BETTER ACCESS AUSTRALIA's INPUT TO THE DRAFT HTA REVIEW TERMS OF REFERENCE

With a 500-word limit, BAA made two submissions to this process, this was further informed by the release of the first communique's from the Committee about the development process for these draft Terms of Reference the afternoon the input was due.

Like other organisations deemed 'not relevant' for consultation by the Reference Committee, BAA was given only two days to respond in this process.

Our input is transparently provided below.

Guiding questions for consultation 1. Do you foresee any challenges in addressing the issues listed for consideration by the HTA Review (per Clause 5.3.2 of the Strategic Agreement)? Which issue(s) and what are the challenges? Challenges/issues - or Nil input? (Please aim to keep the response under 500 words):

Submission One

Better Access Australia notes the lack of focus/mention of the patient as the basis for existence of the PBS, the PBAC and the current HTA processes used to determine whether or not a medicine is subsidised by the government to improve the health outcomes for the individual patient and the community.

Without appropriate context this is nothing more than a guidelines review for methods, rather than a review ensuring the objective of HTA achieve the community's expectations for access.

These TORs should state upfront that "This review and all questions or issues it seeks to answer or explore should be in the context of the vision of the National Medicines Policy to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment."

Submission two

The 500-word limit prevented the consumer advocacy organization I work with from providing a fully response, so I am making a submission both in my role as a member of Better Access Australia and my own experience as a patient in the health system.

Noting the most recent release of the communique's of the HTA Reference committee I, alongside Better Access Australia have significant concerns about how the Committee selectively chose departments (including the dept of health) and a select group of patient organizations as being 'relevant' to consult with at this point of the process.

The consultation with them precluding them from consulting more broadly with threats of retaliatory action from the Committee or the Department were inappropriate and bullying behavior, and any group that acquiesced to this should not have but it appears did. What gives this reference group the right to exclude anyone from commenting on a public health system review at any point of the consultation? Where is that in the terms of reference.

Oh wait it is... the self appointed description of those who participate in this system as being "independent experts... who are the preeminent source of advice to Government on decisions to subsidise health technology (including for whom and at what cost)." It is grossly inappropriate that

they are dictating who in the community can and cannot have a say in the review of the HTA that is used to restrict access to new medicine technologies in Australia.

We remind this reference group of the leadership work in consultation other areas of health embark on, including the preventive health strategy team, the primary care review, the MBS taskforce reviews, and the newborn screening team. These areas of health welcome the input of the community ON THEIR health programs. Why does this program and this area of health continually place itself above the community in the administration and consultation on this program? Why does the HTA reference committee acquiesce at best or lead the charge on this at worst? Is this the standard of consultation we can expect throughout the process?

I would have through this area of the Department had learned the lessons from the National Medicines Policy review process where patients, clinicians and communities were treated as second class citizens, and had to demand genuine consultation. WE as patients and the community also had to demand appropriate time to consider materials and respond... another feature this HTA review seems to also be ignoring, given those who were initially excluded from the opportunity to comment barely 48 hours to do so.

I personally and Better Access Australia challenge the HTA reference committee to show leadership and show genuine understanding of what it is to be in the privileged position of shaping aspects of the world's second oldest public health program. You are steward and custodians... please start to behave as such.

2. Are there any HTA policy and methods issues that do not fall within the areas identified in the draft ToR that you think should be included? What are they? And why should they be included? Other issues - or Nil input? (Please aim to keep the response under 500 words):

Submission One

Better Access Australia notes the emphasis in the TORs on the 'commercial' aspect of medicines and technology and the negative connotations thisconfers on access to a health service, the pejorative language we do not see used in the assessment of a clinical intervention assessed by MSAC for the

MBS (eg surgical procedure, duration of session with specialist.' This inherent or unconscious bias in language should be set aside.

The review methodology does not capture the need for timely access as per the NMP and creates no environment for this to be considered noting the average 820 days to access in this current system.

Are alternative methodologies or pricing negotiation practice a better way to achieve access and affordability. The review should challenge the process methodology applied by Australia and contemplate listing and evaluation thereafter based on PostMarket Reviews as achieving better outcomes for patients and for payers.

Finally Better Access Australia notes that placing a medicine in s100 reduces costs of listing and can significantly impact the HTA VFM assessment. Thisplaces patient access as an afterthought and leads to post-hoc challenges such as the ODTP and medicines such abacavir, adefovir and ataznafiras part listed for access in community pharmacy without appropriate remuneration for the supply chain.

Place of access and treatment public versus acute needs to not be a deciding factor in affordability of an HTA assessment method and a reason to deny access in the appropriate setting.

Submission Two

Why is the paper so focused on 'commercial' and continuing the construct of patients as an afterthought?

Why is the process failing to challenge the outcomes this current HTA process delivers for patients, and only focusing on how you can make the process more convoluted and complex?

Why is this not appropriately aligned to the NMP vision statement, and the demand from the community, not just companies and clinicians for improved timeframes to access.

Why is there no upfront commitment to reviewing the negative consequences of the current methodologies and processes that result in averages of 820 days for subsidised access after ARTG registration?

Why is there no consideration of alternative processes for subsidising and pricing medicines that are beyond traditional HTA If pricing is the issue can the process be flipped making use of pricing contracts and RSA's to conduct post market reviews thereafter with real world evidence of the value of the product as is rumoured to be the contractual basis for Novartis' Kymriah on the MBS.

Starting this review from the premise that HTA is the right thing and the good thing, stops innovative and new thinking about how the systems could better operate.

This should be more than a guidelines review. Noting the pervasive adoption of PBAC processes into other areas of health system subsidy, the basis of continuing with HTA in the first place should be reassessed, noting the conflict within the academic, medical and HTA sector that generate significant revenue from the perpetuation of this approach. This must be a founding principle of this review and not excluded from the process.

Finally, and most importantly - patients patients patients. They are the centre of this program and this HTA review does not instill confidence that this is recognised in the methodologies. In particular the presentations at ARCS, ISPOR and other conferences which highlight the disconnect between data in a HTA submission and the reality of that 6-minute walk test, or improved lung function for a patient and their carers.

We note the Productivity Commission, Services Australia and Veterans Affairs have not been consulted on these TORs yet Finance and Treasury and all the state and territory governments have?

Given Treasury considers the macro impact of health investment surely the Productivity Commission which has published often on the value of health improvements to Australia's economy should be consulted?

What are the states commenting on an exclusively federal health program? Why are treasury and finance providing input but those who have aligned programs and administer the PBS excluded alongside the patients, doctors, pharmacists, the GBMA and non-MA members?

This is a very poor start to this review, but perhaps it truly reflects the intent of the Reference Committee and therefore the community is forewarned of what is to come. Very disappointing. Please change your approach to the community, to patients and this review and its intentions as a matter of priority.

Need more information?

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