The Department may, at its discretion, publish part or all of the information pro the submission. All personal contact details will be removed prior to publishing. Yes, I consent to my identified submission being published ition 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 auth What is your name? Jane Adams Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice Pharmaceutical / Medical technology company What is the name of your organisation? - My organisation is called: - Text Novartis Pharmaceuticals Aus 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 decisi 4.1. Approaches to funding or purchasing new health technologies,4.3. Understanding the performance of health technologies in practice 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 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)? - Publish plain language summaries Don't know 23.2 ed, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including develop 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? Address some but not most of the issue(s) If implemented, 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 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 you would like to expand on your answer above you can do so below: Novartis recognises the importance of considering the impact of health technologies on Aboriginal and/or Torres Strait Islander peoples. If a health technology is identified as potentially benefitting these communities, seeking advice from representatives of Aboriginal and Torres Strait Islander community-controlled health services early in the process will ensure that that the voices and needs of our First Nations Peoples are included. It is important that this perspective is considered by the PBAC in its deliberations as frequently specific evidence within this population. Will not be available for any submission. In addition, the valuation of any impact from a health technology needs to consider the ability to narrow the health inequality gap that is so harmful to improving longer term outcomes in these communities. 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 Don't knov 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) If you would like to expand on your answer above you can do so below: This section addresses some of the issues in relation to the relations to the relationship between state and federal funding however, a federally funded scheme for these therapies which do not fit within the purview of the PBS is required and would reduce the need for negotiation and increase the time to

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 41.3

41.5 [finplemented, 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) delix public hospital inpatients)

Don't know

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

Inclusion of Sponsors within any data sharing activities with Federal and State and Territory governments for health technologies which are being evaluated through NHRA and for those outside the NHRA process needs to be included in any proposal.

If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing
Inclusion of Sponsors within any consultation and work sharing with Federal and State and Territory governments for health technologies which are being evaluated through NHRA and for those outside the NHRA process needs to be included in any proposal.

up on 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).

A federally funded and managed program is required to fund high-cost technologies which do not meet PBS or MSAC criteria. If it is to remain in the current system, a clear process involving hospital costs and process must be agreed before the evaluation process. This mu sts and process must be agreed before the evaluation process. This must also be independently reviewed in the post-market period. A clear process that independently evaluates hospital processes and associated costs should be agreed to in advance of the evaluation process. This process would also apply in any post-reimbursement review process.

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?

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

All of the suggestions presented involve the development of new processes or require investigations with little detail around what these new processes will be, the timelines involved in their development and implementation and the involvement of industry in this. As such it is not possible to support these options until additional detail is shared.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine pathway Don't know

48.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC
Don't know
48.4
fi 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
Don't know
65.1

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

Very negative

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions
Don't know
65.2

bb. 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 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

Atternative option 1: introducing an optional resolution step before RTA 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

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

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

Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised

Don't know

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

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