Consumers Health Forum of Australia

Health Technology Assessment Review: Options Paper, Consultation 2

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P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close,
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

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Introduction

Consumers Health Forum (CHF) is the national peak body representing the interests of Australian healthcare consumers and those interested in healthcare consumer affairs. CHF works to achieve safe, quality, and timely healthcare for all Australians, supported by accessible health information and systems. At the heart of CHF's policy agenda is consumer-centred care, which includes advocating for a consumer-centred HTA process. CHF appreciates the opportunity to provide consumer insight into Consultation 2 of the Department of Health and Aged Care (DOHAC) Health Technology Assessment Review.

The overall health of Australians accessing the healthcare system relies heavily on the availability, safety and quality of health technologies approved by the TGA. Technologies are then subsidised by the Pharmaceutical Benefits Scheme (PBS) after recommendations by organisms like the Pharmaceutical Benefit Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC). Through taxes and out-of-pocket expense, the cost of it all is ultimately borne by consumers. For this reason, consumers are major stakeholders in any attempt at HTA reform. Their input must be taken with the utmost consideration to build the broad-ranging consensus that ambitious reform requires to succeed.

Submission Outline

The evidence provided in this submission has been sourced from CHF's Safety and Quality Special Interest Group (SIG) a group of 43 consumers established to support CHF's policy and advocacy work in improving health systems for all consumers – patients, carers, and communities. The Safety and Quality SIG has provided input in 2023 for the HTA Consultation 1 stage. In 2024, the group met in the months of January and February to discuss the Consultation 2 options paper released on January 25th.

The content of these discussions is organised below in 5 topics, which mirror those presented in the HTA Consultation 2 Options Paper. The submission was originally put forward to the HTA Review Reference Committee via an external survey run by company Bastion Designs, advertised via the Office of Health Technology Assessment Consultation Hub. The document you are reading now presents the content of the CHF submission, drafted in a way that is more accessible and easier to read.

Topic 1: Transparency, communication, and stakeholder involvement

Plain language summaries: Plain language summaries will be pivotal in ensuring consumers can be involved in HTA processes. Currently the high level of technical and health literacy required to engage with HTA is a significant barrier for consumer and community involvement. Care must be taken to ensure the plain language summaries provide useful, accurate and pertinent information. Adequate resourcing must be in place to guarantee their timely update.

Improvements to the HTA webpage including development of a dashboard – Re-designing the HTA webpage in a more consumer-friendly way will help guide consumers through complex HTA processes and reduce the current barrier for consumer and community involvement. The new HTA webpage needs to be easier to find and more accessible. Accessibility can take many different forms, and simple language is only one of them. The HTA webpage needs to cater to Australia's multicultural community by providing content in multiple languages, as well as providing options for various accessibility needs - physical and cognitive. Lastly, the review should also consider whether the term Health Technology Assessment (HTA) should be reconsidered to a different name that carries more meaning to consumers.

Development of an engagement framework: Consumers will enormously benefit from an engagement framework that enshrines their participation within HTA processes. CHF calls for a legislated involvement of consumers, which will ensure that consumer voices become an integral, obligatory component of HTA processes. CHF considers these options all satisfactory and expansive in their effort to engage with consumers. As such, they should all be adopted into the final framework.

If not legislated as a requirement, the engagement framework will fail to implement, and all benefits to both consumer and HTA processes will be missed. Of course, this is an ambitious plan and CHF hopes that adequate resources will be employed for its realisation. Inappropriate funding will result in a half-baked reform riddled with unintended, negative consequences.

CHF believes that there is benefit in understanding how the commercial and clinical processes and perspectives of the HTA process interact; however, in some cases this is bound create a real or perceived conflict of interest. For this reason, CHF calls for this legislation to actively seek balance in HTA consumer consultation processes. This can be done by ensuring that among selected consumers there is a quota that has no previous experience in the pharmaceutical and medical field. Legislation should clearly define the length of each consumer's appointment, and roles should rotate regularly.

This will ensure a more diverse range of consumer views, reducing the risk of any selection bias developing within the legislated organ of consultation. If equipped with dedicated funding, an independent consumer peak body like CHF is perfectly placed to educate and train new consumers to provide valuable input into complex HTA processes.

Strengthening consumer evidence: CHF supports the use of real-world evidence, both qualitative and quantitative, including Patient Reported Outcome Measures (PROMs) and Patient Reported Experience measures (PREMs). We support the development in co-design with consumers of the enabling systems, pathways, evaluation, and research that will optimise access to this type of data.

Additionally, CHF supports all other options in the "strengthen consumer evidence" section, and in particular the promotion of consumer input into clinical trials, and the inclusion of consumers in HTA committee meetings. We note that such evidence should include not only clinical outcomes but lifestyle ones. For example, a new treatment that has similar clinical effects but is taken as a monthly injection vs a current treatment of a daily oral pill may constitute a significant lifestyle/treatment adherence improvement for consumers.

However, consumers are concerned about privacy and data guardianship. If consumer-generated evidence is to be used on a more consistent basis, adequate resources must be in place to guarantee the establishment of strong systems of data safety and guardianship. This will ensure consumers feel safe in releasing information, increasing the quality and quantity of available PREM and PROM data.

Measures should also put in place to prevent consumer-generated data to be used for financial gain. Consumers are adamant that while they are happy to release data for altruistic purposes, its use for financial profit is completely unacceptable. Legislators must not shy away from the challenges of ensuring that there are clauses in place preventing this from happening.

First Nations Peoples involvement and consideration in HTA: CHF welcomes and supports better involvement of First Nations Peoples in HTA processes. News of the widening of the health disparities in Australia between Indigenous and non-Indigenous populations are alarming, and reveal the great need for ambitious health reform, including HTA. CHF supports the creation of a specific sub-set of the priority list, which will be dedicated to areas of high unmet clinical need specifically for First Nations Peoples.

CHF also welcomes and supports the utilisation of resources to assist organisations representing First Nations peoples build the skillsets required to make HTA submissions.

States and Territory Government collaboration in HTA: CHF understands the potential benefit to consumers of central standardised data sharing but is also aware of some of the risks involved. CHF supports an increase of opportunity to provide input for state and territory governments, across the whole health technology lifecycle. CHF supports the reform towards a nationally cohesive approach to HTA. CHF also supports the establishment of timeframes for the accelerated processing of high-cost, highly specialised therapies provided it does not pose unacceptable safety risks to consumers. CHF also supports the establishment of horizon scanning to facilitate timely planning and preparation for adoption by jurisdictions.

As mentioned previously, CHF is concerned by privacy and data guardianship. When consumer-generated evidence is to be used more consistently, adequate resources must be put in place to guarantee the establishment of strong systems that protect and maintain such data. This will lead to a virtuous cycle in which consumers are confident releasing data is safe, leading to a richer, more fit-for-purpose database.

Measures should also put in place to prevent consumer-generated data to be used for financial gain. Consumers are adamant that while they are happy to release data for altruistic purposes, its use for financial profit is completely unacceptable. Legislators must not shy away from the challenges of ensuring that there are clauses in place preventing this from happening.

Topic 2: Health Technology Funding and Assessment Pathways

Streamlining and aligning HTA pathways and advisory committees: Consumers are generally amenable to the idea of unifying the HTA pathway for all technologies. A unified process will allow for better access to health technologies, and reduce the preventable deaths that barriers created by these inconsistencies. Despite this, consumers are also worried about the way such a process will be executed. Proper unification will require a very sizeable amount of funding and HTA structure augmentation. The risk of a half-baked streamlining process will be borne by consumers, who will experience the loss of expertise of de-funded local HTA bodies. If this option is implemented, specialist bodies must be appropriately resourced to enable them to provide advice that is pertinent and up to date.

Proportionate appraisal pathways: CHF is not opposed to a "single front door" approach to triaging submissions, provided that such triaging ability is well resourced and does not become a bottleneck. CHF also supports streamlined processes for technologies that deliver the same benefit to consumers at a cheaper price, as it will stimulate competition and lower prices for technology. CHF understands that this will apply mostly to technologies which are not protected by intellectual property license.

Early resolution mechanisms for submissions of major new therapeutic advances in areas of High Unmet Clinical Need (HUCN): CHF is of the opinion that the current options do not provide enough detail to ascertain which alternative will deliver the best outcome for consumers. Therefore, CHF calls for a more in-depth consultation that focuses on the four options. The options must be presented with case studies examples so that it will be easier to understand intended processes and outcomes. In principle, CHF is likely to support introducing an optional resolution step after HTA committee consideration but before advice is finalised. This option would likely ensure that consumer input is taken in consideration before the sponsor is provided information on a provisional negative recommendation by the HTA committee. CHF would like to suggest that this approach of early resolution mechanisms include also broader benefit considerations. These include improvements in quality of life that a new therapy might produce, and improvements in treatment adherence. As a practical example, this would include therapies allowing consumers to shift from a regimen of daily injections to a weekly one, or from a regimen of daily oral compress to a monthly injection.

Topic 3: Methods for HTA for Australian Government Subsidy (technical methods)

Determination of the Population, Intervention, Comparator and Outcome (PICO): CHF enthusiastically supports increased early input on the PICO from consumer and clinician communities. This will ensure that all relevant patient populations that would benefit from a technology are considered in the HTA. CHF also supports plain language summaries of the PICO, which will increase transparency and communicate the expected outcomes. The previous two options cannot be considered without also applying an intersectional lens. There must be explicit consideration of health equity and priority populations which must be given a voice. This includes (but is not limited to) First Nations Peoples, culturally and linguistically diverse communities, LGBTIQ+ communities, people with experience of mental health issues, and people with disabilities.

Clinical evaluation methods: CHF is broadly supportive of the overarching principles. Principle number 8 - which states that "the acceptability of uncertainty in estimates may be greater in areas of high clinical need" – is particularly important.

CHF understands that the use of nonrandomised and observational evidence requires an in-depth assessment of the bias that might be affecting the data. In principle, CHF supports the proposed updates to methods of assessment for such data. Thresholds for uncertainty – however – must be clearly delineated and established as objectively as possible. There is a potential for these rigorous methods of bias assessment to slow down the process of utilisation of non-randomised and observational evidence, leading to a de-facto under-utilisation of this type of evidence.

Regarding the use of Real-World Data and Real-World Evidence (RWD), consumers are concerned about privacy and data guardianship. Therefore, if consumer-generated evidence is to be used on a more consistent basis, it must be accompanied by the establishment of strong systems of data safety and guardianship. Not only will this ensure consumers feel safe in releasing data, but this will also increase the quality and quantity of available data.

Measures should also put in place to prevent consumer-generated data to be used for financial gain. Consumers are adamant that while they are happy to release data for altruistic purposes, its use for financial profit is completely unacceptable. Legislators must not shy away from the challenges of ensuring that there are clauses in place preventing this from happening.

Increased transparency for stakeholders: CHF acknowledges the mention in the options of consumers being informed with brief lay explanations. These explanations

must not be too brief and provide a comprehensive overview of the different methodologies. There needs to be appropriate resourcing to ensure that the list is maintained and kept up to date and that the information is available in several priority languages.

Develop an explicit qualitative value framework: CHF supports the explicit and systematic use of qualitative evidence during committee deliberations, as it is through qualitative evidence that consumers can demonstrate broader benefits, cost efficiencies, and unintended financial impacts of technologies. This allows the HTA process to elevate itself from a "dollars and cents" view of health and provide recommendations that consider broader economic and social impacts. CHF supports the development of a checklist to assist decision makers integrate equity considerations. There also must be enough funding to periodically update the checklist, to ensure this list remains current.

Finally, CHF supports the call for the development of a Statement of Principles concerning the access and use of genomic technologies and gene therapies that is developed in co-design with consumers, clinicians, and the broader public.

Economic evaluation: In HTA economic evaluation, comparators should not be limited to clinical outcomes only, but also consider broader social/lifestyle outcomes such as quality of life, return to work, and a reduction in workload for carers. CHF supports the running of workshops that will provide the HTA committees with an understanding of when to accept higher prices for health technologies.

CHF agrees that the consultation should include a sample representative of the population, ensuring that there is an adequate number of consumers and that potential conflicts of interest are disclosed ahead of the workshops.

Topic 4: Health Technology Funding and Purchasing Approaches and Managing Uncertainty

Approaches for funding or purchasing new health technologies: As mentioned before in this submission, CHF thinks that comparing technologies should not be limited to clinical outcomes only, but also consider broader social/lifestyle outcomes such as delivering improvements in quality of life, earlier return to work, and reductions in workload for carers. CHF supports the introduction of a pricing offer and negotiation guidance framework if it considers the broader social/lifestyle outcomes mentioned above.

CHF supports legislation that enables conditional listings on the PBS (Pharmaceutical Benefits Scheme) for therapies of High Added Therapeutic Value (HATV) and High Unmet Clinical Need (HUCN). This will ensure that price negotiations between sponsors and the government do not cause unnecessary delays to consumers in accessing life-saving medication.

CHF also supports HTA reform that counterbalances the monopoly-like tendencies of some technologies, and that stimulates downward pressure on prices to increase affordable access. Even if this does not necessarily translate into a decrease of out-of-pocket expenditure (some technology might lower in price but still attract the patient contribution fee) this delivers better value for money to consumers through a better use of taxation revenue.

Post-listing re-assessment of health technologies, particularly the creation of an explicit disinvestment framework, poses risks to consumers who might experience a more unstable supply of the therapies they need, or sudden dramatic price increase for technologies that are TGA approved, but no longer subsidised by the PBS (Pharmaceutical Benefits Scheme). It is fundamental that consumers are involved in the design and implementation of such a disinvestment framework, and that the framework takes in consideration consumer input, qualitative evidence, and broader social benefits of a technology that is being considered for disinvestment. In other words, the technology needs to undergo through the same rigorous and comprehensive process of listing also in de-listing.

Understanding the performance of health technologies in practice: CHF supports the optimisation of access and use of Real-World Evidence (RWD), and in particular an approach that centres consumers, community engagement and co-design. CHF supports the creation of a whole-of-government data infrastructure that is transparent and streamlined, and that is harmonised using international standards.

On the other hand, as mentioned earlier in this submission, this must happen in a way that safeguards the privacy and safety of consumer-reported data.

Measures should also put in place to prevent consumer-generated data to be used for financial gain. Consumers are adamant that they are happy to release data for altruistic purposes, but its use for financial profit is completely unacceptable. Legislators must not shy away from this requirement and ensure that there are clauses in place preventing this from happening.

Topic 5: Future-proofing Australia's systems and processes

Proactively addressing areas of unmet clinical need: CHF supports the development of a priority list for high unmet clinical need, developed in partnership between clinicians, patients, patient organisations, and community. CHF also welcomes the development of priority areas in partnership with Aboriginal Community Controlled Organisations (ACCO's).

CHF welcomes and supports the development of a horizon scanning process in Australia, as well as direct mention of a partnership mechanism with ACCO's to ensure health outcomes and equity for First Nations people is prioritised. The options mention that horizon scanning should be "open" to the use of patient and clinician partnership. CHF argues that a stronger commitment is necessary to ensure that consumers are involved in horizon scanning design and implementation.

Establishment of horizon scanning to address specific informational needs within HTA and the health system: CHF welcomes direct mention of a partnership mechanism with ACCO's to ensure health outcomes and equity for First Nations people is prioritised. The options mention that horizon scanning should be "open" to the use of patient and clinician partnership. CHF argues that a stronger commitment is necessary to ensure that consumers are involved in horizon scanning design and implementation.

Environmental impact reporting: CHF welcomes environmental impact reporting. However, the options in this section are vague in nature and will require more specific consultation prior to design and implementation.

Mechanisms for continuous review and improvement: CHF will always support plans for the continuous evaluation of processes including HTA. Such evaluation processes should always be collected from a variety of sources, include qualitative data, and

should not mistake HTA outcomes with HTA outputs. Naturally, capturing short, medium, and long term HTA outcomes will require adequate funding.

Capacity and capability of the HTA system: With the breadth of scope of the current HTA review, and the sizeable resources that this reform will command, it is paramount for the HTA review to make plans to train and expand the HTA workforce.

Strengthen international partnerships and work sharing: CHF is not opposed to efforts at harmonising Australian HTA processes with international processes, assuming such processes equally prioritise safety, quality, and efficacy. If done well, harmonisation can prevent costly work duplication and deliver better value-for money for consumers.