My name is Ian Noble, I have a consultancy business called Noble Pharma Consulting, which was set up mid 2013 and provides advice to Pharmaceutical companies on how best to make submissions to the PBAC to gain subsidised access to the PBS. In this time I have prepared many submissions to the PBAC. I am also a member of the Medical Services Advisory Committee (MSAC) since 2014 which provides advice to the Minister of Health on the creation of new MBS item numbers for medical procedures.

I am a health economist with 23 years experience of working in and closely with the pharmaceutical industry in the UK, Switzerland and Australia. Most of my experience has been in Australia where I have engaged in the PBAC process since 1999.

My interest in commenting on the draft Version 5 of the guidelines

My interest in the guidelines revision is to see Australia maintain its position as a world leader in the pragmatic application of HTA for decision-making purposes. The primary reason I left Switzerland in 1998 for Australia was because as a health economist I was frustrated with the lack of consideration most jurisdictions gave to economics based decision-making in health care. From my perspective at the time health economics was largely an academic exercise with journal publication being the main goal. I saw Australia as a global leader and one of the only places in the world to engage in real life HTA that led to actual decisions being made that affected people. This is primarily why I moved to Australia.

I am pleased that the Minister of Health has approved a comprehensive review of the guidelines because by being forward looking, consulting stakeholders broadly and comparing yourself with the best in the world we can be assured that Australia will continue to be a leader in the application of HTA. In this regard I'm in particular reassured by the term of reference (TOR), 'Worlds Best Practice '.

There are many things to comment on with respect to the draft guidelines but I want to focus on one issue only where I think more work is needed, that being enhancing the role of the patient/consumer in HTA.

The patient voice in HTA in Australia

In Australia there have been recent advances in bringing patients into the process of PBS listings with hearings at PBAC meeting and the recruitment of a second consumer representative on the PBAC. These are very welcome additions to the process. Notwithstanding this however the voice of the patient remains very small in HTA decision-making.

There are no terms of reference that point to enhancing the voice of the patient. Considering the TOR 'worlds best practice' and 'consistency with international standards' it is not clear to me how these can be achieved without an overhaul of how patients are brought into the heart of the decision making process. In the time I have been in Australia (1999) other countries such as England and Scotland among others have not only created from scratch, entire HTA systems (NICE and SMC respectively), they have surpassed the efforts made by Australia to engage with patients. England's NICE has its Citizen's Council and Scotland's SMC has its Patient And Clinical Engagement group (PACE).

The patient voice needs to be brought into the PBS process earlier, more systematically throughout the process and with feedback loops so that continual improvement is possible. There should be on-going education between PBAC and consumers on how both sides need to communicate with each other to convey effectively important information. There needs to be commitment from government, industry and patient / consumer organisations to make this happen.

Although this requires a general overhaul, which has implications beyond the guidelines review, there are important practical steps that should be considered as part of industry and patient submissions to the PBAC, which should be included in version 5 of the guidelines.

A practical step that might be considered is guidance on methods that allow patients to explain the characteristics of their disease that are most important to their daily lives (and the lives of their carers). Currently there is no systematic process of capturing and quantifying the patient perspective. Qualitative and quantitative methods can however, be used to achieve this aim. For example, the use of discrete choice experiment (DCE) methods can be deployed to help provide a patient perspective in language that makes sense in the world of HTA. DCE requires in-depth interviews with patients and semi-structured quantitative surveys to explore the experiences that patients have with their illness, with their current therapies and even the impact of illness and treatments on caregivers. The outputs of such analyses can be used directly in submissions to the PBAC either stand alone or embedded in a sponsor’s submission as part of Section 1 (Context). Section 1 of the proposed guidelines describes the vital first step in an HTA, which outlines the clinical issues to be addressed and the clinical algorithms. This provides overarching context for the entire submission. The context created in Section 1 will be strengthened by a clearer articulation of what is most important to the patient and this articulation will add value to the subsequent analyses of randomised controlled trials which occur in Section 2 (Clinical evaluation) and the economic modelling that occurs in Section 3 (Economic Evaluation).

The PBAC should continue the good work with respect to holding patient hearings at PBAC meetings, making them more transparent, systematic and putting guidance around them. However, there should be an expectation by all stakeholders that the Australian patient view be embedded in submissions to the PBAC. This is the primary document used as the basis for PBAC decision-making and the patient view needs to be at its core.

Summary

In summary when other ‘HTA’ countries around the world are reaching out and embracing the patient view in a more systematic and holistic way, there is less evidence that this is happening here in Australia. I urge that the guidelines be updated to signal a willingness to see more from the patient perspective embedded in submissions to the PBAC.

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