

**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

3  
**What is your name?**  
 Andrew Giles

7  
**Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice**  
 Patient or consumer (or representative organisation)

8.1  
**What is the name of your organisation? - My organisation is called: - Text**  
 Neurological Alliance 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, 1.3. First Nations people involvement and consideration in HTA, 1.4. State and territory government collaboration 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, 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. 4. Health Technology funding and purchasing mechanisms and decisions**  
 4.1. Approaches to funding or purchasing new health technologies

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, 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?  
 Mostly address the issue(s)

22  
**If you would like to expand on your answer above you can do so below:**  
 The NAA is pleased to see the intention to:  
 'cPublish plain language summaries of the various stages of HTA processes  
 'cMake improvements to the HTA webpage including development of a dashboard  
 These improvements should include some indication of the timeline for listing new or amended medicines on the PBS including any interim arrangements in place between the recommendation to list and the listing itself. Ultimately, consumers are most interested in when the new medicine can be prescribed and is available in the pharmacy.  
 It will be important to develop key performance indicators to ensure these improvements are aligned to the goals of the HTA review, most importantly, to reduce time to access.

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)

28  
**If you would like to expand on your answer above you can do so below:**  
 The NAA supports all of the proposals in this section as they will strengthen consumer evidence and input into HTA processes.  
 It is essential that the proposed framework is co-designed with consumer representatives.  
 The NAA is concerned about:  
 'cLack of any indication of funding or resources for consumer bodies, to ensure they can engage equitably, especially for those smaller peak bodies representing rare conditions  
 'cLack of any indication of providing training for consumers "" HTA processes are necessarily complex, consumers need to be trained to engage effectively with the pharmaceutical industry and Department of Health representatives who have expertise and resources at hand  
 'cCommercial-in-confidence issues "" these are often a barrier to transparency and should be addressed through the framework process

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)

34  
**If you would like to expand on your answer above you can do so below:**  
 The NAA supports all of the proposals in this section that are intended to lead to improved outcomes for First Nations people. Once again, KPIs will need to be developed to measure progress.

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?  
 Address some but not most of the issue(s)

40  
**If you would like to expand on your answer above you can do so below:**  
 There is a need to significantly improve the relationship between Federal and State governments/regulators (possibly through the National Health Reform Agreement (NHRA)) to ensure there is more clarity around improved data sharing arrangements and speeding up/alignment of approval processes and funding arrangements, especially the funding of specialised therapies.

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

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)

47  
**If you would like to expand on your answer above you can do so below:**

The NAA supports proposed measures to reduce delays and increase timeliness and equity in access for patients.

The NAA is pleased to see:

'Recognition of the need to create more efficient timelines

'Recognition of the need for clarity of pathways, especially for new, innovative technologies

'Proposal to streamline processes through a single entry point, though a concern is that this may become unmanageable and lead to further delays in achieving timelines. This proposal for expansion, will need significant investment to ensure it is appropriately resourced given the current workload of PBAC members.

NAA members representing rare disease groups, including Mito Foundation, are cautious about the proposal to integrate the life-saving drug program (LSDP) decision-making process into the PBAC process.

It is essential that the existing guidelines and clinical expertise - a strength of the existing LSDP process - be retained, while still realising the timeliness benefits of a single assessment process.

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

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))**

It is essential that the existing guidelines and clinical expertise - a strength of the existing LSDP process - be retained, while still realising the timeliness benefits of a single assessment process.

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?**

Mostly address the issue(s)

64

**If you would like to expand on your answers above you can do so below:**

The NAA supports the proposal to develop a disease specific common model, which has the potential to benefit a number of conditions represented by the NAA.

65.1

**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)**

Positive

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?**

Mostly address the issue(s)

78

**If you would like to expand on your answer above you can do so below:**

The NAA supports the proposals in this section though in relation to increased early stakeholder input there is a need for equity, especially where relationships have not been established between peak consumer bodies and sponsors.

In supporting these proposals, we reinforce the need to undertake this work while not creating further delays. Early engagement with relevant consumer groups and expert clinicians, particularly as a result of horizon scanning, is a key means for this to be accomplished.

79.1

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased early stakeholder input**

Positive

79.2

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased transparency for stakeholders**

Positive

79.3

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

Positive