the approach.

Imposing limits around the number of resubmissions could have the unintended consequence of slowing time to medicines access. The linking of an abbreviated cost-minimisation pathway to price reductions would also have a very negative impact on the time to patient access, the choice of therapies available and numbers of treatments available to Australian patients

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
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))
LSDP eligibility does not cover innovative medicines that improve quality of life and address or delay progression to disability, in addition to those that extend life. The Inquiry into New drugs and Novel Medical Technologies highlighted that there is a need to elevate quality of life in the consideration of funding new medicines for rare diseases. As outlined in our Consultation 1 submission, AZ supports this recommendation and believe that a statement of rationale for the LSDP be published that reflects broader eligibility of access to the program, along with guidance on value-for-money consideration. The cost-effectiveness of treatments for rare diseases can be highly uncertain because of rare disease natural history data gaps, limited availability of comparator efficacy data, and small patient populations which limit the statistical analyses of clinical studies. The development of value for money criteria suggested in the Options paper should reflect the data limitations associated with rare diseases. An LSDP sub-committee should be established as part of PBAC to consider submissions. The program should remain separated from the PBS

61

If you would like to expand on your answer above you can do so below -Expanding role of PBAC
AZ believe that the proposed consolidation of assessment functions could have a positive impact on improving HTA evaluation efficiency. The approach for having one committee should be investigated for co-dependant and cell and gene therapies. The pathway for vaccines could be streamlined by removing the requirement for Sponsors to receive ATAGI advice prior to submission. AZ supports the option that the PBAC Economic Sub-Committee (ESC) could be supplemented by the appropriate ATAGI representatives to provide formal (ESC + ATAGI) to provide advice to PBAC. AZ agree with the Options paper that such changes should not preclude the ability for Sponsors to seek early advice from ATAGI or remove any of functions of ATAGI. A unified approach could include a single HTA advisory committee of necessary experts, which is augmented with additional permanent members, or topic specific groups that provide advice. It would add significant workload to the Committee's already very heavy agenda. Therefore, this option would need to include increased resourcing and increased length of the Committee's meetings from the current length of 3 days

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?
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
Very positive

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

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
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
Positive

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
Very positive

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
Very negative

65.9