18 June 2009

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Dear Matthew

INPUT INTO THE CONSUMER ADVISORY COMMITTEE TERMS OF REFERENCE REVIEW

Thank you for the opportunity to provide input into this review and for the extension you have granted the Researched Medicines Industry (RMI) Association on this occasion.

As requested, we have structured your submission around the questions posed. However, the main points of our submission are:

- The role of the Consumer Advisory Committee (CAC) role should be more focused on liaising with consumer groups (thus enabling it to provide a direct and independent link between these groups and the PHARMAC Board) and it should not require PHARMAC's permission to do so.
- CAC should not have to be invited to provide advice to PHARMAC on any proposal.
- CAC should be involved in the development of all PHARMAC's consultation letters with a specific view to ensuring that the information provided to consumers is clear and that sufficient time and information is provided.
- There should be greater involvement and/or greater transparency around CAC's involvement in PHARMAC's prioritization process since CAC should be uniquely positioned to independently review and assess the needs of competing consumer groups.
- CAC's members should at least be nominated by consumer groups.
- The PHARMAC Board should be required to formally respond to issues raised by CAC.
- Many of CAC's current activities should become secondary/optional functions in order to improve its focus on the issues of real importance to the consumers it represents.

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a) What is the optimal role for the Consumer Advisory Committee and how is this best described.

The RMI believes that the optimal role for CAC is to facilitate communication between PHARMAC (Board and staff) and consumers/consumer groups and to foster understanding between these parties in relation to matters of concern about access to and subsidies for medicines or more generally, the Pharmaceutical Schedule.

The wording of the current purpose of CAC "To provide the Board with input from a consumer or patient point of view" is broad and unspecific in respect of which of PHARMAC's activities it was intended that CAC provide input into.

The interpretation of CAC's purpose adopted when its Terms of Reference (TOR) were first developed by PHARMAC has effectively, maybe even deliberately, prevented CAC from providing any direct or meaningful input into PHARMAC's decision making.

Fortunately, the lack of specificity in the current purpose does not preclude the option of giving CAC a more meaningful role under revised TOR.

CAC is currently limited to providing advice only "when requested by PHARMAC" to do so. The fact that there is no requirement on PHARMAC to seek the advice of CAC means that decisions can (and it would seem, usually are) be made without input from CAC.

There are only limited provisions for CAC to engage with the community and/or other relevant consumer groups. It seems from CAC's activities in the last 5 years that these provisions have essentially eliminated either the will or the value (from either perspective) of CAC engaging in this way.

CAC's functions also specifically exclude its involvement in PHARMAC's consultation processes – an extraordinary exclusion given the legislatively defined purpose of the committee.

Instead, PHARMAC has included an extremely broad range of other functions within CAC's TOR, some of which are appropriate. However, if viewed from a cynical perspective, many of these functions have served mainly to occupy CAC on matters which have no bearing on the outcomes of PHARMAC's significant decision making processes.

The fact that CAC may only provide a consumer perspective on the implementation of PHARMAC's decisions "where appropriate" is a significant concern. Surely the need for this sort of input is among the reasons which prompted the establishment of the committee.

CAC's input into matters concerning access and use of medicines is limited to "existing listed pharmaceuticals" effectively excluding CAC from providing input into a significant concerns for most consumers – access to new medicines.

The RMI believes that CAC's activities should ideally be focused on the following areas:

- Monitoring all the concerns of known consumer/interest groups;
- Ensuring that the PHARMAC Board is aware of these concerns; and
- Providing advice to relevant consumer/interest groups in relation to activities planned or being undertaken by PHARMAC which may impact them in any way.

We also consider that CAC should be consulted on PHARMAC proposals in the same way that individual stakeholders are consulted, if not prior to the formal consultation process.

b) What lessons can be taken from consumer engagement in other contexts, whether health funding bodies or other public organization?

The RMI notes that there is a general perception amongst stakeholder and consumers that PHARMAC's processes lack transparency. The purpose of engagement with consumers – whether on pharmaceutical issues in other countries or in other industries – if fundamentally to allow consumers to air their views and concerns, and to obtain information and feedback on issues that concern them. Major decisions in other industries such as power, roading etc are often the subject of public meetings. While not every PHARMAC decision would warrant such measures, the RMI believes that there have been examples of issues in PHARMAC history (e.g. major switches within therapeutic sub-groups, proposals to decline funding applications etc) where this sort of public consultation would have been well received by consumers.

Periodic engagement of this nature for more general issues was in fact proposed under *Medicines New Zealand* but has not really eventuated. The RMI is disappointed that PHARMAC has only held on stakeholder forum in its entire history and that it is approaching two years since the last one.

c) What responsibilities and functions align with the desired role of CAC you described in question a)?

CAC's current functions would need to be amended significantly in order to be an effective conduit to PHARMAC staff and the PHARMAC Board for consumers and consumer groups on all matters relating to access to and subsidies for medicines as described in question a).

- They would have to be permitted to provide unsolicited advice to PHARMAC (i.e. without a prior request) in the same way as PTAC was once permitted to before the last review of its TOR.

- Their primary (as opposed to optional) functions, still subject to confidentiality provisions, would be to:
    - engage and consult with the community and/or relevant consumer groups; and
    - work with special focus/interest groups on specific issues/problem solving.

  They should be allowed to do this without a specific request from PHARMAC.

- In addition, they would have a specific responsibility to report to the Board on these engagements and provide feedback to the relevant groups.

- They would be required to liaise with relevant groups affected by the implementation of PHARMAC's decisions (both prior to, during and after the event) where such decisions are known to create disruption/concern (such as some brand switches). It is not expected that CAC's liaison would replace the liaison between the relevant group and PHARMAC staff but CAC would provide an independent contact with the group which could be useful (e.g. if the group did not consider that PHARMAC staff were responding to its concerns.)

- Similarly, CAC should review PHARMAC's proposed consultation letters to ensure that:
    - the clarity and content of the letter are appropriate from a consumer perspective,
    - all the relevant groups receive the letter; and
    - the consultation period is sufficient.

  CAC has previously asked of PHARMAC that they have a seat at the PTAC table, but their request was declined. While it may not be necessary for CAC to have direct link with PTAC, the RMI considers (as previously stated) that it would be reasonable and indeed appropriate if CAC's role also included the provision of its own advice to PHARMAC on investments via its consultation processes.

- They would be permitted to liaise with relevant groups about the prioritization of pharmaceuticals by PHARMAC. In order to do this, CAC would need access to relevant information about the status of all pharmaceutical applications and PHARMAC's priorities. We have seen no evidence in the minutes of CAC's meeting that it currently receives this information despite the existence of function (f). The RMI would go as far as to say that this (i.e. a List of Need) should be public information in any case.

There are also other areas where the RMI considers CAC's role/activity should be reduced. We note that there are other initiatives in place to promote the responsible use of medicines and monitor access to pharmaceuticals by Maori and Pacific Island peoples. While consumer input into these matters is clearly very important, we consider that the separate initiatives are probably sufficiently resourced to ensure this occurs without making it a primary function of CAC. From the minutes of CAC's meetings, it appears that are large amount of the committee's time is spent reviewing Demand Side plans and materials when their time could be better spent (from the perspective of the consumers they represent) coming to grips with specific issues of concern and identifying where they may be able to assist the Board and or consumer/interest groups in this regard. We therefore believe that functions (a), (b) and (e) should be made optional rather than primary objectives.

We are also concerned that CAC has on several occasions requested and reviewed information in relation to usage of medicines (for example paroxetine in adolescents, atypical anti-psychotic agents in children etc) suggesting that it sees itself as having a role

in monitoring the safety of medicines. This is clearly the role of Medsafe and, while broadly related to the responsible use of medicines, these activities are not consistent with any of CAC's functions. According to CAC's functions, the committee is expected only to provide a consumer or patient perspective on initiatives to promote the responsible use of medicines. Furthermore, it should only do so when requested by PHARMAC. It would not appear or seem likely that PHARMAC requested that CAC investigate these matters.

This concern may add weight to the argument for reducing the significance of function (a). Alternatively, it may indicate that function (g) – any other matters relating to the management of the Pharmaceutical Schedule – needs clarification.

d) Should CAC advise on funding applications for medicines and, if so, on what basis?

The RMI considers that while it is probably appropriate that CAC does not advise on whether specific medicines should be funded, it should be permitted to review PHARMAC's funding priorities and to comment on proposals relating to funding applications from a consumer perspective.

As consumer's only direct link with the PHARMAC Board, we believe that CAC's role should including monitoring and reporting of concerns/changing levels of concern amongst consumers about access to new medicines (i.e. what is not funded and reacting to funding proposals). This role is not included within its current functions – indeed in may be prohibited by (d).

While PTAC also has a role in assessing unmet need, it tends to do so from a medical rather than patient perspective. It also tends to focus more on the evidence, often negatively, in relation to the pharmaceutical.

If permitted to function as described under questions a) and c) above, CAC would be in a unique position to brief the Board about perceptions of need from a consumer perspective, including any increase or decrease in that regard over time. This might actually assist the Board to deal with any gap between perceptions and reality in terms of the likelihood of funding and/or misconceptions about evidence etc.

In order to do this, CAC would need access to relevant information about the status of all pharmaceutical applications and PHARMAC's priorities. It would also have to be permitted to discuss the prioritization of pharmaceuticals by PHARMAC with relevant groups. Some direct exposure to PTAC's deliberations might also assist the committee to ensure that it provides a balanced view of need.

e) What relationship, if any, should CAC have with stakeholder groups?

The RMI would like to see CAC's relationship with stakeholder groups characterized by the following:

- Providing an alternative forum (to PHARMAC staff) in which for stakeholder groups to raise and discuss their concerns regarding pharmaceuticals.

- Inviting stakeholder groups to raise their concerns in that forum as well as with PHARMAC.
- Providing independent feedback to stakeholder groups regarding their concerns.

The key element of this relationship, seemingly missing at present, is *contact*.

Contact (to or from CAC) might be in writing or in person as appropriate.
The frequency of contact would depend on the issue. At the current rate of processing, we envisage that most issues relating to "live" applications would require contact only once or twice a year – or when there is a significant development. Some issues would require a short period of more frequent contact.

Clearly, CAC and stakeholder groups would need to be free to liaise at any time without such contact being subject to the current restriction of "when requested by PHARMAC."

f) How would these relationships support CAC in achieving the optional role you describe in question a)?

The effect of a direct relationship needs very little explanation. Clearly, without the relationship described above, CAC cannot be properly informed about the consumer or patient point of view and therefore cannot fulfill its legislative objective. Under the current TOR, CAC appears to have (perhaps by necessity) created or gone looking for issues to justify its existence.

Allowing stakeholders and CAC to communicate freely with the expectation that CAC will objectively convey the concerns of stakeholder groups to the PHARMAC Board and relay any response to the stakeholder groups would, at very least, create a more meaningful role for CAC.

The RMI considers that, more than making the committee more relevant and able to perform its statutory functions, the existence of an advisory group of this nature, with direct access to the PHARMAC Board, would be of considerable comfort to stakeholder groups and consumers.

g) What resources do you think the committee would require to support these relationships?

With very little information available about the resources CAC current consumes or has available to it, it is difficult to comment on what else it may require. It is conceivable that a committee whose functions and relationships are properly aligned with its statutory objectives (as proposed) might require additional resource in order to perform effectively.

h) What is the optimal membership of the Committee?

The RMI does not believe that it is possible to define optimal membership of a committee like CAC in terms of numbers, desirable characteristics and experience of members.

No committee, regardless of size or composition, could ever fully represent consumers.

While we note that other countries have adopted different approaches/structures, we would not presume to know what the perfect model would be.

We consider that, of greater concern and value to the functioning of CAC is its relationships with stakeholder groups. CAC would function more effectively as the "voice" of consumers to the PHARMAC Board if were allowed to freely engage with the consumers it represents.

i) How should membership appointments be made?

Again, the RMI considers that an ability for CAC to engage freely with stakeholders would offer more benefit than any modifications to the current appointment process.

However, we do note that the membership of CAC is currently at the sole discretion of the PHARMAC Board and the process should perhaps be more akin to an election like the District Health Boards.

If CAC is to have any credibility in representing consumers then its members should at least be nominated by consumer groups. After all PTAC members are in many instances nominated by various professional bodies.

j) What is the optimal length of time for members to serve on the Committee and are there any circumstances in which extensions should be granted.

It is impossible to define an optimal length of time for members to serve on CAC. An election process might better ensure that members are retained only as long as their experience and input are relevant within the mix of membership and range of issues confronting PHARMAC and CAC.

k) What is the optimal relationship between CAC and PHARMAC staff?

The risk with any relationship between PHARMAC staff and an advisory committee, like the relationship with PTAC, is that PHARMAC staff will be able to exert influence over the committee.

However, where the role of CAC is to liaise or to act as a conduit as proposed, this may be less of a risk since CAC would not be expected or even permitted to have a view on any particular issue and its advice would be limited to raising awareness and perhaps suggesting approaches to certain issues.

In any case, in order for CAC to be able to determine where its services might be required, it would need to have a fairly open relationship with PHARMAC staff.

PHARMAC staff would need to provide information to CAC.

The Committee would need to be kept informed (in a timely manner and with relevant information) of all PHARMAC's planned activities, included in the planning stages of any

major initiatives, consulted on the wording of key consultation documents and advised of any unplanned developments.

CAC would also need to receive regular updates as to the status of all funding applications, where they rank in relation to PHARMAC's priorities and any related issues.

In return, CAC would need to provide PHARMAC staff with direct advice (as opposed to via the Board) on matters relating to consultation and implementation at least.

l) What is the optimal relationship between CAC and the PHARMAC Board?

The obvious problem with the current relationship between CAC and the PHARMAC Board is that, while CAC provides written advice to the Board (but in our view, not enough of the relevant issues – a matter to be addressed via its functions), and the Board is required to take these reports into account, the Board is not required to respond to CAC's concerns. Its only obligation is to seek any clarification required.

In short, CAC's advice currently falls into a black hole with no reliable way for CAC or consumers to tell whether it has been taken into account.

The effect of the current and proposed TOR appears to be that CAC's advice is usually ignored. For example, they have repeatedly requested that large scale brand switches are formally and prospectively monitored by PHARMAC to assess the impact on patients. PHARMAC however continue to avoid this and simply conduct "uncontrolled experiments" on New Zealanders relying on Medsafe's assessment that they are the "same".

It is noted that a member of CAC is now permitted to attend Board meetings which gives a little more assurance that CAC actually knows what happens to its advice.

However, the RMI submits that in order for the relationship between CAC and the PHARMAC Board to be effective, the Board must be required to formally respond to issues raised by CAC.

m) How should the role of CAC be periodically evaluated?

There is no easy way to evaluate the role of CAC as there are few measurable outputs to assess. However, it would not be unusual for the performance of a committee or organization of this nature to be assessed via a stakeholder survey. The RMI submits that in its current form CAC would be found wanting in terms of the relevance, awareness of and/or level of satisfaction amongst consumers it represents.

Under the TOR proposed by the RMI, there might be more measurable indicators of performance such as frequency of contact with stakeholder groups, changes made to draft consultation letters etc. Clearly, in using any form of measure, it would be important not to create the wrong incentives for CAC.

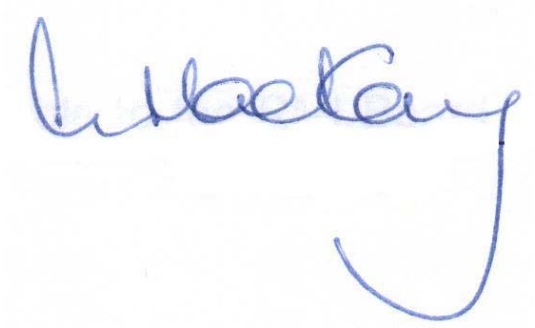
n) How can the quality of the Committee's advice to PHARMAC be evaluated?

Again, under the current TOR there is little to assess in terms of the quality of CAC's advice. Indeed, even the volume of advice seems pitifully small.

Presumably though, were CAC to be afforded more latitude with stakeholders, the quality of its advice could be evaluated and compared by survey from two perspectives – PHARMAC's and stakeholder groups – hopefully with similar results.

We thank you again form the opportunity to provide input into your review and trust that you will take the points we have made into consideration.

Yours sincerely



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