

Response
2 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? Lucas Tocchini
7 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 Biogen
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,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,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,5.5. 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? Address some but not most of 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 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 Neutral
26 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 Biogen support transparency in the process but questions whether a dashboard would be useful for patients and consumers. This would most likely be utilised by industry itself. It would need it be a high level summary consumers and patients to have any benefit.
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 Positive
31 If you would like to expand on your answer above you can do so below -Develop an engagement framework Biogen supports the development of an engagement framework, as it bring consumers and patients closer to the process.
32 If you would like to expand on your answer above you can do so below -Strengthen consumer evidence Biogen is particular supportive of including consumers/patients in the co-design process of enabling systems, pathways, evaluation, and research to optimise access and use of Real-World Data (RWD) in HTA. Consumer involvement is needed in increase confidence, awareness, and acceptance of RWE in HTA. Consumer and patients should be part of the process of defining criteria that would satisfy the "for public benefit." There should be a commitment from government to facilitate greater use of linked datasets (closely related to 1.4)
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 Neutral
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 Neutral
37 If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making Biogen broadly supports the partnership of First Nations People in decision making
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 little or none 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 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 Neutral
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) Negative
43 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 This will facilitate greater utilisation and access of linked datasets, which is particularly important to rare and ultra rare diseases.
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) Biogen agrees with the Medicines Australia suggestion that the best way to simplify access pathways for these products is to have them fully federally funded, with all the HTA also done at the federal level. In order to allow for the holistic consideration of product costs (therapy plus delivery), the States and Territories would need to provide a full articulation of the costs of product delivery, to be included as inputs into the HTA process from the beginning.
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)) 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 Negative
50	Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP)) Biogen support the the streamlined pathway for drugs for ultra-rare diseases. The PBAC advisory role to recommend listing of a medicine on the LSDP must be made to the Minister and the CMO as the Minister's delegate as in the existing framework
60	If you would like to expand on your answer above you can do so below -Vaccine pathway Biogen supports a streamlined pathway for vaccines, provided the ATAGI advice remains sufficiently broad, including advice on the program, clinical evidence and inputs to the economic model, and sufficiently robust. There will be need for transparency in how this advice was considered by the PBAC.
61	If you would like to expand on your answer above you can do so below -Expanding role of PBAC This options would be supported assuming that it would speed up decisions on co-dependent submissions
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 Not required. This seem overly simplistic to only have one HTA committee given the different complexities of the respective pathways (i.e. medicines, advanced therapies, blood and blood products)
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 little or none of the issue(s)
65.1	If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager Negative
65.2	If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions Neutral
65.3	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
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 Negative
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 Negative
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 Negative
65.6	