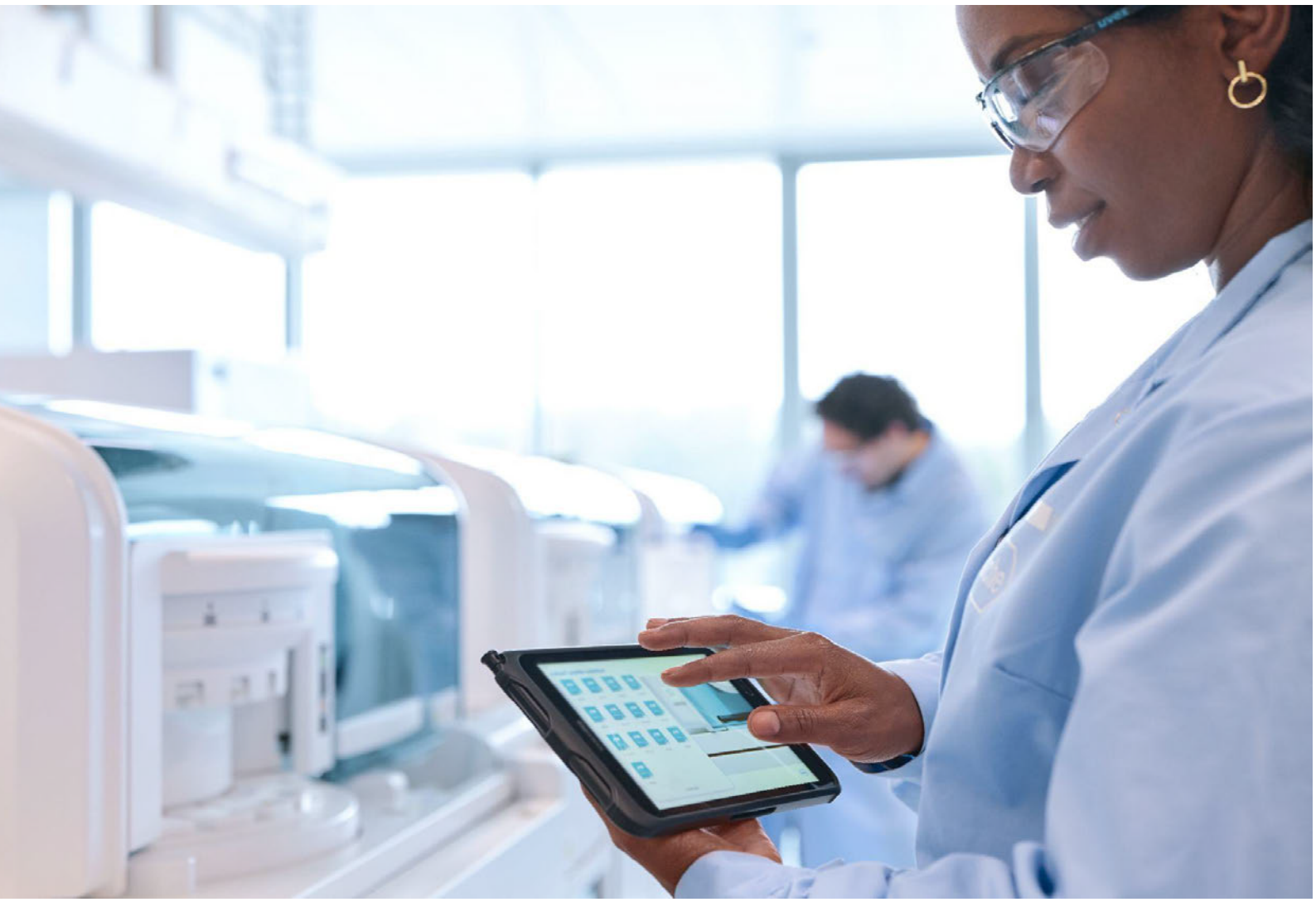
Roche Response to the HTA Policy and Methods Review

Consultation 2: February 2024



About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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Summary

Roche welcomes the opportunity to comment on the Options Paper provided for consultation as part of the Health Technology Assessment (HTA) Policy and Methods Review. Roche welcomes the Options Paper and acknowledges the substantial work of the Reference Committee throughout the Review, as well as a multitude of stakeholders who have tirelessly and diligently provided input into the Review.

Roche believes that this is a pivotal review, which will shape how Australians access new health technologies and medicines into the future, and will ensure the system can be adaptable to the range of innovations being developed.

Roche broadly agrees and supports the Medicines Australia response; the Roche response intends to show support or provide further context and/or considerations for the next phase of Option development and finalisation. Roche recognises that the Options represent a first step to modernise our HTA system, with the important aim of putting Australian patients at the centre of the process, and delivering faster access to medicines.

No single option will achieve the necessary reforms on its own. The options that Roche supports work synergistically and need to be implemented together to achieve the desired reform, complemented by a commensurate mindset shift towards investing in healthcare, and a more balanced approach to decision-making.

Roche has viewed the options through the lens of faster access, patient/clinician choice and value recognition of innovation and anchored to the Summary of Recommendations submitted by Roche as part of Consultation 1 of the HTA Policy and Methods Review.

Overall, as noted in our response, many of the proposed options lack sufficient detail or implementation approach to make an informed judgement on their impact. Roche suggests further substantive consultation and co-design prior to considering implementation is needed.

A number of options are outlined that would have a detrimental impact on patients' timely access to new medicines which Roche does not support. In addition, as each option is presented in isolation, with little cumulative impact analysis outlined, there is a risk of unintended consequences such as increased assessment complexity and red tape which may lead to slower patient access to innovative medicines.

Ensuring that there is broader value recognition of the benefits that medicines access provides beyond the direct health impact needs to continue to be explored. The simplified rationale to limit the inclusion of these broader elements in HTA as presented in the options paper requires further discussion and consideration. The significant additional societal benefit that is being garnered from medicines needs to be better recognised by the Government.

Exclusion of broader societal benefit results in the continued disfavouring of health technology investment due to a narrower sector-only perspective relative to the impact of other government decisions outside of health, which are justified using cost-benefit analyses which can take a broader perspective

In the Options Paper, there are a multitude of options for HTA methods which represent further development and guidance to present information matters in a HTA submission. However, we continue to highlight that more HTA guidelines alone do not fundamentally enable faster access to medicines in the absence of increased acceptability, especially in the context of utilising clinical or economic analytical methods that are largely used and acceptable in other HTA jurisdictions, and in the absence of a mindset shift how evaluation approaches need to consider the broader societal benefit of medicines.

Roche looks forward to ensuring that the next phase of the HTA Review builds towards the aims of the 2022-2027 Strategic Agreement; reducing the time for Australian patients to access new health technologies whilst maintaining the attractiveness of Australia as a first-launch country.

It is essential that our HTA assessment processes keep pace with rapid advances in health technology, and barriers to access are minimised to continue to build on Australia's reputation as a world leader in providing patients access to affordable healthcare.

Considerations

As noted earlier, Roche has viewed the options through the lens of faster access, patient/clinician choice and value recognition of innovation. Roche aimed to address matters pertaining to:

- Whether the proposed options achieve the intended outcome, with a focus on *Reducing the time for Australian patients to access new health technologies whilst maintaining the attractiveness of Australia as a first-launch country;*
- What the impact on stakeholders is, with a focus on *patients, clinician choice, society and Roche as an organisation;* and
- Whether there are any unintended outcomes or challenges stemming from the proposed options.

Roche believes the proposed options may meet the intended outcome, but only if they are approached as a package of integrated reforms, with the detail developed further in a collaborative and co-designed approach. This is essential to determining whether the proposed options will achieve their intended objectives and to minimise any potential unintended consequences. Implementation will require all relevant stakeholders to collaborate transparently on the options and co-design the necessary policies, methods and processes.

There are four options that are either detrimental to patient access, value and choice, are not viable, do not address the issues, or are outside the terms of reference for the review.

There are also a number of options that will only partially meet the outcomes and need to be strengthened. These are discussed in more detail below.

We emphasise that there are many features of the current system that are working well and should be retained (and in some cases enhanced) including: special pricing arrangements and confidential pricing, indication-based pricing, deeds of agreement, parallel processing, defined timelines, the PBS process improvements, flexibility in decision making, transparency of process, the TGA reforms, patient and prescriber choice, consumer and industry representation on PBAC and face to face PBAC meetings.

Options that will not meet the intended outcome

Option 4.1 Approaches to funding or purchasing new health technologies: recognising competition between new health technologies that deliver similar outcomes: 'require offers of a lower price' or 'incentivise offers of a lower price'

Roche strongly disagrees with this option and believes this will have a detrimental impact on patients' access to new health technologies.

A significant number of pricing and cost control mechanisms are already in place across the PBS, and further pricing controls are unwarranted, whilst also putting the incentive to launch new medicines in Australia at risk.

From a Roche perspective, this option will undoubtedly lead to significant delays to important treatment options for patients, and result in Australia no longer being considered attractive as a first launch market. A mature and well-administered healthcare system would recognise that the current cost-minimisation analysis is a methodology to assess the impact of a new therapy, and not a reflection that a therapy provides no added benefit to patients or the healthcare system. We note that this proposed option would infer that a newer therapy applying as a cost-min-minus would be the latter. In fact, the approach would suggest that the new therapy is inferior to the preceding standard of care, which is evidently not the case.

For example, if this option was in place today, several Roche therapies which provide important treatment options and benefits for patients and clinicians, but assessed on a cost-minimisation basis due to limitations with the current HTA process, would simply not be available to Australian patients. It should be recognised that a cost-minimisation submission does not always infer a therapy has no added benefit. Therapies assessed under cost-minimisation

pathways often deliver treatment benefits to patients such as less invasive administration, longer treatment intervals, or more time before disease progression, and in turn deliver savings to the healthcare system.

Australia is already considered a low-price country in the global context and at the very least price parity and/or appropriate relativity to other therapies within the same class is a bare minimum requirement to allow these life-changing treatments to come to market.

Additionally, this option is inconsistent with the intent of the 2022-2027 Strategic Agreement which includes:

- The Agreement will strengthen the Australian medicines ecosystem by encouraging companies to continue to bring to Australia innovative medicines,
- A goal of keeping Australia a global priority for the launch of new and innovative treatments,
- Stability and certainty for investment in innovative medicines, including recognition of the role that a predictable and stable PBS plays in encouraging investment, and
- Shared recognition of the importance of a sustainably funded PBS as well as the need for business certainty, and acknowledge that the PBS is an uncapped, demand driven, health program.

Option 4.1 Approaches to funding or purchasing new health technologies: Pricing offer (PO) and negotiation guidance framework

Roche does not support the introduction of a pricing offer and negotiation guidance framework. Introducing another pricing and cost control mechanism will only result in unsupported lower prices being requested, such as the proposed funding eligibility for a streamlined cost-minimisation therapy, which will delay access to patients.

Post-PBAC pricing negotiations are already conducted under a robust guidance framework informed by the PBAC, its sub-committee deliberations, and final PBAC recommendations. Additional frameworks will add unnecessary complexity and rigidity and further slow down the process.

Option 4.1 Approaches to funding or purchasing new health technologies: post-listing reassessment of health technologies

Roche does not support the proposed option of rapid post-listing reassessments of health technologies. The well established and recently updated post-market review process already provides a systematic approach to monitoring medicines following PBS listing to inform decision making relating to ongoing access and subsidy.

Roche also does not support introducing an established disinvestment program. In Roche's experience, this would introduce an unnecessary complexity; the ordinary life cycle of health technologies when superior alternatives become available naturally results in decreasing utilisation, expenditure, risk, and the eventual delisting of products from the PBS. Roche also recognises that residual utilisation sometimes exists in certain conditions due to treatment response which can be jeopardised in the circumstance of divestment. To advance this through an established program will limit clinician choice and jeopardise responses in these patients further.

Regardless, pricing competition driven through first new brand reductions and price disclosure ensure prices are continually adjusted downwards in line with market behaviour. This encourages and may even accelerate the disinvestment and withdrawal of products from the market. It is unclear what expectations the current disinvestment mechanisms are not meeting, nor what objectives the proposed disinvestment framework is working towards achieving. Roche is therefore not in a position to support this option.

Option 5.6 Strengthen international partnership and work-sharing: collaboration with international jurisdictions to deliver sustainable access to health technologies

Roche is concerned that this recommendation will have the opposite effect to that which is intended. As acknowledged in the Options Paper, 'Australia is a small market within a global context'; Australia also has some of the lowest prices in the world compared to similar jurisdictions.

If Australia were to join a buying group with other markets, it is expected that sponsors would need to waive rights to confidential pricing among the payers within the buying group to generate a common price. Consequently, this would have detrimental international reference pricing implications, of which the lowest/lower priced markets would lose out. It would ultimately result in new health technologies simply not coming to Australia. Alternatively, the price Australia would be required to pay which could be accepted by the Sponsor would likely increase from the level which the Commonwealth has become accustomed to.

Options that need to be clarified or strengthened to meet the intended outcome

Option 3.1 Determination of the PICO

Roche supports the options proposed with regards to increasing early stakeholder input and transparency, and ensure that the PICO scoping phase identifies the patient populations that could potentially benefit from the health technology. However, it is unclear how this will be implemented and whether this will improve the HTA process and expedite access to new health technologies. As noted in the Options Paper, there can be sometimes a desire for a technology to be used outside the trialled evidence base for a multitude of reasons. Roche believes that sufficient context be provided to stakeholders providing input, including that it is unlikely that a specific evidence generation package will be developed specifically for Australia where it differs from the PICO informed by the trialled evidence base. This means that there needs to be considerations about the realistic level of evidence available to answer specific questions in the PICO process.

Roche notes that a PICO step should largely be optional, especially in the circumstance that the sponsor has a high level of confidence in an appropriate PICO and does not believe that the PICO scoping phase will add value that outweighs the scoping time.

In addition to updated guidance on health equity and priority population indications, Roche highlights the need for transparency for how this is likely to impact the decision-making process and/or outcomes.

Option 3.2 Clinical evaluation methods

Overarching principles for adopting methods in Australian HTA

Roche supports the proposed implementation of overarching principles and an update of methods for assessing non-randomised and observational evidence (including RWD/RWE). Roche supports the implementation of overarching principles to guide methods in Australian HTA, particularly the following points cited (p.103, Options Paper):

- Provision of feedback to sponsors/applicants on the use and presentation analyses derived from more complex methods,
- Acceptance of complex methods that introduce considerable uncertainty in the estimates when paired with provisional funding pathways, and
- Greater acceptability of uncertainty in estimates in areas of high clinical need (which will need to be defined so that this can be applied consistently).

However, to sufficiently address the issues, the proposed options need to be accompanied by:

- Increased flexibility and acceptance of non-traditional evidence,
- Increased transparency on the role and impact (i.e. weighting) of less readily quantifiable and broader value elements on decision-making, and
- Adoption of innovative approaches to manage uncertainties and providing earlier access.

Roche supports the proposed options with regard to guidance and updates to methods relating to the assessment of non-randomised and observational studies, RWE/RWD and surrogate endpoints.

As discussed above, guidance on the use of RWE/RWD in HTA (including definitions) should be accompanied by the increased recognition and acceptance of data to fill evidence gaps and reduce uncertainty.

Curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors

Roche supports the development of a curated list of methodologies that decision-makers prefer, as this will help provide sponsors important guidance for developing HTA submissions, especially in areas where evidentiary deficiencies exist (e.g. rare diseases, targeted and advanced therapies and genomics). However, as stated previously, increased flexibility and acceptance by decision-makers is critical.

Roche encourages the Review Committee to also consider the level of acceptable evidence and/or argument to support (or alternatively, modify), Special Pricing Arrangement (SPA) criteria, which states that the medicine generates substantial incremental benefit for the intended patient population, especially in the circumstance when the technology may provide important patient, clinician or system level benefits but may not demonstrably improve health outcomes and that comparator pricing (or components within a combination product) may have substantially eroded due to biosimilar or generic market competition. We note that the operationalisation of SPA criteria would be workable in the circumstance that the new technology is single branded.

Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

Roche supports the options proposed for addressing issues around the HTA of therapies that target biomarkers, particularly when considered as part of a transition to a unified HTA pathway for all health technologies, together with the increasing intersection between medicines and other types of health technologies (e.g. genomics and digital health).

However, Roche notes the following:

- In addition to the guideline of the assessment and appraisal of tumour agnostic therapies, Roche notes the importance of evaluators, decision-makers and/or payers providing actionable feedback to sponsors/applicants on areas of the submission that have contributed to negative or neutral recommendations.
- Statement of Principles around access and use of genomic technologies and gene therapies should be co-designed with a range of stakeholders (including sponsors, developers and researchers) in addition to patients, clinicians and citizens who do not have an immediate vested interest in these technologies.

Option 3.2 Develop an explicit qualitative value framework

Roche supports the development of an explicit qualitative value framework in consultation with stakeholders. Roche notes that this should be run as an independent policy initiative, and independently of the HTA committee, to incorporate broad perspectives from all relevant stakeholders to develop the framework.

Roche notes that a reasonable starting point to commence are the Elements of Value specified in the *Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report (Figure 1*).[1] It would be anticipated that this value framework includes criteria for circumstances where second-order effects on patients and their caregivers, such as social welfare and carer impacts, and productivity benefits are included in the HTA assessment process (and be acceptable and incorporated into any base case analyses). This includes workable qualitative and/or quantitative methodologies for the transparent inclusion of second-order effects or patient benefits.

This would be welcomed as an important first step in recognising the broader value of new health technologies.

[1] Lakdawalla 2018, Defining Elements of Value in Health Care - A Health Economics Approach. Value in Health, Vol 21, Issue 2, pp.131-139.

Option 3.3 Economic Evaluation: selection of the comparator, valuing of long-term benefits, valuing overall

Perspectives on a narrow healthcare system focus

Roche notes that the Options Paper states that the funding of health technologies is the consequence of a "*rigorous process for evaluation and price setting used for health technologies which, in turn, ensures a significant (although unquantified) return on investment in terms of welfare gain for society*", underpinned by the "*narrower perspective than that used for cost-benefit analyses which are used to value the impacts of other government decisions (e.g. policy proposals prepared for consideration by the Australian Government)*".

Exclusion of broader societal benefit results in the continued disfavouring of health technology investment due to a narrower sector-only perspective relative to the impact of other government decisions outside of health, which are justified using cost-benefit analyses which can take a broader perspective.

With the health-only perspective taken by the PBAC and Medical Services Advisory Committee (MSAC) for HTA, these broader societal benefits are not adequately incorporated. The PBAC Guidelines specifically outlines that submissions should take a health-only perspective which captures direct benefits to the specific patient and direct costs to the Federal Health Budget:

'Do not include costs and outcomes that are not specifically related to 'health and/or provision of health care' in the base case'[2]

This excludes important indirect benefits and costs which would be included if a societal HTA perspective was taken. Examples of broader HTA effects which are valued by society, but currently captured outside the clinical trial settings include: health outcomes for primary carers, social welfare impacts, psychological benefits, system efficiencies and productivity gains.

As a case point, carer effects are important to consider in order to measure and value the full health and wellbeing impacts of patient services on society.[3] Failure to consider carer effects means the economic evaluation is incomplete from a societal perspective and may provide misleading information on the impact of a health intervention on societal health or wellbeing.

The importance of including carer effects is explicitly highlighted in other comparable HTA markets methodological guidelines for economic evaluation, for example, the NICE in the UK, and Zorginstituut in the Netherlands.[4] Where the health condition has a substantial effect on the quality of life of carers, Roche contends there should be an option to include carer based utility decrement and this should be considered acceptable as part of the economic evaluation base case.

While it is currently possible to include indirect costs in an economic evaluation, the PBAC guidelines allow for inclusion as supplementary analyses.[5] Roche's experience has been that this evidence is given little weight in decision making, as it is not often captured within Phase III clinical trials, and there are no standardised methods in the PBAC guidelines for estimating indirect cost and benefits in economic evaluations.

Need for broad engagement with the community

Roche supports broad engagement with the community to better understand and quantify the overall value Australians place on their health and access to medicines. Significantly more detail would be required to assess the

[2] Pharmaceutical Benefits Committee 2016. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee Version 5.0, 3A. 1.4, p.64.
[3] Al-Janabi H, Efstathiou N, McLoughlin C, et al. The scope of carer effects and their inclusion in decision-making: a UK-based Delphi study. BMC Health Serv Res. 2021;21(1):752.
[4] Basarir H, Brockbank J, Knight C, et al. The Inclusion of Utility Values for Carers and Family Members in HTAs: A Case Study of Recent NICE Appraisals in the UK. Presented at ISPOR May 18-22. 2019.
[5] Pharmaceutical Benefits Committee 2016. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee Version 5.0

impact of this work on aims of the HTA review. The success of this particular recommendation will rely heavily on the translation of the captured sentiment into implementable strategies.

Roche would recommend the inclusion in these workshops of a topic of broader societal value associated with medicines access to reflect the holistic benefit medicines can have on Australians and Australian society more broadly. As noted in the options paper, Government investment in medicines produces a net welfare gain to society through broader benefits beyond the direct health outcomes, of which little is captured or reflected consistently in current evaluation methods.

Simplifying and restricting the consideration and inclusion of the broader benefits that medicines and health technologies provides on the basis of net welfare gain and producer cost basis models does not reflect broader Government evaluation models used in other portfolio areas (such as education).[6] Further detail and clarity is needed by the Department of Health and Aged Care, and other Government agencies, to further outline how a broader societal perspective can be included in HTA such that the Budget Operational Rules can support the stated objective of improving Australian's wellbeing.

Roche would request further consultation and inclusion in the proposed workshops on ways to regularly include the societal benefit perspective in HTA evaluations to increase the balanced sharing between sponsors and Government of the welfare gain to society provided by patients' access to medicines. We note that surplus sharing is not necessarily a new concept in the PBAC Guidelines.[7]

Comparator selection

Roche supports the proposal for greater clarity early in the HTA process with regard to comparator selection.

Roche has previously iterated in Consultation 1, and proposes that:

- The PBAC utilises the comparator as the therapy(ies) most likely to be replaced in clinical practice by the new intervention, aligned with other HTA bodies and good HTA practice. This is consistent with the earlier interpretation of the National Health Act 1953 (pre-2015).
- Where there are multiple comparators, the economic assessment should calculate a weighted average price of the new therapy based on the proportion of use that it replaces of each of the comparator therapies.

Likewise, further work should look to international approaches for multi-comparator appraisals which enable a cost-effectiveness claim to be established on the basis of indirect clinical evidence.

Roche also supports Medicines Australia's proposal for legislative change to create clarity with respect to comparator selection.

Valuing of long-term benefits

Roche supports a reduction in the discount rate, noting that a reduction of any magnitude will better reflect the value Australians place on their long term health. It must be noted, however, that the proposed range of 3.5-4% is misaligned with international best practice and may not go far enough in prioritising early intervention and preventative health strategies.

Option 1.4 State and territory government collaboration in HTA: health technologies that are jointly funded by the Commonwealth and state and territory governments

Prioritising the actions from the National Health Reform Agreement (NHRA) Addendum is critical to improved inter-governmental collaboration. The current pathway for Highly Specialised Therapies (HSTs) is challenging for

[6] Deloitte Access Economics 2016. The economic impact of improving schooling quality. Department of Education and Training.
[7] Pharmaceutical Benefits Committee 2016. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee Version 5.0, Appendix 6.

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.

The Evohealth April 2023 report on CAR T-cell therapies 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.[8]

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 budget 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.

Consequently, 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.

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.

Roche further notes that further work could be done to extend the reach of HSTs in order to address geographic inequities, particularly for patients not living near urban treatment centres. For example, legislative changes (outside the scope of this review) could be made to extend the reach of HSTs to private hospitals; this may be warranted when capacity issues may represent a barrier in the public system. Further capacity could be obtained by training regional hubs in the follow-up care of patients having to travel to urban centres for treatment.

Option 2.1 Streamlining and aligning HTA pathways and advisory committees: Pathway for drugs for ultra-rare diseases (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 additionally notes that 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: *"Entry 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: *"PBAC advises the Minister on key requirements to enable listing on the LSDP based on a comparative assessment of effectiveness* and *cost."*

[8] Evohealth. CAR T-cell therapy: Is Australia ready, willing and able? Available from: https://evohealth.com.au/media/reports/2023_CAR-T_Ready_Willing_Able.pdf, accessed 25 May 2023.

Option 2.1 Streamlining and aligning HTA pathways and advisory committees: Expanding role of PBAC and Unified HTA pathway for all health technologies with Commonwealth funding

Roche supports the efforts to improve the timeliness and consistency of HTA consideration for co-dependent technologies in principle. However, further detail on the expanded role of the PBAC, and the legislative amendments which will presumably underpin this expansion, will need to be understood ahead of assessing the full impact of this reform option. It is essential that the scope and breadth of the legislative changes proposed are sufficient to meet the intent of the recommendation but do not reach beyond that.

Roche supports a unified pathway for all health technologies in principle, however, it is unclear how this reform option will specifically address simplifying and streamlining the HTA process.

Roche notes this is reflected in the reform option itself which proposes investigating approaches to introduce such a pathway, and agrees that significant further detail on the framework, governance, resourcing, and committee expertise will need to be understood ahead of assessing the full impact of this reform option. We note that any key positive features specific to each pathway to meet the needs of the assessed technology should not be lost in pathway consolidation.

Roche would seek further consultation on this with further detail shared on how the implementation may be achieved, whilst ensuring that any new pathway does not further delay patient access.

Roche recommends that any proposed co-designed pathway, policy and legislative changes be documented alongside the original intent of the change, such that a future retrospective review of the implemented changes can be assessed against the original intent and be monitored for unintended consequences.

Option 2.2 Proportionate appraisal pathways: triaging submissions

Roche supports a submission triaging stage in principle, however, further detail is needed ahead of assessing the full impact of this reform option.

Roche notes that there must be clarity for sponsors around the criteria for each pathway, the information to be presented for triaging (for example, the PICO scoping step should be at the request of the sponsor to avoid inefficiencies), and what options are available to sponsors when they do not agree with the decision. Roche notes that the triaging phase must be appropriately resourced so that sponsors can have meaningful interactions with departmental personnel. Roche has found that communicating solely via the Health Products Portal (HPP), or by emails is inefficient, especially in the circumstance where there are points of difference.

Roche notes that if triaging is not undertaken by the HTA committee, ensuring the appropriate expertise is involved in this stage will be critical. A lack of expertise will likely result in therapies being triaged inappropriately which would create additional barriers and longer delays to patient access. Similarly, it is also noted that triaging should be conducted in a timely manner as delays to submission assessment might occur (compared to the current status quo), in the circumstance where the appropriate HTA committee needs to convene to assess the appropriate pathway.

Roche would strongly support the involvement of patient perspectives, and further consideration should be given to the interactions with sponsors in determining the potential HTA pathway. Roche supports the introduction of a transparent decision tree, however, the decision-making criteria, deliberations and outcomes of the triaging body must also be transparently reported.

Option 2.2 Proportionate appraisal pathways: streamlined pathway for cost-minimisation submissions

Roche would welcome an abbreviated evaluation process if designed to reduce the time to access for patients, however, this should not be undertaken at the expense of not recognising the value of a therapy which has been assessed under a cost-minimisation pathway.

We note that the approach to decision-making, especially in the context of determining and managing uncertainty sometimes results in sponsors either electing, or the PBAC determining, that submissions follow a cost-minimisation pathway for therapies which have provided a demonstrable improvement in health outcomes. Roche would be happy to supply the Reference Committee with examples on request.

The criteria for a streamlined cost-minimisation pathway must be developed in consultation with stakeholders and must acknowledge cost-minimisation is an assessment / analytical pathway and not simply a reflection of a therapy providing no added benefit. Roche notes that the many therapies also assessed under this framework provide important patient convenience benefits, clinician choice or healthcare system efficiencies.

Further consideration must also be given to the timing of the release of comparator pricing information as the deliberations of the HTA committee can often inform cost-minimisation calculations across therapies with different dosing regimens, treatment durations, and equi-effective doses which inform the final recommended cost-minimised price.

In the proposed streamlined pathway, rather than the PBAC Executive remaining the sole decision maker, sponsors should retain the option to progress to consideration by the HTA committee.

Option 2.2 Proportionate appraisal pathways: early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

Roche supports the introduction of early resolution mechanisms for cost-effectiveness submissions, however, clear criteria to determine what are considered major new therapeutic advances, and deemed areas of HUCN, are needed.

Consideration should also be given to the need to satisfy a submission timeframe of 6 months from the first regulatory approval in comparable international jurisdictions. There can be several factors as to why it would not be practical for a submission to be made within that time frame, and should therefore not be a condition of eligibility for early resolution mechanisms. Further, Roche does not support any cap on the allowable number of resubmissions as this unfairly denies patients access.

With respect to the preferred Option Resolution Step, Roche supports *Alternative Option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised*.

To effectively use an early resolution mechanism and ultimately avoid negative recommendations and resubmission churn, it is important that all evaluation considerations and positions, including those of the HTA committee, are available to inform the resolution process itself. Whilst other alternative options address this to a degree, there would still be a level of uncertainty in terms of the position of the HTA committee until after the resolution process has concluded.

Option 2.2 Proportionate appraisal pathways: expanding early resolution step to all relevant cost-effectiveness submissions

Given the uncertainty with what therapies qualify as HATV in areas of HUCN, Roche supports expanding the resolution step to all cost-effectiveness submissions after a pilot as soon as practicable. We note that a pilot covering one to two PBAC cycles would be appropriate; expanding the resolution step would drive faster access for patients.

Subsequently, the pilot should also extend to include non-HATV therapies, given the uncertainty around the definition of HATV.

Option 2.2 Proportionate appraisal pathways: Decouple the requirement for the TGA Delegate's overview to support PBAC advice

Roche supports decoupling the requirement for the TGA Delegate's overview to support PBAC advice, however, without further detail on how this will be managed (e.g. will other post-PBAC processes also continue in the absence of the TGA Delegate's overview) it is unclear how this reform option will reduce time to access for patients.

Option 2.2 Proportionate appraisal pathways: Case Manager

Roche supports the introduction of a case manager for all cost effectiveness submissions if this contributes to simplifying and streamlining the HTA process and ultimately reducing the time to access for patients. It is, however, unclear how the proposed reform option, or even the existing arrangements, currently achieve that objective.

Roche further notes that, with respect to case managers used in other phases of the PBAC process (ie. post-PBAC case managers for Pricing Pathway A therapies), the availability of a case manager did not result in an accessible point of contact where there was a need to facilitate a resolution. Consequently, it has been noted that for this option to add meaningful value, a case manager must have the relevant expertise to provide advice and help facilitate resolution directly (ie. direct interaction / discussion, and not via the HPP or email).

Option 2.2 Proportionate appraisal pathways: Additional comments or concerns

It is noted that the options suggest that the further facilitation and focus by Department of Health and Aged Care staff on submissions would be required to assist with navigating the multiple process steps required for the evaluation of cost-effectiveness submissions.

The addition of further processes and steps are often accompanied by additional cost recovery fees. It is noted that the current cost recovery framework already is a substantive burden on sponsors making submissions.

Roche proposes that additional resolution pathways and case managers should not incur any additional cost recovery fees above that which is already applied for a Category 1 submission with a facilitated listing process (Pathway A). There is risk that whilst sponsors may pay for the facilitation and case manager, there are no guarantees that this will lead to a successful submission, and the cost recovery fees become a barrier for further submissions.

Option 4.1 Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN

Roche supports either establishing bridging funding coverage or enabling conditional listings on the PBS for earlier access to therapies of HATV and HUCN. Roche would seek further consultation on this option with further detail shared on the key stages of the program being considered particularly the early identification/priority list designation, eligibility requirements, HTA application approaches, data collection, and final assessment stages. It is also important to ensure that any new funding mechanisms do not result in further delays, or create inequities to patient access.

Option 4.1 Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools

Roche supports revised guidance and policy arrangements to encourage the creative proposition and use of managed entry tools and instruments. Roche would seek further consultation on this option with further detail shared on what parameters would be tolerated, and how implementation may be achieved.

Roche encourages the Review Committee to also consider revising policy arrangements to support more creative use of existing risk-sharing arrangements and SPAs, and how this also may seek to benefit patient access.

Option 4.1 Approaches for managing uncertainty - Further comments or concerns

As noted in the Options paper (p.145, Revised Guidance on the uses of different managed entry tools), revised guidance and policy arrangements and/or bridging funding coverage needs sponsors and the Commonwealth to engage with uncertainty more constructively and collaboratively, as part of improving timely access to health technologies.

Critical to the success of these revisions relies upon trust between the parties and therefore, avoiding any perverse disincentives applied when each has negotiated terms of a managed entry scheme (MES) in good faith. It should be noted that the risk of taking an incorrect funding or pricing decision must be shared rather than shifted. Failure to do so, regardless of further guidance and options, will result in a similar lack of MES uptake, as per the current state of play, continuing to result in delays to patient access.

Option 4.2 Approaches to incentivise development of products that address antimicrobial resistance (AMR): funding and reimbursement-related changes to support availability of antimicrobials

Roche supports mechanisms that incentivise further research and development through to patient access of new antimicrobial therapies. Whilst fee exemptions are one option, further incentives should be considered and Roche would welcome further consultation and detail on what these mechanisms could look like.

Roche would also recommend that the Department of Health and Aged Care make the existing work program more transparent to stakeholders, with clear timeframes and models where stakeholders can be further involved in co-design and consultation.

Roche would welcome further workshops and consultation where possible alternative payment and incentive models are shared with stakeholders prior to them being tested.

Option 4.3 Understanding the performance of health technologies in practice

Roche supports an open and trusted health-data ecosystem, as well as the secondary use of health data to increase the value of currently collected data, and in appropriate circumstances within the HTA lifecycle. In turn, Roche supports optimising access to and use of RWD in HTA, and increasing confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA. This should also be coupled with a data infrastructure strategy and implementation plan, and methods and guidance frameworks.

Roche notes that the use of RWD to understand the performance of health technologies in the Australian setting through the collection of utilisation and outcome data is best placed for provisionally listed health technologies or areas of significant uncertainty. Roche recognises that the structures may take a number of years to effectively establish, given the scale and scope of potential change and the potential consequences, intended and unintended, for this to come to fruition.

Roche supports the option to develop a whole of government data infrastructure and would welcome further consultation to ensure that industry's role in RWE is included as part of the co-design process.

Roche recommends that further work on RWD is aligned to existing work currently being undertaken by the TGA.

Option 4.3 Understanding the performance of health technologies in practice - Further comments or concerns

There is a risk that RWD is only examined when the expected health outcomes are not achieved, and that recognition of a health intervention exceeding the expected outcomes through RWD is ignored. A balanced approach is needed to ensure that RWD is used objectively in the circumstance where the application may be broadened beyond provisionally listed health technologies or areas of significant uncertainty.

Option 5.1 Proactively addressing areas of unmet clinical need and gaps in the PBS: early assessment and prioritisation of potentially promising therapies

Roche supports the development of a priority list of high unmet clinical need priority areas and the potential future opportunity to accelerate access for treatments in these areas. Roche notes that the development of a priority list should not come at the expense of established pathways and consideration of technologies that may not address an area of high unmet clinical need (ie. a therapy that may have high added therapeutic value, but not in a HUCN).

Further detail and clarity is needed on how this list would compare and connect with National Health Priority areas. Likewise for antimicrobials and vaccines, further clarity would be required to understand the rationale for any

significant non-regional specific deviation from the WHO's Global Priority Pathogens or Vaccine-Preventable Diseases lists

Consistent with Option 1.3, Roche also supports a subset of the priority list to be developed in partnership with First Nations people representative organisations for areas of unmet clinical need and gaps in funded access for First Nations peoples.

Similarly, Roche supports a PICO scoping phase, especially in the circumstances where implementation requirements and challenges can be identified. Roche notes that early PICO scoping would be particularly useful for the preparation of potential stakeholders impacted by the introduction of a new technology. From an industry perspective, early PICO scoping would be useful to ensure more rapid adoption of the technology within the clinical community, once funded, ensuring that the benefit from the technology can be optimised as soon as it becomes available.

Option 5.1 Proactively addressing areas of unmet clinical need and gaps in the PBS: early assessment and prioritisation of potentially promising therapies

Roche supports the option of incentives to encourage prioritising therapies identified through horizon scanning. The outlined options may help to address the current issues with attracting therapies which address areas of HUCN, however, Roche does not believe that these incentives replace appropriate value recognition commensurate with a technology that addresses HUCN to ensure the attractiveness of Australia as a first launch country is maintained.

Similarly, a provisional funding program for patients to obtain access would also only be viable if an acceptable pricing arrangement could be agreed to by sponsors and the Government.

Timelines also need to be jointly agreed with the sponsor rather than a predefined notification to Government with the acceptance of a proactive submission offer. Depending on the situation and circumstance, a 4-6 week time period may be insufficient to assess the potential viability and consequences, within and external to Australia.

Option 5.2 Establishment of horizon scanning programs to address specific informational needs within HTA and the health system + help operational and capacity planning for HTA and health systems + meet priority areas

Horizon scanning offers the greatest benefit when it enables meaningful preparation and action from impacted stakeholders. Roche supports the level of consultation described in the Options paper; engaging with relevant Committees, Commonwealth, State and Territory Governments, and industry. Significant consultation would be required to understand expectations of the joint investment from industry to warrant the support in horizon scanning. Roche notes that to optimise the introduction of horizon scanning, international collaborations where extensive investment has already gone into establishing horizon scanning processes should be leveraged wherever possible.

Roche recommends that the current aim of 'addressing specific informational needs' is a first step in ensuring a responsive HTA and health policy system is prepared and ready to enable the delivery of new healthcare innovations.

Roche additionally recommends:

- A commitment to the establishment, responsibility and accountability for horizon scanning with clear and regular timelines for meetings and reporting;
- An 'enduring' structure is established to ensure continuity and consistency for horizon scanning. As seen with previous structures, such as HealthPACT, horizon scanning efforts were disbanded when the Australian Health Ministers' Advisory Council (its parent committee) was dismantled;
- Early and meaningful industry engagement to ensure critical endorsement, noting NHRA consultation and current International HTA Collaboration meetings have not been extended to industry;
- Further consultation and clarity on the rationale for 'cost-sharing' and 'joint investment' from industry in the absence of agreement on the scope and objectives of the horizon scanning process;

- Agreement on the proposed scope which is currently stated to include 'advanced therapies' and 'other potentially disruptive technologies';
- The Commonwealth taking a lead role which extends to securing Commonwealth funding for implementation of horizon scanning on behalf of the States and Territories which can be further detailed in the next NHRA;
- A collaborative approach with industry to accelerate establishment of horizon scanning, as opposed to industry providing advanced notice as proposed in the option;
- A flexible time horizon not fixed at 18-24 months but calibrated according to the level of disruption expected. For example, longer lead times may be required for significant changes to workforce capability and capacity or investment in new complex infrastructure; and
- Further rationale for cost recovery being proposed for international collaboration when as noted in the options paper, "horizon scanning in the healthcare context can be taken to broadly describe a process that is intended to help different stakeholders be aware of the implications of technologies that will affect healthcare policy or delivery in some way, and (where necessary) provide an evidence base to support the case for changes to the health system in some form." As these activities would have a benefit to multiple stakeholders (not just sponsors) it is not reasonable to cost recover horizon scanning.

Roche also supports an ongoing role of the Department of Health and Aged Care in annually producing the 'Emerging Health Technologies' report undertaken for the purpose of this Review. Roche notes that the report could have been provided to sponsors (where their technologies have been cited) for comment enabling further input with respect to future HTA or implementation issues prior to its release as part of this Review.

Option 5.3 Consideration of environmental impacts in the HTA: environmental impact reporting

Roche is proud to be recognised as one of the most sustainable healthcare companies in the Dow Jones Sustainability Indices since 2009, and is mindful of its environmental footprint.

If introduced, the potential weighting of environmental impacts in the decision making process would need to be clarified. There is a risk of adding further complexity to the evaluation process with the inclusion of environmental impact components, particularly whereby corporations are already bound by other existing legislative requirements to report and deliver on environmental impact targets. It is unclear how including the environmental impacts in HTA will improve timely access to new health technologies.

We note that, whilst reporting carbon emissions related to a technology related to an asthma inhaler may be relatively more straightforward, factoring in carbon emissions and quantifying the environmental impact externalities could be a substantial resource requirement. Furthermore the added requirement of reporting and compliance may be administratively burdensome.

Guidelines would need to be standardised into recording and reporting mechanisms to ensure reporting is meaningful, including an agreed calculation method. An example of an area where further clarity is required is how environmental impact elements might be weighted in the decision making process, and the effect the collection of this data might have on timely access to new health technologies. Roche recommends further consultation so that all stakeholders can better understand, have greater clarity and co-design potential alternative approaches where necessary, noting the broader whole of Government requirements for environmental impact reporting.

It is unclear from this option how including the environmental impact of medicines in HTA will further improve patients' timely access. There are a number of potential unintended consequences from this option, with additional information and clarity required:

- 'Incentives required' if companies are required to factor in emissions externalities into the development and manufacture of medicines, then Governments should have a higher willingness to pay for medicines that have an included environmental benefit.
- The paper notes that a technology with a larger emissions footprint (but delivers similar health outcomes) could lead to a funding request being rejected. Roche believes that the Australian Government should look

to incentivising the reimbursement of environmentally better medicines, rather than through disincentives or penalties.

- Further consultation would be required to better understand how the environmental aspects would be weighed against clinical benefit.
- Further clarification on transportation calculations. As many therapies available in Australia are manufactured overseas, Australia has a significant dependence on international air travel and sea freight which other countries may not have. This is coupled with adhering to manufacturing compliance in other countries (any local costs to meet local emissions targets are likely being passed on to Australia).
- There should be further consideration of the broader environmental and societal impact of patient travel in Australia as this may be a large driver of impact. A more holistic broader approach to valuing the benefits of health technologies is needed, whilst balancing equitable access.
- The focus should not be on the creation of onerous new evidentiary or information requirements on an already onerous system. We note that if manufacturing is already examined by another auditing process it should not be included due to double counting.

Lastly, there is a discrepancy in the proposed options of including the broader environmental impacts of medicines, whilst other broader societal perspectives (such as carer and productivity impacts) have not been proposed to be included.

Roche recommends that further consultation is needed to ensure that a holistic approach to broader benefits and impact is considered rather than selecting particular second order effects.

Option 5.4 Mechanisms for continuous review and improvement

Roche supports in principle options which address the outlined need for a continuous approach to reviewing and updating guidelines, methods, policies and processes, so that HTA in Australia can keep pace with the evolution in health technologies. Roche notes that more clarity is required to understand the parameters of the proposed reviews, implementation of potential findings, expectations and contributions from industry and other stakeholders, and resourcing requirements. Roche has previously noted that more guidelines does not necessarily translate to improved or accelerated access, especially in the circumstance that the valuation of technologies is not befitting that of a first-wave country.

Additionally, any reporting should outline specific measurements on the policy and method changes implemented as a result of this Review. This will allow both successes and failures to be assessed against the agreed intent in an open and transparent manner with input from all relevant stakeholders.

Option 5.6 Strengthen international partnership and work-sharing: work-sharing for individual submissions

Roche supports the harmonisation of HTA across jurisdictions on the basis of improving international consistency, time to listing and HTA capacity. Priorities for the HTA collaborations must be to establish and ensure a streamlined, well-integrated process that improves patient access to innovation across all countries (timely and equitable access), uses a state-of-art assessment approach, and engages with industry, patients, clinicians, academia and other experts throughout the process. Processes need to be appropriately resourced to ensure a clear, workable and predictable framework, delivering consistent high-quality outputs.

Roche supports the harmonisation of HTA methods. International alignment on technical matters may result in Australia better understanding the methodological approaches considered best-practice by HTA agencies, such as NICE, leading to wider adoption in Australia. Consequently, this may enable earlier submissions in Australia by reducing the need to respecify base case parameters or develop Australian specific cost-effectiveness models beyond simply adapting specific local costs.

To achieve this however, the PBAC and its sub-committees must be willing to soften long held positions where they differ from those; Roche noted this in Consultation 1. The alternative would result in even further delays to submissions and evaluations and would need to be conducted in sequence rather than in parallel.

Roche supports international collaboration on clinical components of HTA evaluations and would welcome the opportunity to participate in a proposed clinical evaluation pilot. Each of the four pathways proposed have merit and could be appropriate for specific circumstances.

Options that are not required

Option 2.2 Proportionate appraisal pathways: development of a disease-specific common model for disease areas with high active product development

Roche does not support the introduction of a disease specific common model.

Roche notes that sequential listing of multiple therapies on the PBS targeting the same population, largely means that therapies listed on the basis of cost-minimisation are "accepting" the parameters that determined cost-effectiveness for the first therapy in the first instance, and it is unclear where the efficiencies with this option lie.

Further, Roche has noted that the experience with disease-specific models for non-small lung cancer (NSCLC) has been trialled in the UK. Based on Roche UK's experience during this trial, it has been difficult to create a model that captures sufficient complexity to enable it to be used by multiple sponsors where parameters have been flexible enough to accommodate different patient populations (and subpopulations) drug classes, disease stages, lines of therapy (and impact on subsequent lines of therapy), dosing regimens and all key components of an economic model.

Failure to reflect this complexity in these models will likely lead to inaccuracies in capturing the full value of the therapy. Rapid changes in disease management and standard of care will also lead to the rapid redundancy of these models. It is noted that the effort required to develop a range of workable disease-specific common models would likely outweigh any efficiencies gained, and those resources would be better directed to other options where there is more certainty of accelerating access.

Options supported that enhance governance, transparency and collaboration

Option 1.1 Transparency and communication of HTA pathways, processes and decision

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.

Roche supports the option to publish plain language summaries as a way to address the identified issues in principle. However, Roche would also expect a reasonable level of multi-stakeholder co-design to ensure that the plain language summaries would meet the issues articulated.

Roche has further comments to the plain language summaries options which we believe would help inform decision-making;

- Consistent with the CEEU pilot, sponsors preparing the initial Consumer summary focused for patient communities has worked reasonably well. It would be envisioned that the additional preparation of a summary for clinician groups would not be administratively burdensome.
- 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.
- 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 plain language summaries informing PBAC committee deliberations, it would be reasonably expected that sponsors would be able to review the plain language outcome and provide a sponsor comment similar to the MSAC consumer summary. It is important to note that the views reflect that of an HTA committee only, and are not necessarily a reflection of the performance of the technology.

For plain language summaries of HTA pathways, consideration should be given to build on the work of organisations such as the Patient Voice Initiative[9] that have extensively consulted in patient groups to create layperson language guides.

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

Option 1.2 Consumer, clinician and other stakeholder engagement and consideration in HTA

With consumers and consumer organisations

Roche supports the development of a consumer engagement framework and the proposed mechanisms for strengthening consumer evidence collection and utilisation. 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.

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.

With clinicians, clinician groups and other impacted stakeholders

Roche similarly notes that, clinicians and/or clinician groups involvement, whilst acknowledged in the chapter heading, is covered in relatively limited detail, and that a consistent understanding and co-design on the involvement of peak clinical groups (similar to how the Oncology Drugs Working Group of the Medical Oncology Group of Australia provides input) is warranted.

Additionally, input from impacted stakeholders (clinicians, healthcare professionals, healthcare system administrators) is warranted in the circumstance where a change in the implementation and use in the health technology is anticipated, to ensure the broader healthcare system benefits beyond health outcomes alone are understood.

Roche further highlights that it is important local consumer evidence that might need to be generated within the existing time period preceding submission lodgement is useful and relevant for decision-making purposes. This will ensure that submission lodgement is not delayed solely for evidence generation which is not valuable to the HTA committee, resulting in unnecessary delays to patient access.

Option 1.3 First Nations people involvement and consideration in HTA

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.

[9] The role of patient experience and participation in https://www.patientvoiceinitiative.org/patient-experience-and-participation/

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.

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.

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.

Conclusion

As noted in our response, many of the options proposed lack sufficient detail or implementation approach to make an informed judgement on their impact. Roche suggests further substantive consultation and co-design prior to considering implementation is needed.

A number of options are outlined that would have a detrimental impact on patients' timely access to new medicines which Roche does not support. In addition, as each option is presented in isolation, with little cumulative impact analysis outlined of the options, there is a risk of unintended consequences such as increased assessment complexity and red tape which may lead to slower patient access to innovative medicines.

Roche looks forward to the final report being made available to stakeholders and to further consultation on co-designing any options that the Government may wish to proceed with.