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?

Daniel Tan

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

Roche Products Pty Ltd

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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

1.1. 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

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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

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,5.4. 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?

Address some but not most of the issue(s)

22

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

Roche supports increased consumer input, given the limited current consumer input into HTA deliberations. The increased input will improve the person-centredness of decision-making, one of the key objectives of the HTA Review.

Overall, Roche supports the Options put forth in Chapter 1.1. Roche recognises a significant level of co-design and creation, inclusive of industry, is required to expand on the specifics of the options to ensure that the issues are more completely addressed.

Roche reiterates that it should be the case that the input from stakeholder involvement anticipated to be collected during the HTA evaluation process, sits within existing timelines and does not slow down existing processes, which would delay patient access.

Further comments specific to each subheading have been provided below.

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

25

If you would like to expand on your answer above you can do so below -Publish plain language summaries

Roche supports in principle and would also expect a reasonable level of multi-stakeholder co-design to ensure that the resultant plain language summaries would meet the issues articulated.

Roche notes;
â—Process co-design would include an intent to ensure an appropriate level of detail is provided to ensure stakeholders have sufficient information to enable their input in the HTA process.
â—Sponsors continue to retain authority to exclude commercial-in-confidence information, of which, the sponsor is the determinant of what is commercial-in-confidence.

For summaries informing PBAC committee deliberations, it would be expected that sponsors would review the plain language outcome and provide comment similar to the MSAC consumer summary. It is important to note that the views reflect that of a HTA committee only, and are not necessarily a reflection of the performance of the technology.

For summaries of HTA pathways, consideration should be given to build on the work of organisations such as the Patient Voice Initiative (https://www.patientvoiceinitiative.org/patient-experience-and-participation/) that have extensively consulted in patient groups to create layperson language guides.

In the interest of continuous improvement, as part of the multi-stakeholder co-design process, a reasonable review timeframe would be agreed upon to re-convene stakeholders and re-assess whether the implementation has met the original intended objectives.

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

Roche supports in principle, given the anticipated benefit of improving consumer understanding of a technology progressing through the HTA system, and to ensure HTA system performance assessment. Roche would expect multi-stakeholder consultation and co-design to ensure that the resultant output is anticipated to meet the issues articulated in the Options paper prior to a pilot rollout.

Roche notes that:
â—Consultation would be required to provide key regulatory dates which may not already be in the public domain, and to ensure that current commercial in confidence information is respected. Whilst TGA publishes the acceptance date for 'œPrescription medicines under evaluation', but does not currently capture all technologies (e.g. new presentations, biosimilars or generics) nor publishes the date of sponsor submission.
â—Consideration needs to be given if there is discordance in overseas decisions and the implications for the consumer public. Roche has had the experience of products/indications which have been registered by the FDA, EMA and MHRA which have not achieved regulatory approval in Australia.
â—Segmentation and/or public exportation of key dates and dashboard fields enable performance analysis.

Roche does note these improvements on improving reimbursement timelines. However, future benefits of a well operationalised dashboard will analyse the impact of introduced reforms, past, present, and future.

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:

Roche supports the development of a consumer engagement framework and the proposed mechanisms for strengthening consumer evidence collection and utilisation. The increased input will improve the person-centredness of decision-making. Roche acknowledges the work of the HTA Consumer Consultative Committee (CCC), the Department's CEEU and the Co-design working group of the HTA CEEU and the Patient Voice Initiative that has been progressed to date.

Overall, Roche supports the Options covering Chapters 1.2. Roche recognises a significant level of co-design and creation, inclusive of industry, is required to expand on the specifics of the options to ensure that the issues can be more completely addressed.

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

Neutral

31

If you would like to expand on your answer above you can do so below -Develop an engagement framework

Roche has the following comments:
â—The needs of future patients are considered throughout drug development at Roche. Patient reported outcome measures (PROMs) are commonly captured in the majority of our clinical trials,
â—Locally, Roche collaborates with and provides support to patient groups in Australia (applying the Principles of the Medicines Australia Working Together Guide and our global Working with Patient Groups '" Good Practice Guidelines).
â—Globally, Roche obtains early and systematic input by way of patient community councils to embed the patient perspective in what the organisation does; topics include the need for insights, identification of unmet needs (including therapy and separate therapy) and defining and co-creating solutions. Central to this is a better understanding of the patient-reported experience.

32

If you would like to expand on your answer above you can do so below -Strengthen consumer evidence

Roche recognises the importance of providing further guidance and a curated list of methodologies around consumer evidence and RWE. However, increasing the acceptance of this type of data as a mechanism for improved decision-making is even more critical. Roche notes that more formal structured methods of elucidating patient preferences could be valuable for decision-making, but would require a level of clarity to determine the importance in decision-making prior to committing resourcing, given the involvement and requirements for local execution in Australia that would need to occur concurrently with submission preparation.

Methods to improve the representativeness and generalisability of patient aspects (beyond QALYs) should be progressed once the gravity of these aspects in the decision making process has been agreed and quantified.

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:

Roche is supportive of improving First Nations people's involvement and consideration in HTA, and establishing dedicated resources to support HTA education and submission development. Roche believes that First Nations people and their representatives are best placed to comment on these proposals, and Roche is willing to work in partnership with First Nations people and their representatives on the proposed options, when and where appropriate.

Given the expertise the health technology industry can contribute to this option, consideration should be given to its involvement in supporting submission development, as well as, potential arrangements for repurposing and proactive submission requests.

Roche notes a potential future role for the proposed National Aboriginal Community Controlled Health Organisation (NACCHO) and Medicines Australia (MA) Health Equity Collaboration in furthering the options to address the identified issues.

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

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

Positive

37

If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making

In Roche's experience working with NACCHO, establishing a partnership with First Nations peoples in HTA (and other) decision making processes is a positive step towards supporting self-determination and the widely endorsed principle amongst First Nations peoples of "Aboriginal health in Aboriginal hands".

Guidance particularly with the priority list of therapies and indications, areas of unmet clinical need and gaps in funded access, and clearer pathways for priority list, repurposing and proactive HTA submissions, will provide direction for the health technology industry in supporting the First Nations peoples partnership in HTA decision-making.

38

If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submissions and education

Building expertise and providing dedicated resources for HTA submissions will assist the health technology industry in partnering with First Nations peoples representative organisations in developing HTA submissions, which address identified areas of unmet need and gaps in funded access for First Nations peoples.

Consideration should also be given to extending this dedicated resource to educate other patient representative organisations to encourage engagement in the HTA process, and support those who do not have the expertise, nor the resources, to develop HTA submissions in their own capacity.

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)

40

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

The Evohealth April 2023 report on CAR T''cell therapies (Evohealth 2023. CAR T-cell therapy: Is Australia ready, willing and able. https://www.evohealth.com.au/reports/car-t-cell-therapy-is-australia-ready-willing-and-able/) indicated that some State and Territory Governments received inadequate notice that a CAR T-cell therapy would be recommended for public funding by the MSAC, and with no funding allocation set aside, faced pressure to divert resources to cover 50% of the cost of delivering CAR T-cell therapy to eligible patients.

While separate from the Terms of Reference for this review, differences in funding mechanisms among cell and gene therapies are driving an inequity in patient access. This could be addressed by allocating 100% of funding from the Commonwealth for all HSTs in the next NHRA. By doing so, this would reduce the requirement for State and Territory Governments to absorb the cost of HSTs within existing hospital and state health budgetary expenditure. There are opportunities to use existing reimbursement models (ie. sponsor and Commonwealth price and risk-share arrangements) and data infrastructure which currently apply to the PBS, that could reduce contractual requirements pertaining to the cost of the HST. This would simplify the application and negotiation framework, with the State and Territories still equitably contributing to support patient access through the provision of infrastructure and the workforce needed to deliver these treatments.

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

Roche notes that Industry must be able to access the utilisation and outcome data from the proposed central standardised data sharing system to avoid information asymmetry.

As noted earlier, development of a central standardised data sharing system for utilisation and outcome data would be more efficient than different separate databases for each new indication or separate databases in each state/territory.

44

If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing

Industry consultation and input on NHRA issues pertaining to HTA is essential due to the potential overlap in timing of key considerations informing the future funding of both the HST itself and the implementation of the HST.

It is noted that consultation with States and Territories already occurs during the HTA triaging, this was an initiative recommended in the 2020-2025 Addendum:

'œGreater transparency and improved consultation processes so all jurisdictions can engage and be informed in MSAC decision making process' (Huxtable 2023, https://www.health.gov.au/sites/default/files/2023-12/nhra-mid-term-review-final-report-october-2023.pdf).

Work sharing during this engagement in MSAC processes is also evident, as documented in the Public Summary Document for MSAC application 1625, where a similar technology was used in public hospitals, so that costing data could be provided.
Roche supports an ongoing role of the Department of Health and Aged Care in annually producing the '˜Emerging health technologies' report undertaken for the Health Technology Assessment Policy and Methods Review. We note that the Report could have been provided to sponsors (where their technologies have been cited in the report) for comment as further input may have been able to be provided with respect to future HTA or implementation issues prior to its release. Consequently, this report's impact could have been magnified to trigger meaningful action for impacted stakeholders.

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)

Prioritising the actions from the National Health Reform Agreement Addendum (NHRA) is critical to improved inter-governmental collaboration.

The current pathway for Highly Specialised Therapies (HSTs) is challenging for governments, consumers and sponsors. The geographical inequity and delays in patient access to new HSTs, as well as, the funding arrangement complexities must be addressed via the NHRA process as a priority.

As noted earlier, this may ease State and Territory Government budget pressures to cover costs for treatments in the short time and delineate between issues pertaining to the value of the HST (ie. cost of the HST), and the funding and valuation behind the implementation, including administration of the HST and subsequent patient monitoring. State/Territory input is important for informing the broader value discussion and to identify system (i.e. infrastructure/workforce) implications, however, this must be conducted in a manner that does not prolong the HTA process, and further delay patient access.

Within the scope of the review, inequities across states and territories would be partly addressed by these measures particularly (2) establishing timeframes for the implementation of HSTs and (6) initial implementation planning when combined with horizon scanning, which can be shared with, rather than conducted by, the states and territories.

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?

Don't know

47

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

Based on the information provided within each of the reform options Roche believes that with the level of detail provided, it is unclear how either of the options would address the outlined issues that relate to them. To fully consider the impact on all stakeholders, further detail and development of the reform options should be shared.

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))

Don't know

48.2

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

Neutral

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

Neutral

50

Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))

Roche supports, in principle, arrangements that simplify process and consolidate assessment by multiple sequential Committees. Reducing double handling, without extension of the evaluation process, and thereby accelerating access for patients, is supported in principle.

Roche is supportive of a streamlined pathway for the consideration of products under the LSDP, but only on the basis that double handling is reduced, and access for patients is accelerated. Consolidation of HTA committees should not result in the removal of key programs; Roche does not support the removal of the LSDP as it remains a vital access program for patients who require life-saving treatments in rare conditions which are not considered cost-effective enough to list on the PBS.

Further scoping and consultation of the PBAC's remit is required given that:

'œEntry to the existing LSDP pathway requires that a drug is not cost-effective but does not explicitly require consideration of value-for-money'

yet the proposed Option states:

'œPBAC advises the Minister on key requirements to enable listing on the LSDP based on a comparative assessment of effectiveness and cost.'