www.breastcancer.org.nz

14 July 2018

PHARMAC Consumer Voice 2018 consultation

Breast Cancer Aotearoa Coalition submission

Introduction:

Breast Cancer Aotearoa Coalition (BCAC) appreciates the opportunity to present our submission on steps that should be taken to improve the consumer voice at PHARMAC.

We believe the patient voice should be at the core of all PHARMAC decision making including decisions on medicines, medical devices and policy. Implementing this change will improve the quality of decisions made and lead to better treatment, equity and outcomes for all patients.

About Breast Cancer Aotearoa Coalition

BCAC is an umbrella organisation representing more than 30 breast cancer-related groups in New Zealand. Our role is to support, inform and represent people with breast cancer. We are committed to transforming the lives of those diagnosed with breast cancer by seeking world-class detection, treatment and care.

We regularly consult with:

- patients with breast cancer
- our member groups
- cancer clinicians and researchers.

Some of our achievements include:

- engaging with PHARMAC, Ministers and the Ministry of Health over the public funding of a range of breast cancer medicines including taxanes, aromatase inhibitors and HER2-targeted molecules
- providing support and information for women with secondary breast cancer
- informing women and their families about the latest in breast cancer news and research through our comprehensive and regularly-updated website
- supporting women with information and resources via our *Step by Step* publication distributed free of charge via BCAC's website and through a nationwide network of breast and cancer clinics, hospitals, and support organisations
- helping to develop the *Guidelines for the Management of Early Breast Cancer* and the *Standards of Service Provision for Breast Cancer Patients in New Zealand*
- providing a consumer voice to many expert clinical groups and international scientific meetings and ensuring our knowledge remains current.

Overview of breast cancer in New Zealand

Compared to Australia and other developed countries, New Zealand has poorer cancer services and delayed delivery of treatment[1], reduced access to effective treatments, worse outcomes and higher death rates. New Zealand has the seventh highest age standardised mortality rate from breast cancer in the world [2] and New Zealanders are 40 per cent more likely to die than their Australian counterparts[3][4]. Māori have the highest breast cancer incidence of any population group in the world, 28% higher than New Zealand European women and 60% higher mortality, while Pasifika women have a breast cancer survival rate lower than Māori women.[5]

A number of factors are thought to contribute to New Zealand's higher death rate for breast cancer including health service and patient variables, later diagnosis, slower access to quality treatment and less effective therapy than in Australia. In New Zealand, Māori (rural) and Pasifika (urban) women have poorer rates of screening, diagnosis and treatment.

[1] Ministry of Health 2014. New Zealand Cancer Plan: Better, Faster Cancer Care 2015 – 2018.
[2] How to Improve Outcomes for Women with Breast Cancer in New Zealand. The University of Waikato, June 2018.
[3] Campbell I.D., Scott N., Seneviratne S., Kollias, J., Walters D, Taylor, C, Webster F, Zorbas H and Roder DM 2014. Breast cancer survival in New Zealand women. ANZ J Surg. 2015 Jul; 85 (7-8):546-52. doi: 10.1111/ans.12851.
[4] Sandiford, P., Abdel-Rahman, M. E., Allemani, C., Coleman, M. P., & Gala, G. (2015). How many cancer deaths could New Zealand avoid if five-year relative survival ratios were the same as in Australia? Aust N Z J Public Health, 39(2), 157-161. 10.1111/1753-6405.12344
[5] How to Improve Outcomes for Women with Breast Cancer in New Zealand. The University of Waikato, June 2018.

BCAC's view of the current PHARMAC consultation processes

- We believe PHARMAC must collaborate and partner with consumers/patients at every step of the decision making process, in place of the current very formal and closed PHARMAC structure. This will improve decisions leading to enhanced outcomes for all those involved including consumers, family, whānau, communities and PHARMAC.

- Currently, we believe that consumers are not involved in the PHARMAC decision making process in a meaningful way that allows them to have genuine input into the process.

- Consumers are technically able to apply for a medicine to be funded but in reality a genuine application can only be made by a person or entity with access to the published data, which is not available to the average consumer.

- There is also no genuine involvement for patients/consumer groups in the evaluation and decision making processes. Consumers only have the opportunity to respond to a PHARMAC consultation once PHARMAC has completed its committee processes and made a decision to fund a medicine. It is only then that consumers are invited to comment on the impact on patients of receiving or not receiving this medicine and how it should be delivered.

    - This means that consumers and consumer representatives are in reality most often only able to have input at the very end of the process when a decision has essentially already been made and only very minor changes are able to be made. This is too late in the process and gives an impression of being a token gesture rather than genuine consultation.

    - This means patient experience and viewpoint and the impact on people are not genuinely taken into account in the process, including the requirement to assess need, contained in the Factors for Consideration. The absence of a consumer voice is detrimental not only to patients but also to the PHARMAC process in terms of PHARMAC's ability to understand the impacts of its decisions and improve future decisions.

- A more engaged process, where there is genuine consumer collaboration, partnership and genuine input into decision making, would lead to greater acceptance of PHARMAC decisions by patients and the public. It would also enable PHARMAC to better meet the requirements in the Factors for Consideration including the need consideration.

Summary of BCAC recommendations:

Breast Cancer Aotearoa Coalition recommends the following changes to ensure an authentic consumer voice is at the heart of all PHARMAC processes:

- Ensure consumer involvement throughout all PHARMAC processes in a collaboration and partnership model.

- Ensure earlier, broader, deeper and genuine consumer and clinician involvement in the decision making processes – enabling the best advice to be provided on particular medicines/medical devices.

- Ensure that all processes are inclusive of people of diverse cultures, including Māori and Pasifika people.

- **Medical and Medical Devices Advisory Committee**: Create a single Medical and Medical Devices Advisory Committee to replace PTAC and its sub-committees such as CaTSoP. This new committee would incorporate consumer and clinical representatives.
    - There would be standing clinical members and one standing consumer representative.
    - Additional consumer and clinician representatives would be brought in to provide input and expertise when particular medicines/medical devices are being considered.
    - The additional consumer representatives would be nominated and selected by a Patient Group Coalition.
    - This new model would ensure the right clinical and consumer expertise is in the room from the beginning and throughout the process, enhancing decisions and outcomes.

- **Patient Group Coalition**: Replace the Consumer Advisory Committee with a new Patient Group Coalition that is part of the entire PHARMAC process. It would be more broadly and genuinely representative of consumers/patients. It would be involved throughout the entire PHARMAC process, including being able to make applications, bringing knowledge and experience when medicines/medical devices are being considered by PHARMAC and being included in decision making. Members of the Patient Group Coalition would be nominated and selected from consumer advocacy and advisory groups, rather than being appointed by PHARMAC.

- The new Patient Group Coalition would be truly representative of and connected to their consumers/patients and would remain in consultation and communication with their groups, thus providing authentic voice for the groups they represent.

- The new Patient Group Coalition should have input and oversight of PHARMAC operating policies and procedures, and input into consultations and changes being considered. Consultations should also include the public.

- The new Patient Group Coalition would have full involvement in the consideration of new brands, including considering information on how the medicines are used and tolerated in

similar jurisdictions such as Canada and Australia. If a medicine is changed, access to the original medicine should remain available to physicians to prescribe to patients for whom the new medicine has significant side effects or does not have the intended clinical effect.

Outcomes: The changes we suggest in our recommendations would improve the timeliness, transparency and integrity of PHARMAC's processes and would result in better understanding by the public of the process and greater acceptance of decisions.

SEE:

Appendix 1: Revised Process Flow: for the changes to committee structure and PHARMAC process we are recommending
Appendix 2: Why should PHARMAC adopt BCAC Recommendations?

Additional recommendations

We believe that PHARMAC should:

1. Speed up the decision making process

- Set and implement deadlines. Deadlines for decision making give patients, clinicians and suppliers certainty.

- Improve organisation and timeliness of committee meetings, which is critical to fast and effective decisions.

2. Ensure clear accountability and guidelines

- Ensure clear accountability and guidelines which improves acceptance of decisions by patients and the public.

3. Ensure transparency around decision making

- Be open and transparent about the reasons for funding and not funding medicines. Do not state that medicines are not effective when evidence shows they are effective and they are being successfully utilised overseas. Be clear if the reason the medicine is not being funded is lack of funds available.

4. Separate efficacy from purchasing

- Separate the processes of determining efficacy and clinical benefit from purchasing decisions. Medsafe is responsible for the regulation of medicines and medical devices in New Zealand. Medsafe ensures that medicines and medical devices are efficacious and acceptably safe. There should be full acknowledgement of the role that Medsafe has in the health system in New Zealand and no duplication of the work in determining efficacy.

4. Seek further funding

- Take a more active role in seeking more funding for medicines that are effective and that other countries have funded.
- Move from a focus on budget control to patient centric decisions.

BCAC's responses to Pharmac Consumer Voice 2018 consultation questions:

Question 1

Are there parts in this process where consumer input could be incorporated or changed?

We call on PHARMAC to:

- Seek earlier, broader, deeper and genuine input from consumer representatives and clinicians to ensure an authentic voice.
- Incorporate the views of consumers, and clinicians with appropriate expertise, throughout every step of PHARMAC's decision making process including the committee process.
- Ensure that perspectives of all cultures are taken into consideration, including Māori and Pasifika people who are disproportionately represented in a number of disease groups.

Refer to Appendix 1: showing where consumer input can be incorporated.

Question 2

What should the nature of that input be (e.g. inform, consult, involve, collaborate, empower)?

- Have consumer representatives and the right clinical expertise in the room at every step of the process. These people must be active participants in decision making whose views and knowledge are incorporated into decisions. This means a collaboration and partnership approach that empowers those impacted by the decisions.
- PHARMAC should provide feedback and engage in dialogue on decisions with consumer representatives/groups that have, and have not, been directly involved in the decision making process.

Question 3

How do you suggest PHARMAC should seek this input?

- Create a single **Medicines and Medical Devices Advisory Committee** to replace PTAC and its sub-committees such as CaTSoP. This new committee would incorporate consumer and clinical representatives.
    - There would be standing clinical members and one standing consumer representative.
    - Additional consumer and clinician expertise would be brought in to provide input when particular medicines/medical devices are being considered.

    - The additional consumer representatives would be nominated and selected by the Patient Group Coalition.
        - This would ensure the right clinical and consumer expertise is in the room from the beginning and throughout the process.

        - The committee should thus include two consumer members – one should be a longer-standing representative of consumers and another should be brought in as a representative of the particular disease group being considered in each case.

- Replace the Consumer Advisory Committee with a new **Patient Group Coalition** that would be an integral part of the entire PHARMAC process. It would be broadly and genuinely representative of consumers/patients. Members of the Patient Group Coalition would be nominated and selected from consumer advocacy and advisory groups, rather than being appointed by PHARMAC.

Question 4

How do you think it would help improve the quality of PHARMAC's decisions?

- Having one Medicines and Medical Devices Advisory Committee to replace PTAC and its sub-committees such as CaTSoP, incorporating focussed consumer and clinical representation, would enable flexibility to have the right consumer and clinician expertise at the time recommendations are being made. Having a single committee would significantly improve the timeliness of decisions. It would mean matters would not have to be referred to another committee which can add many months to the process.

- Replacing the Consumer Advisory Committee with a new Patient Group Coalition would enable decisions to take account of genuine patient experiences and concerns, and would therefore ensure medicines meet patient needs. Patients wouldn't just be hypothetical recipients of medicines but real people whose needs were truly considered. The patients' knowledge would improve decisions and enable PHARMAC to better take into account impacts on patients, family, whānau and communities – those voices would be right there in the process.

Question 5

How could the consumer voice be better incorporated when we change the brand of a medicine?

We believe the consumer voice should be incorporated at every step of PHARMAC processes, as an authentic voice. Full information on the medicines should be provided to consumer representatives to allow informed input and result in better informed decisions. The information should include how the medicines have worked, and been accepted and tolerated, in similar jurisdictions to New Zealand such as Canada and Australia. This information would provide informed input and contribute to high quality decisions.

If a medicine is changed, access to the original medicine should remain available to physicians to prescribe to patients for whom the new medicine has significant side effects or does not work. This would require arrangements between PHARMAC and two suppliers but is essential for a patient-centric system with a focus beyond budgetary outcomes.

Question 6

[In relation to ongoing engagement with consumer advocacy groups, PHARMAC forums, Operating Policies and Procedures, Consumer Advisory Committee]:

Does the consumer voice need to be enhanced in any areas of the above areas of work? If so, how?

Engagement with consumer advocacy groups, PHARMAC forums and Consumer Advisory Committee:

- Replace the Consumer Advisory Committee with a new Patient Group Coalition that would be involved throughout the entire PHARMAC process, including bringing knowledge and experience when medicines are being considered by PHARMAC. It would be broadly and genuinely representative of consumers/patients. Members of the Patient Group Coalition would be nominated and selected from consumer advocacy and advisory groups, rather than being appointed by PHARMAC.

- One member of the coalition would be nominated as a standing member on the proposed new Medicines and Medical Devices Advisory Committee (replacing PTAC and its committees such as CaTSoP). Other members of the coalition would be available to be nominated by the coalition to sit on the committee when particular medicines/medical devices are being considered.

- Establishment of a broadly representative Patient Group Coalition would assist PHARMAC in achieving high turn-out and better public engagement at PHARMAC forums as these groups would use their networks to ensure affected patients and their representatives knew of such meetings and understood the value of attending. There would be greater trust that community views would genuinely be taken into account in PHARMAC's evaluation and decision processes.

Engagement with Operating Policies and Procedures

The new Patient Group Coalition should have input and oversight of PHARMAC's operating policies and procedures, consultations and changes being considered. Consultation should also include the public. PHARMAC's over-arching policies and day-to-day operations have ultimate impact on patients, family, whānau and communities so it is important to ensure a genuine consumer voice is included at every step of the process. Timeliness, transparency, engagement and integrity would be improved by making these changes.

Question 7

How would it help improve the quality of PHARMAC's work?

Replacing the Consumer Advisory Committee with a new Patient Group Coalition would enable decisions to take account of genuine patient experiences and concerns and would therefore ensure medicines meet patient needs. Patients wouldn't just be hypothetical recipients of medicines but real people whose needs are genuinely understood and incorporated into decisions. The patients' knowledge would improve decisions and enable PHARMAC to better take into account impacts on patients, family, whānau and communities – those voices would be right there in the process.

The changes we recommend would improve the timeliness, transparency and integrity of PHARMAC's processes and this would result in better understanding and engagement by the public in the process and greater acceptance of decisions.

Question 8

What should membership on the CAC look like?

- We suggest the CAC is replaced by a new Patient Group Coalition that is part of the entire PHARMAC process. It would be more broadly and genuinely representative of consumers/patients. It would be involved throughout the entire PHARMAC process, including being part of the decision making.
- Members of the Patient Group Coalition would be nominated and selected from consumer advocacy and advisory groups, rather than being appointed by PHARMAC.
- Their role should be broad and include the ability to recommend medicines, contribute to decision making on medicines funding in a collaborative/partnership capacity and have input into policy.

Question 9

What skills, experience or characteristics do you think members of the CAC should have?

- The Consumer Advisory Committee should be replaced with a Patient Group Coalition that is part of the entire PHARMAC process including decision making.

- We believe members of the Patient Group Coalition should have the following skills/experience/characteristics:
    - Knowledge and/or experience of a disease or diseases
    - Ability to bring not only their own knowledge and/or experience of a disease to the table, but also their understanding of the perspectives and concerns of others with the same disease(s), and
    - Ability to understand and take into account the views and experiences of people with other diseases. It is important they are able to take a broad view and contribute constructively and fairly to decisions affecting a range of patients and a variety of diseases.
- They should be well-connected to other consumers/patients and stay in consultation and communication with their groups, thus providing authentic informed consumer voice to the decision making process.
- Members of the Patient Group Coalition should have training in PHARMAC processes to fully understand the system and what is required of them to be patient representatives in PHARMAC's processes. This nature of training should be determined in partnership with the Patient Group Coalition. The training would include how to empower patients to effectively use their knowledge of not only their own experience, but also that of others who are impacted by diseases and to contribute to decision making without bias.

Question 10

What role do you think the CAC can have in supporting PHARMAC to ensure it is receiving and considering consumers' views and perspectives?

- Our recommended new Patient Group Coalition should have input at every stage of the process including the committee and decision making stage.
- They should be involved at the outset of the process, be able to recommend medicines for funding. They should have formal membership of every advisory committee.
- Their role should include understanding and expressing the needs and views of consumers/patients.
- Their views and knowledge should be clearly and evidently taken into account and incorporated into the decision making processes at every stage in a collaboration/partnership model.
- It is important that consumer representatives comment, contribute, be listened to, be in the room during all discussions and decisions and have their views incorporated in a partnership/collaboration model into decisions.

Question 11

Are there consumer voices that are not represented?

We believe that overall the consumer voice is not heard in a meaningful way in PHARMAC processes. This is why we are recommending a new robust Patient Group Coalition with genuine consumer representation in place of the Consumer Advisory Committee; and consumer representation on a new committee, the Medicines and Medical Devices Advisory Committee, formed by combining PTAC and sub-committees including CaTSoP, in which appropriate clinical experts are invited to participate depending on agenda items.

We believe it is important to ensure processes and consumer representation are inclusive of people of all cultures including Māori and Pasifika people.

Question 12

Are there examples that you are aware of, where the consumer voice is well represented?

There are many examples overseas where consumer input is an embedded part of the processes of the PHARMAC-equivalent bodies. We believe the patient and public voice models in Canada and Australia are particularly noteworthy and worth emulating/drawing from in New Zealand. These systems show that genuine consumer consultation can and does work.

Appendices

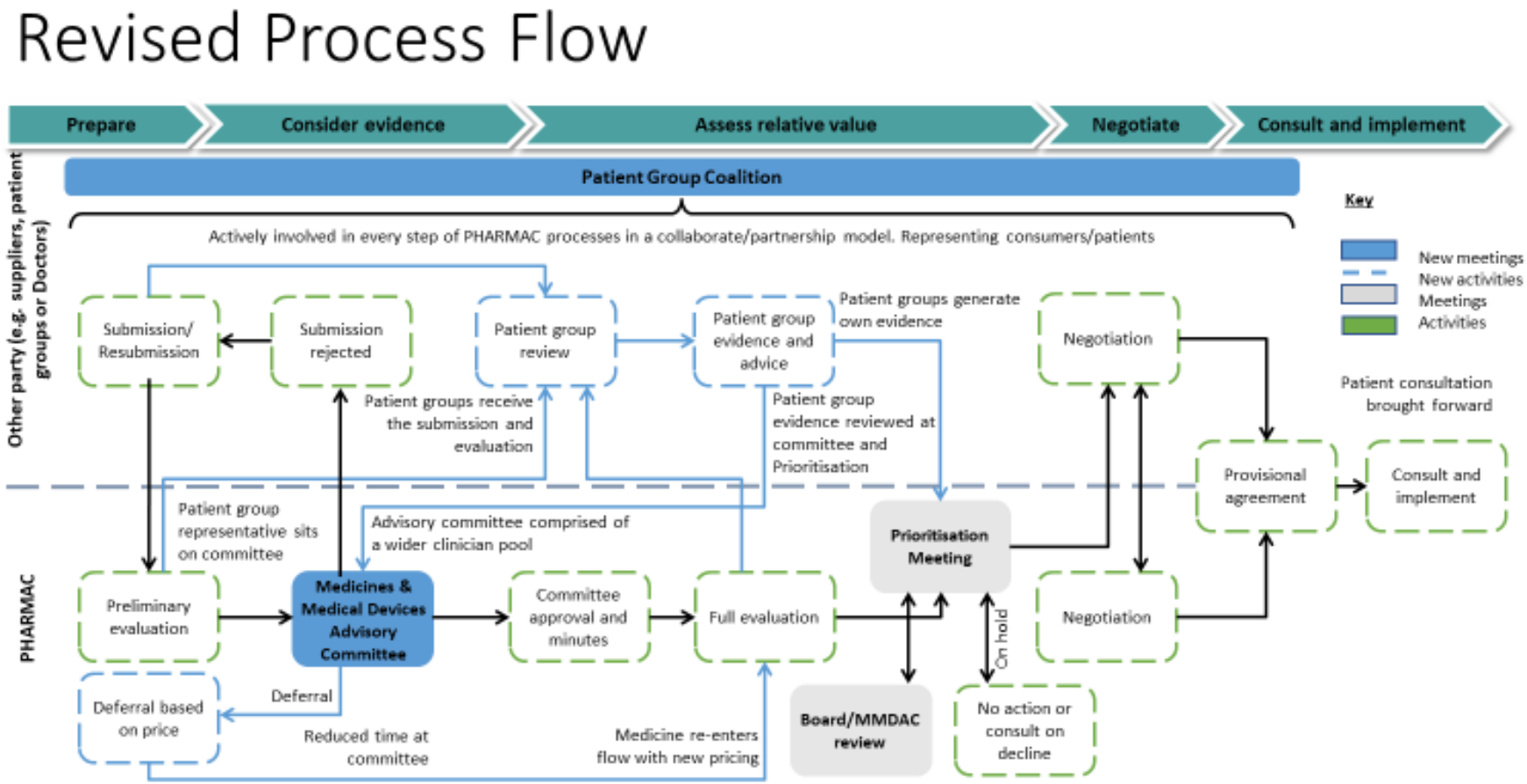
Appendix 1: Revised Process Flow: for the changes to committee structure and PHARMAC process we recommend.

Appendix 2: Why should PHARMAC adopt BCAC recommendations?

Appendix 3: International Assessment – Patient and Public Voice:
A diagram representing the models of a number of jurisdictions that incorporate the public voice throughout the decision making process including Canada and Australia.

Appendix 4: International Assessment – Visibility of Decision Process

APPENDIX 1


Revised Process Flow
Prepare
Consider evidence
Assess relative value
Negotiate
Consult and implement
Other party (e.g. suppliers, patient groups or Doctors)
Patient Group Coalition
Actively involved in every step of PHARMAC processes in a collaborate/partnership model. Representing consumers/patients
Key
New meetings
New activities
Meetings
Activities
Submission/ Resubmission
Submission rejected
Patient group review
Patient group evidence and advice
Patient groups generate own evidence
Negotiation
Patient consultation brought forward
Patient groups receive the submission and evaluation
Patient group evidence reviewed at committee and Prioritisation
Provisional agreement
Consult and implement
Patient group representative sits on committee
Advisory committee comprised of a wider clinician pool
Prioritisation Meeting
PHARMAC
Preliminary evaluation
Medicines & Medical Devices Advisory Committee
Committee approval and minutes
Full evaluation
On hold
Negotiation
Deferral
Deferral based on price
Reduced time at committee
Medicine re-enters flow with new pricing
Board/MMDAC review
No action or consult on decline

APPENDIX 2

Why should PHARMAC adopt BCAC recommendations?

If adopted these recommendations would:

- Improve patient centricity
- Generate a new form of evidence (patient voice) that would improve decision making
- Create greater buy-in and acceptance of decisions
- Reduce time scheduling meetings, attending meetings, and writing minutes
- Accelerate the committee phase

The win-win is that PHARMAC can improve patient engagement and accelerate access while maintaining evidence focus and value for money

APPENDIX 3

International Assessment – Patient and Public Voice

Process	Scotland (SMC)	UK (NICE)	Canada (CADTH)	Australia (PBAC)	New Zealand (PHARMAC)
Patient and Public Voice	Yes – systematic process to include patient view	Yes – systematic process to include patient view	Yes – systematic process to include patient view	Yes – voice in appraisal committee	Limited
	• SMC meetings are public involving patient groups and health charities • Patient group submissions are allowed • SMC partners with patient groups to understand patient experience • Patient group evidence is a key part of committee considerations • 3 public partners ensure views of the public are taken into account • Patient groups have the option to attend SMC meetings (non-voting) • Patient group statements and Patient and Clinical Engagement Group (PACE) statements given good share of voice in meetings	• Advise sought from lay members (e.g. a carer) to ensure decision relevance to those affected • Patient expert input into appraisal • Appraisal committee open to the public and press • Masterclasses on NICE provided publicly • Public Involvement Programme to develop patient/public involvement • Citizen's Council provides advice to NICE's Board • Patients Involved in NICE (PIN) – coalition of patient groups to provide guidance • Opportunity for public to comment on NICE guidance, and join committees or working groups • Training provided to lay members and public looking to get involved	• Patient (includes caregivers) group input (questionnaires) sought for experience and perspectives on living with a disease, the existing treatment, and the treatment under review. Information is pulled into briefing pack. • Patient groups are notified by email of the input request • Information used by Common Drug Review (CDR) team and Canadian Drug Expert Committee (CDEC) • Patient input summarised, discussed, and as relevant included in the recommendation • A public member on committee represents patients interests • CADTH Patient Community Liaison Forum available to share information and collaborate	• Patients are welcome to provide comment on the submission • Stakeholder meetings include patient groups • Individuals and organizations participate in the appraisal through the Consumer Comments facility on the Pharmaceutical Benefits Scheme (PBS) website • 6 weeks to make comments • Improvements to promote greater engagement under development • PBAC consumer representative reviews and summarises material for each PBAC meeting • All comments considered	• Patient group submissions allowed • Patient evidence is not proactively encouraged as a process step • Limited patient involvement or consultation in decision process • Public consultation including patients once a funding decision is made • Patient groups contacted on an ad hoc basis

APPENDIX 4

International Assessment – Visibility of Decision Process

Process	Scotland (SMC)	UK (NICE)	Canada (CADTH)	Australia (PBAC)	New Zealand (PHARMAC)
Visibility into process	Public meetings allow clear visibility into the process and decision making	Public meetings allow clear visibility into the process and decision making	Clear view with publishing of recommendation	Clear view with public summary documents, and supplier/ patient input into appraisal	Clear view from Committees No insight into Prioritisation and why a drug is funded
	• Clear visibility into decision making process and who is involved • Public meetings • Decision made by voting • Criteria: efficacy, which patients benefit, and good value for money • Criteria weight not specified	• No criteria, decisions based on economic and clinical evidence • Objections published online as part of technology appraisal guidance • Public meetings • Closed session for actual decision • Value for money threshold visible	• Reason behind recommendations published • Cost-effectiveness is an important criteria • Process and timelines are published online • Suppliers know when it's a price issue	• Process flow and description of steps published online • Calendar view of dates at which deliverables are due and decisions are made • Suppliers given a strong indication into key areas of concern for PBAC	• Dates of committee meetings published • 2 step decision process with PTAC then Prioritisation • PTAC minutes published providing insight on evaluation • Decisions made using Factors for Consideration • No visibility into high/low priority or Prioritisation metrics • No Factor weighting
Other	• Separate process for end of life and rare diseases	• Reference agency globally	• Resubmissions based on a reduced price may be submitted by email • 1 copy of the submission required • Experts drafted into team where expertise unavailable • Pay for submissions ($70k for a new molecular entity)	• Risk-share arrangements becoming more common • Advisory committees set timelines • Cost recovery model	• Opportunity for bundle deals