INTRODUCTION

The Centre for Community Driven Research (CCDR) is a non-profit organisation committed to supporting meaningful community engagement in health and the medical research sector. At CCDR community includes the government, clinicians, industry, researchers, patient communities and the general population. Our role is to facilitate connection between each stakeholder group with a particular focus on supporting patient communities and the general population to engage in the decision-making process.

Our approach is less about 'us and them' and more about what we can do as a community that values the experience of patients and their families, the expertise of clinicians and researchers, the contribution of industry and the role of the government.

CCDR has a wide range of community engagement strategies that are being implemented to inform and educate the community about the regulatory and reimbursement process in Australia. CCDR supports the community by providing feedback and keeping the community up-to-date about submissions and opportunities for involvement. Our platform includes videos, fact sheets and a community register for individuals who are interested in keeping informed or participating in the decision-making process. CCDR also collaborates with various non-profit organisations, community groups and pharmaceutical companies to develop and coordinate research-based approaches to Pharmaceutical Benefits Advisory Committee (PBAC) submissions.

Due to the emphasis that CCDR places on community engagement, we advocate for greater knowledge and meaningful participation of the community in the Australian health care system, including in the Pharmaceutical benefits Scheme (PBS) and PBAC processes.

CCDR appreciates the opportunity to provide feedback in relation to the PBAC Guidelines, specifically in relation to the addition of criteria that demonstrates the value that the PBAC place on community engagement and providing transparent and meaningful feedback to patients groups and the broader community.

Challenges driving the need for greater community engagement in decision-making.

It is acknowledged that the PBS and PBAC face a number of challenges particularly in relation to the process of listing new medications, affordability and timely access to treatments, and transparency of the PBAC process.

Before submission to PBAC, review time through the Advisory Committee on Prescription Medicines (ACPM) and the Therapeutic Goods Administration (TGA) can take up to 17 months (1). Lengthy approval times of medicines significantly effect the population who require new treatments and are often time-constrained due to the nature of their disease itself.

The dynamic landscape of research and drug delivery has allowed for new, improved therapies and personalised treatments. As an example, new subtypes of cancers are being isolated and cancer drugs specialising in specific subtypes have greater effectiveness in either overall survival (OS) or progression free survival (PFS) (2). Cancer as a disease is complex, with various stages of illness often determining the value patients place on outcomes of specific medications such as quality of life gained, and also quantity of life gained (2). Emerging cancer therapies can have significant clinical benefits for certain groups of people rather than the wider population. The heavy reliance PBAC decision-making places on cost-effectiveness means that not enough weight is given to the benefits and value that emerging, affordable and accessible drugs provide for patients (2).

There is need for increased transparency and understanding of the PBAC decision-making process. Decisions around regulatory and reimbursement approval have caused discourse amongst stakeholders regarding the perceived inconsistencies in decisions made by Australian authorities compared to equally thorough evaluation processes in other countries (2). The community is also calling for more meaningful and transparent feedback following PBAC meetings to better understand the rationale for decision- making.

Community engagement in the PBAC process.

Current opportunities for the community to engage in the PBAC process include mechanisms such as an online feedback system and a community hearing (that was recently trialled). These mechanisms on their own do not provide an optimum environment for the community to provide feedback or articulate their experience in the context of the decision being made. They ask the community to engage in the PBAC environment, however for optimal community engagement, it is important that the PBAC develop mechanisms that also engage the community in their own environment.

The CCDR does not suggest displacing the economic or clinical components of decision- making. What we do suggest is to make more room to assess the value that the community places on access to affordable and timely therapeutics, and the values that they would like to see included in the decision-making process. It is this kind of input from the community that provides the context in which decisions are made at the PBAC.

CCDR have been testing various community engagement mechanisms and recommend additions to the PBAC Guidelines and submission process based on the following four principles:

1. Inclusion of community value and values: It is proposed that a dedicated section within a PBAC submission be allocated to establish the value that the community places on the therapy that is being considered and the values that they would like to see included in decision-making. This will also help demonstrate the importance that the PBAC assign to community feedback, which is not always clear.

2. Transparency: Encourage a research-based approach to submitting community perspectives or feedback. This will result in the views of a broad section of the affected population being represented and clarity in relation to whom the demographic providing feedback is. It will also allow more people in the general community outside advocacy groups to have the opportunity to engage in the process. This may be done by qualitative and quantitative research.

3. Accessibility: CCDR would like to take the opportunity to note that while the trial of ‘community hearings’ in 2015 was welcomed, if

hearings are to be continued they should be held in a location and environment that allows patient groups to access the opportunity. The nature of many diseases makes it unrealistic for patient representatives to travel to Canberra and also, unlike industry and government, there is often no funding to support active engagement of this kind. It is also recommended that the term 'hearing' is not particularly enticing to the community and that an alternative term be used to encourage participation. An alternative would be forums within a community setting to hear from patients the value that they place on accessing the therapy under review.

4. Evaluation: Structured community engagement in health and medical research is a relatively new addition to the decision-making process. The evaluation of mechanisms used to engage the community in the PBAC will need to be monitored and evaluated to demonstrate their effectiveness and also, to be able to provide detailed information back to the community on how their feedback was received.

The challenge, however, is that there is no sustainable funding available to actively support the community to engage in the PBAC process. Until this inequity is addressed, the level and quality of community engagement will likely remain ad hoc and underutilised, limiting the potential value and wealth of insight that the community can offer the PBAC process.