

SUBMISSION TO REVIEW OF THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) GUIDELINES

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Access to appropriate and safe medicines is a key part of any modern health system. Consumers in Australia place a high value on the role the Pharmaceutical Benefits Scheme (PBS) plays in providing timely, reliable and affordable access to necessary medicines. CHF supports the aim of the National Medicines Policy to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.

One of the strengths of the PBS is that expenditure is uncapped which gives consumers confidence that they are able to access the medicines they need. Consumers understand that PBAC is the gatekeeper and there is an appreciation of the role it plays in ensuring that new medications are value for money as well as being safe to use and providing good therapeutic outcomes. What consumers are looking for is reassurance that PBAC uses a process which is fair and takes account of issues that are important to them, as the users of medicines.

Consumer Involvement in Health Technology Assessment

The involvement of consumers in the process of assessment varies across countries in terms of when consumers are involved and how they are involved. In looking at how to improve patient and broader consumer involvement in the process CHF suggests that the values developed by the Health Technology Assessment International (HTAi) special interest group that looks at patient and citizen involvement in the health technology assessment (HTA) process are a useful starting point.

*Values for Patient Involvement in HTA*¹

- **Relevance**

Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.

¹ HTAi Values and Standards viewed at <http://www.htai.org/interest-groups/patient-and-citizen-involvement/pcig-home/values-and-standards.htm> on 18/9/2015

- **Fairness**
Patients have the same rights to contribute to the HTA process as other stakeholders and have access to processes that enable effective engagement.
- **Equity**
Patient involvement in HTA contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly among all users.
- **Legitimacy**
Patient involvement facilitates those affected by the HTA recommendations/decision to participate in the HTA; contributing to the transparency, accountability and credibility of the decision-making process.
- **Capacity building**
Patient involvement processes address barriers to involving patients in HTA and build capacity for patients and HTA organisations to work together.

There are two levels of consumer engagement in this process, at the general HTA level and for individual assessments. It also needs to make a distinction between the involvement of the broader community as consumers or in HTAi terms citizens who have an interest in seeing the system deliver optimal outcomes to benefit everyone and the involvement of patients in individual assessments who have a vested interest in the particular medicines assessed. The PBAC guidelines need to address both level of public involvement.

CHF concerns

There are a number of issues that need to be addressed at both the overall level and the individual HTA level with respect to future PBAC practices.

There needs to be a more systematic approach to involving consumers in the whole process. The Scottish Medicines Consortium (SMC) which is considered to be good practice has a Public Involvement Network Advisory Group which provides a forum for patient and carer groups to engage with SMC as partner that helps SMC engage with the public. This ongoing mechanism is not tied to individual assessments but more to the process of engagement and provides a way of identifying areas of concern for consumers and patients, training and support needs and a process of revision and reflection to ensure there is a process of continuous improvement.

CHF recommends that PBAC look to establish a similar mechanism to guide its future work around how best to involve consumers and consumer organisations in the assessment process organisations.

In the interim there are a number of ways the process can be improved.

The first is around consumer representation on PBAC where the decisions are made. Currently there is only one consumer on PBAC which is not consistent with the notion of active engagement or providing adequate support for consumer participation. CHF has consistently argued for a second consumer representative on PBAC and the recent change to

the legislation which enlarges PBAC provides scope for that. Having two consumer representatives would give the following benefits:

- allows more diversity of consumer experience and perspective with each consumer having access to their own networks and support mechanisms;
- allows the representatives to specialise in particular areas, to work with patient groups in those areas and some provide more in depth analysis and advice to PBAC; and
- provides some pathway for succession planning as there can be a process of rotating the two positions so a new consumer representative has the support of an existing person.

Related to this we do not believe enough effort has been put into training members of PBAC on how to engage and work with consumers and how to use consumer input in their deliberations CHF would be well placed to work with PBAC members to improve their capacity to obtain and interpret consumer experiences and how to use these to balance the perspectives being put forward from the sponsors.

CHF welcomes the recent move by the Minister to ensure that more consumer input into the process is gleaned with PBAC holding consumers and consumer organisations hearings prior to each meeting. This is a significant step forward. This could be enhanced by having a robust process of calling for consumer submissions for all assessments. There needs to be a mechanism similar to the SMC Public Involvement Officers that provide support to patients and patient organisations on how to put in a submission as well as a proforma that people can follow to have their say. This could be supported by a process of consumer engagement such as the one previously used by MSAC which used a third party (CHF) to work with consumers in focus groups and one-on-one to get their input into all proposals going to MSAC. It also systematically collected consumer stories and experience to add to the quantitative data available from the sponsors. This process needs to be formalised and become the norm. If the patients' submission were built into the assessment flowchart as they are in the SMC model it would be more transparent in terms of, who is involved and how this input feeds into PBAC decision making process. It would also be built into the Guidelines. There would need to be adequate resources with training for consumers and consumer organisations to allow them to participate in the process fully.

CHF supports the idea of PBAC meetings being opened up to the public so interested patients and consumers can see how the Committee operates. However this would only be effective if the patients and consumers had been adequately briefed on the process beforehand.

Another area which needs some attention is post-PBAC communication and education. The HTAi standards recommend a clear process for providing feedback to consumers who have had input into the proposal or have an identified interest in the outcomes. The current documents around recommendations are not consumer friendly and are not accompanied by any process of education for consumers about what they mean. Again the example of the SMC is instructive as the Public Involvement Officers not only support patient groups to put submissions in but are also responsible for providing feedback to them. CHF recommends that PBAC adopt a similar process for feedback to consumer groups as this would reduce the chances of confusion, disinformation and disquiet that sometimes follow when the meaning

of the decision is not clear e.g the recent PBAC decision around “a flagging” of biosimilars was not well understood and lead to many groups taking public positions in opposition. Some of this opposition could have been avoided with a clearer statement on what was being recommended.

One of the key issues which come up from consumers and consumer organisations is a view that there is an over emphasis in the economic evaluation on improved health outcomes and not sufficient weight given to improvements in the quality of life. These are not the same thing. Whilst the guidelines talk about quality-adjusted- life years gained being the appropriate measure, patients are much focused on not just possible time gained, but also critical enhancement to quality of life over that time. For some conditions the extra time may be very short but that the quality of life improvements would be significant and this is not always perceived to be adequately reflected in the deliberations and/or decisions made by the Committee

This is where specific and targeted consumer input into the process would be beneficial and sponsors should be encouraged to include it, possibly in Section F of their submissions. This is the catch all for all other relevant information but does not explicitly identify consumer stories/experience as being a possible source of information. We think there should be a new F.3 that explicitly identifies consumer experience. This section should require sponsors to show how they have engaged consumers in the discussion and how they have elicited information from them. This could be cross checked with the patients’ submission as outlined above.

Consideration of costs and savings need to have a greater whole system perspective. The costs and savings could also be revised to allow for the inclusion of potential savings in areas other than the health budget to be included in the overall cost effectiveness evaluation. For many chronic conditions there is evidence that there could be savings in other areas of expenditure with a better treatment option e.g. more effective treatment of rheumatoid arthritis should mean people being able to live more productive lives and so making savings on income support expenditure. Whilst collecting and agreeing on what should be included in such data can be difficult we think it would add value to the process.

CHF would support the development of a more concise and clear Guidance document as this would make it easier for consumers to understand and to identify opportunities for input. All documentation should be in plain English and made available through an accessible website and hard copy as required.

Conclusion

This review of the Guidelines is an opportunity to continuously improve the way PBAC assesses proposals and we see it as an opportunity to give consumers more opportunity for input into the process. If this potential is to be realised then there needs to be adequate resourcing provided to support consumers and consumer organisations to participate.

CHF looks forward to seeing the draft revised guidelines and being able to comment on them as outlined in Point 4 of the items to be included in the review.