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?
Anna Schulze
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
CSL Limited
9
Are you making feedback on behalf or 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
1.2. Consumer, clinician and other stakeholder engagement 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
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
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?**
Address some but not most of the issue(s)
28
If you would like to expand on your answer above you can do so below:
CSL welcomes the intention to increase stakeholder engagement with the HTA process by developing a framework to include consumers, clinicians and other stakeholders more consistently throughout the HTA processes (1.2.1). However, we are concerned that the framework outlined in the proposal does not specifically address the inclusion of submission sponsors. It is also unclear how ongoing dialogue between the sponsor, submission evaluators (clinical and economic) and advisory committees (e.g. ATAGI) will be incorporated in the framework.
29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework
Positive
29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence
Don't know
31
If you would like to expand on your answer above you can do so below -Develop an engagement framework ĉATAGI and PBAC must allow sponsors the opportunity to formally engage with them during the assessment process. 'ĉThe proposed engagement framework should include processes for ensuring that consumer feedback is obtained equally for submissions in disease areas with no readily identifiable patient organisation or peak body of clinicians, as well as those where a recognised patient organisation exists.
32
If you would like to expand on your answer above you can do so below -Strengthen consumer evidence ĉAny new guidance regarding the inclusion of RWE and preferred methodologies must be developed in close consultation with industry, to ensure that the proposed requirements are feasible and realistic. 'ĉA transition period is required for the adoption of any new guidance regarding the inclusion of RWE in HTA submissions. 'ĉAdditional evidence requirements for RWE should be aligned with those of other jurisdictions.
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:
CSL supports state and territory government collaboration with federal HTA agencies to centralise and facilitate the sharing of utilisation and outcome data, and believes that this will benefit the Commonwealth, patients, clinicians and sponsors. An immediate option for reform could be the linkage of the Australian Immunisation Register (AIR) to hospital admission data, which would allow monitoring of vaccine effectiveness in real time.
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
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
ĉProposed initiatives to centralise sharing of utilisation and outcome data must be developed in consultation with industry, to ensure that the data collected are useful, informative and fit for purpose.
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 proposed reform option currently only specifies high-cost Highly Specialised Therapy (HST's) delivered to inpatients in public hospitals. However, each of the points for reform could also be applied to HSTs that will be delivered to outpatients and are jointly funded by the Commonwealth and state and territory governments. CSL strongly supports an expansion of this option to explicitly include all high-cost HSTs, delivered in all clinical settings, such as near-market gene therapies to be funded through the National Blood Authority (NBA). This would help to ensure equitable, timely and a cohesive, national approach to HTA for all high-cost HSTs. Recommendation: 'ĉReform option should explicitly include all high-cost HSTs, delivered in all clinical settings, such as near-market gene therapies to be funded through the National Blood Authority (NBA).
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)
47
If you would like to expand on your answer above you can do so below:
CSL supports the overarching goal of a 'œsimplified single entry HTA gateway' (i.e., a single submission to PBAC for NIP listing, with ATAGI and PBAC evaluators collaborating to develop a single assessment report) but believes that the option to seek pre-submission advice from ATAGI must also be retained. Notwithstanding our support for alignment of the evaluation processes for vaccines and pharmaceuticals through the single entry HTA gateway proposal, we maintain that there are some important considerations unique to the evaluation of vaccines that must be accommodated within a new amalgamated process. It is unclear how and when during the process the PBAC and ATAGI evaluators will interact, and whether this is via individual collaboration or committee discussion to gain consensus. It is important that the opinions of the PBAC and ATAGI evaluators are able to be presented independently and given equal consideration in the evaluation 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

60

If you would like to expand on your answer above you can do so below -Vaccine pathway

ĊThe nature and timing of interactions between the PBAC and ATAGI evaluators, and the evaluators and sponsors, must be clearly defined within the new amalgamated PBAC/ATAGI process.

'ĊPlanned interactions must allow for more frequent opportunities for discussion and resolution of questions between the evaluators and sponsors.

'ĊExperts and evaluation groups selected to evaluate vaccine submissions and provide advice to ATAGI, PBAC and ESC must have relevant expertise in the specific disease area and be highly skilled in dynamic modelling required for infectious diseases.

61

If you would like to expand on your answer above you can do so below -Expanding role of PBAC

This option needs significantly more clarity and detail to fully understand the implications. In this section, issues related to a broad range of situations including advanced therapies (including cell and gene therapies), co-dependent technologies, medicines for ultra-rare conditions and vaccines are discussed. For example, it is unclear how the expansion of the PBAC HTA advice would affect therapies traditionally funded through the NBA such as blood and blood-related products, and gene therapies funded through the NHRA or NBA.

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

Reform of the HTA pathways for appraisal and funding of blood products should be included in the recommendations of this Review and patients who need blood products should have comparable transparent and timely access to therapies inline with patients of non-blood products.

For all health technologies, HTA pathways, unified or not, should be transparent, equitable, with established timelines and published decisions.

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)

64

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

CSL supports in principle the triaging of vaccine submissions and their evaluation being proportionate to the level of risk identified, provided that addition of a triaging step does not itself add time and complexity to the HTA process.
Expedited evaluation of new vaccines that represent a low fiscal risk to the Commonwealth would be beneficial to patients by allowing them faster access to new vaccine technologies.

65.1

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

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)

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

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

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

Positive

65.9