

# Rationale for Draft Terms of Reference for the PHARMAC Consumer Advisory Committee

March 2010



## **Introduction**

PHARMAC is reviewing the Terms of Reference (Terms of Reference) of our Consumer Advisory Committee (CAC). The review was required in *Actioning Medicines New Zealand*, the action plan accompanying the Government's Medicines Strategy, *Medicines New Zealand*, and provides an excellent opportunity to ensure that CAC gives PHARMAC the best possible advice from a consumer and patient perspective.

We have undertaken the review of the CAC Terms of Reference in the broader context of a review of all PHARMAC's consumer participation work. Using this approach, we can ensure the CAC's role is clearly defined and well-understood in relation to our other consumer participation activities.

We initiated this work with the *Consumer Advisory Committee Terms of Reference Review* consultation document in May 2009 and subsequently launched the *Consumer Participation Discussion Document* at the PHARMAC Forum in October 2009. We sent both these documents to approximately 380 people / organisations for comment.

PHARMAC received 23 submissions on the *Consumer Advisory Committee Terms of Reference Review* and 16 submissions on the *Consumer Participation Discussion Document*. We have used the information in these submissions to inform the development of the draft revised Consumer Advisory Committee Terms of Reference which we are seeking your views on in this current document.

## **CAC's legislative role**

CAC is an advisory committee established by the PHARMAC Board as required by the New Zealand Public Health and Disability Act 2000 to '*provide input from a consumer or patient point of view*'.

The legislation describes CAC as an advisory committee and as such its role is to make recommendations to the PHARMAC Board. However, the PHARMAC Board is not bound to accept CAC's recommendations. While the Board is required to consider CAC's advice, it must also consider other factors about which CAC does not have complete information (including resourcing, staffing limitations, and competing work priorities) that affect its decisions about whether CAC's recommendations will be implemented.

The inclusion of CAC as an advisory committee in the legislation means CAC cannot operate independently from PHARMAC. However, the Committee needs to be able to provide unfettered advice to PHARMAC.

## **Draft Terms of Reference**

These draft Terms of Reference (ToR) have been developed taking into account the submissions to both the *Consumer Advisory Committee Terms of Reference Review* and the *Consumer Participation Discussion Document Seeking Your Views*.

These draft ToR appear much longer than the present ToR for the committee but this is in large part due to the addition of new sections which reflect operational processes and expectations that currently apply, but have not been formally recorded. These additional sections do not represent new restrictions or conditions on the committee's activities.

While the submissions on the *Consumer Participation Discussion Document Seeking Your Views* have been considered in the drafting of these ToR, not all of the issues raised in the document and submissions responding to it relate to the ToR for CAC. The other issues will be addressed in other ongoing work on PHARMAC's consumer participation activities, and are not part of this current consultation.

A number of substantive issues were raised in the process of the ToR development, including in submissions. Given the importance of these issues, and the significant focus on them, we consider it useful to explain our proposed position and seek further stakeholder views on these, as well as on the content of the draft Terms of Reference.

### **Process for providing feedback**

Discussion questions are included throughout the document and a complete list is provided on page 9. To assist our consideration of submissions, we encourage you to provide reasons supporting your views.

We will consider all submissions received by **5pm, 1 April 2010**.

To provide comment, please submit an email, fax or letter to:

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Fax: (04) 460 4995

PHARMAC  
PO Box 10-254  
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We encourage you to advise us of any other groups or individuals who would be interested in receiving this document so we can distribute it to them.

### **Application of the Official Information Act**

Your submission and all correspondence you have with PHARMAC may be the subject of requests under the Official Information Act 1982 (OIA). If there is any part of your submission or correspondence that you consider could properly be withheld under the OIA, please include comment to this effect along with reasons why you want the information withheld. The reasons for withholding information under the OIA are contained in Appendix 1.

If you are making your contribution as an individual as opposed to an organisation, we will omit your personal details from the submission if you include the following statement at the front of your submission and sign it:

'I do not give my permission for my personal details to be released to persons requesting my submission under the Official Information Act 1982.'

**Please include the following information in your submission:**

- Your name
- Contact email
- The organisation the submission is from (if applicable)

# Key Issues

## 1. CAC's purpose and role

### *Submitter comments*

The primary purpose of CAC, as described in the legislation, is to provide the Board of PHARMAC with *input from a consumer or patient point of view* on matters related to PHARMAC's activities.

A number of submissions on the CAC Terms of Reference Review noted the members of CAC could not possibly represent all consumer views. These submitters identified PHARMAC consumers as a hugely diverse group who hold a diverse range of views, some of which are at odds with each other. The submitters commented that CAC cannot act as a conduit for all of these views, nor adequately synthesise the range of views into a single position or view – especially when opposing views exist.

While a few submitters suggested CAC members should be made up of 'medicine users' from special interest groups as a way of representing the views of consumers, others suggested it would not be possible to have all of those groups represented on the committee nor have all consumers' views represented.

### *Proposed role*

Recognising the difficulties of representing the wide range of disparate views held by consumers, the proposed CAC ToR do not describe CAC's role as representing all consumer views. Instead CAC's primary functions would be to provide advice to PHARMAC on how we can best access the diversity of consumer views and consider these when carrying out our role. CAC would do this by giving PHARMAC advice on how we should run our consultation processes, providing advice on our communications with consumers, and ensuring we use appropriate processes to canvass and consider consumer/patient views.

The proposed activities for CAC described in the draft ToR are intended to reflect its role as an advisory group assisting PHARMAC with its consumer engagement activities, rather than it acting as a conduit for individual consumers' or consumer groups' concerns.

### *Consumer contact with PHARMAC staff*

Under the proposed ToR consumers and consumer groups would continue to make their own representations to PHARMAC on issues related to medicines funding decisions through the submission process, and by meeting with PHARMAC staff. A number of submitters noted a preference for direct contact with PHARMAC staff, indicating they thought it would be difficult for CAC to relay the complexities of every individual consumer and all consumer/ patient groups' views in full. PHARMAC staff also have a preference for direct contact with consumers and consumer groups as we consider direct communication will more likely provide us a sound understanding of consumer views.

We are keen that CAC should not be regarded as an impediment to consumers communicating directly with PHARMAC. However, the draft ToR would not prevent consumers who prefer to use CAC as a means of approaching PHARMAC from doing so.

**Question 1:**

*Do you have any comments on the rationale for CAC's role and activities as described in the draft ToR?*

## **2. CAC engaging and consulting with consumers**

### *Submitters' comments*

While almost all submitters indicated they thought one of CAC's primary functions was to 'engage and consult' with consumers, and to pass consumer views expressed to CAC on to PHARMAC, they also noted they wanted to maintain the ability to contact PHARMAC directly. Submitters who expressed concern about losing direct contact with PHARMAC staff, if they were required to use CAC as a conduit, noted CAC members would need a very broad knowledge base of a wide variety of diseases to be able to fully understand and represent the views of the very diverse range of medicine users.

Some submitters commented on the 'invisibility' of CAC and the lack of transparency of its activities, and indicated this affected consumer confidence in the committee.

### *PHARMAC staff view*

PHARMAC staff also expressed concern at losing direct contact with consumers, noting that if they were to receive all consumer comment through CAC, important details would likely be missed in the transfer of the information. We consider it would be more efficient to communicate directly with consumers and consumer groups rather than reading a note of a discussion with a third party.

This means PHARMAC staff members responsible for particular areas or medicines would be able to discuss issues directly with consumers and/or patient groups and gain a better understanding of their concerns. This is more likely to foster productive relationships than working through a third party such as CAC.

### *Proposed activities*

We recognise the importance of consumers understanding the Committee's role, having access to information about what the Committee does, and having confidence that Committee members are aware of the general issues impacting on consumers. To this end, the proposed draft ToR include the following provisions:

- Support for CAC to engage and consult with consumers through forums, and attendance and participation at conferences and meetings which consumers attend.

- The opportunity for observers to attend CAC meetings - this would not only give CAC the opportunity to seek consumer views but would also increase the transparency of CAC's activities. The presence of observers would be at the discretion of the CAC Chair who would ensure observers represented a range of different interests. The provision for observers to attend CAC meetings should not only increase transparency but also allow consumer representatives to provide feedback to their own constituencies on CAC's role and operations.
- CAC meeting minutes being published on the PHARMAC website. In addition to this it is proposed the CAC Chair provide consumers with a commentary / report on CAC's activities and discussions from time to time. Recognising the strong consumer interest in PHARMAC's response to CAC's recommendations, PHARMAC will consider how it can do more to make explicit the results of CAC recommendations.

The intent of these proposed activities is to ensure members would be aware of, and understand, the broad range of issues that affect medicine consumers. However, CAC members would not be expected to discover or understand every detail of each of the consumer/patient groups' particular concerns about particular medicines. As explained above, CAC's proposed role is to advise on PHARMAC's processes, and to ensure consumer and patient interests are taken into account, not to try and represent all individual consumer or consumer group concerns.

#### **Question 2:**

- a. Do you consider the activities described above would increase consumer confidence in, and the transparency of, CAC and its activities?*
- b. If not, why not?*
- c. What other suggestions do you have that would increase consumer confidence in CAC?*

### **3. CAC appointment process**

The draft ToR clarify the appointment process for CAC. According to the proposed process PHARMAC would advertise CAC positions widely, including to all those on its consumer database, and work with the CAC Chair to select and interview candidates. Recommendations for appointment would be sent to the PHARMAC Board which would make the final decision.

#### *New criterion for members of CAC*

Taking note of a small number of submissions on the CAC ToR which expressed a strong desire for the committee to be made up of people with experience of being 'health consumers' and /or 'medicine users', an additional appointment criterion has been added to include '*an appreciation of the issues associated with medicine use.*'

Recognising the views of other submitters who noted that it would be difficult for members from special interest groups to put aside their own interests, and indicated a preference for CAC

members to come from people with a broader range of consumer/patient experience, we propose the other criteria for membership remain the same. This should ensure members' experience and their constituencies cover a broad range of consumer interests.

#### *Length of term*

The submitters who commented on the length of term for CAC members consistently recommended an initial 3 year term with one additional 3 year term. The draft ToR reflect these comments.

In response to submitters who noted that several of the present committee members have served on the committee for a very long period and felt there was a need for 'new blood', the term of committee members in the draft ToR propose members be limited to serving a maximum of two terms i.e. 6 years. This reflects the need to achieve a balance of members who are experienced and knowledgeable about PHARMAC and its processes, and the need for new perspectives and connections into a variety of consumer communities.

#### *Training and review of performance of CAC members*

The draft ToR also propose training for new CAC members, the CAC Chair, and the Committee as a whole, a review of member performance and a process for termination of service for committee members.

#### **Question 3:**

*Do you have any comment about the proposed appointment process, membership criteria and limited term?*

#### **4. CAC Meetings**

The proposed number of face to face meetings of CAC remains at a minimum of two with usually four a year, but provision has been included in the draft ToR for additional teleconferences and email discussions for issues that arise between the regular meetings.

#### **5. CAC involvement in prioritisation and funding decisions**

Responses to the questions in the consultation document *Consumer Participation Discussion Document Seeking Your Views* asking whether or not consumers should be involved in the prioritisation of medicines and funding decisions did not provide a consensus view. Opinions were divided.

Generally submissions did not indicate that consumer involvement in the prioritisation and funding process would greatly increase consumer confidence in PHARMAC decision-making. Though some submitters noted they would like consumer, or CAC, involvement in funding decisions others noted that:

- CAC would be unable to represent the views of all consumers and it would not be possible for CAC to consolidate consumers' views into one opinion without the risk of misrepresenting the views of some consumers
- it would be unrealistic to expect consumers to put aside their own interests
- there is a risk of consumer capture by manufacturers
- confidentiality issues would be a barrier
- '*human considerations*' could undermine scientific decisions and '*emotions cloud the issues*'
- the complexity of the science and economic factors to be considered would require specialist knowledge and skills.

Several consumer groups noted a preference for representing their own views through the submission process and/or direct contact with PHARMAC, rather than relying on a consumer representative who might have other interests at heart.

It should be noted that it is proposed consumers and consumer groups would continue to be consulted on funding decision issues, and continue to be able to submit their views to PHARMAC directly. CAC's proposed role would be to advise on how these consultations are best carried out, but the committee would not be involved in the funding decision process.

**Question 4:**

*Do you have any comment on CAC having a role in advising on the process of funding decisions but not being involved in the decision making on specific funding decisions? Bear in mind that consumers can provide input directly into the funding decision making process by making a funding application and/or contacting PHARMAC directly about an active funding application or through consultation.*

**Question 5:**

*Do you have any further comments on the draft ToR for CAC?*

**Questions:**

1. *Do you have any comments on the rationale for CAC's role and activities as described in the draft ToR?*
2. *a. Do you consider the activities described above would increase consumer confidence in, and the transparency of, CAC and its activities?*  
*b. If not, why not?*  
*c. What other suggestions do you have that would increase consumer confidence in CAC?*
3. *Do you have any comment the proposed appointment process, membership criteria and limited term?*
4. *Do you have any comment on CAC having a role in advising on the process of funding decisions but not being involved in the decision making on specific funding decisions? Bear in mind that consumers can provide input directly into the funding decision making process by making a funding application and/or contacting PHARMAC directly about an active funding application or through consultation.*
5. *Do you have any further comments on the draft ToR for CAC?*

# Appendix 1

## Relevant Provisions of the Official Information Act 1982

### 9. Other reasons for withholding official information

(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

(2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to;

- (a) protect the privacy of natural persons, including that of deceased natural persons; or
- (b) protect information where the making available of the information;
  - (i) would disclose a trade secret; or
  - (ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or
- (ba) protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information;
  - (i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
  - (ii) would be likely otherwise to damage the public interest; or
- (c) avoid prejudice to measures protecting the health or safety of members of the public; or
- (d) avoid prejudice to the substantial economic interests of New Zealand; or
- (e) avoid prejudice to measures that prevent or mitigate material loss to members of the public; or
- (f) maintain the constitutional conventions for the time being which protect;
  - (i) the confidentiality of communications by or with the Sovereign or her representative;
  - (ii) collective and individual ministerial responsibility;

- (iii) the political neutrality of officials;
  - (iv) the confidentiality of advice tendered by Ministers of the Crown and officials;  
or
- (g) maintain the effective conduct of public affairs through;
- (i) the free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or
  - (ii) the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or
- (h) maintain legal professional privilege; or
- (i) enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities;  
or
  - (j) enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or
- (k) prevent the disclosure or use of official information for improper gain or improper advantage.