2 December 2009

Jessica Dougherty
Corporate Team Assistant
PHARMAC
PO Box 10-254
WELLINGTON 6143

Dear Jessica,

Consumer Participation Discussion Document

Thank you for the opportunity to participate in this discussion. Please note that the RMI has not attempted to respond to the individual questions you have posed in the document. We have structured our comments around the various headings under which the discussion document has been presented.

Comments on "Background on Consumer Participation"

1. It is disappointing that none of the ideas discussed in your document relate to how PHARMAC engages with suppliers. You have defined consumers as being "anyone with an interest in PHARMAC." While PHARMAC may not wish to concern itself with the commercial interests of suppliers, they are none-the-less important stakeholders (PHARMAC would not exist without them), and their interests in PHARMAC's activities extend well beyond what is purely commercial.

   The RMI considers that PHARMAC should review the way it engages with <u>all</u> consumers, including suppliers.

2. You have suggested that there is a correlation between the understanding of consumers regarding how and on what grounds PHARMAC makes it choices, and consumer confidence in PHARMAC's decisions.

   The RMI agrees that consumers need to have confidence in PHARMAC's decisions.

   Based on the feedback given at your October 2009 PHARMAC Forum, it would appear that there is already strong and widespread understanding of PHARMAC's purpose and how it operates. PHARMAC has clearly made progress since Forum 2007 in developing this understanding and must be congratulated for doing so.

Researched Medicines Industry Association of New Zealand Incorporated
Level 8, 86-90 Lambton Quay, Wellington 6011 | PO Box 10-447, Wellington 6143 | Tel. 04 499 4277 | Fax. 04 499 4276
www.rmianz.co.nz

However, the RMI considers there to be less evidence that PHARMAC has achieved as much in terms of understanding and appropriately considering the perspectives and experiences of others, including consumers.

Your document places particular emphasis on two key drivers which motivate consumer participation activities within Government agencies like PHARMAC:

- Increasing citizen's opportunities to participate in decision-making; and
- Using citizen participation to inform the development or redesign government services.

However, PHARMAC's consultation processes, and the information it makes available to consumers about its funding decisions, still place significant limitations on the extent to which consumers can be involved in and/or influence the outcomes.

PHARMAC gave an undertaking following Forum 2007 to investigate the use of longer consultation periods, when appropriate. Despite this, the opportunity for consumer feedback on proposals remains largely time-pressured and occurs so late in the process that there is rarely any prospect of responses to consultation influencing outcomes significantly.

For this reason, the RMI considers that there is a better case for the investment of additional resource in initiatives which are aimed at increasing PHARMAC's understanding of consumers and providing greater opportunities for them to have input into decisions (i.e. (d), (e) and (g)) rather than those aimed at further enhancing consumer's understanding of PHARMAC – namely proposals (a), (b), (c) and (f).

Comments on "PHARMAC's Current Consumer Participation"

3. As noted by the RMI on numerous occasions, a key issue with PHARMAC's current approach to consumer participation is the lack of information available on PHARMAC's website about the status of funding applications and the lack of a search engine to facilitate access to the information that is there. We understand that improvements to these systems are underway but note that they are long overdue. As it stands, PHARMAC's communications and Public Relations efforts have ensured that consumers have become well informed about PHARMAC's purpose and how it works. However, they have been kept largely ignorant of the effect of these policies, by a lack of information about what is not being funded, how long the process takes, PHARMAC's priorities relative to PTAC's advice etc.

We also remain disappointed that you are not willing to consider making public your Cost Utility Analyses (CUA), or summaries of them even after the relevant commercial contract has been ratified and the product has been listed on the Pharmaceutical Schedule. You currently list no more than a dozen or so new pharmaceuticals per year. We therefore consider that the release of this information would not require significant additional time or resource on PHARMAC's part since the details could be simply uplifted from the original reports. Even without

inclusion of confidential pricing information, availability of these reports would greatly enhance transparency around your processes.

We are also very disappointed that you have decided against the publication of Public Summary Documents, despite this being a promised outcome of the National Medicines Strategy and an action point following Forum 2007. We question whether this was a unilateral decision by PHARMAC or whether Government has endorsed this position.

The amount and accessibility of information available on PHARMAC's website about funding applications and decisions remains a critical concern and improvements are urgently required.

4. Efforts have also apparently been made to improve PHARMAC's consultation letters. However, the RMI considers that significant improvements are still required.

Firstly, the detail contained in these letters is often still insufficient and, it is our view that this deficiency is not always defensible on the grounds of commercial sensitivity. One example of this is PHARMAC's consultation on the Levetiracetam Special Access Panel in which there was lack of clarity around a number of aspects of the proposal - who would administer the criteria, whether the product would be listed on the Pharmaceutical Schedule and what the exit criteria would be. We are aware of other examples.

We also consider that some of the language used in your consultation and notification documents, particularly where the language is inconsistent, can raise concerns and/or cause confusion. As an example, PHARMAC has recently consulted on generic listing of risperidone and topiramate. In referring to the effect of the proposals on other, currently listed brands of these pharmaceuticals, PHARMAC has stated that "*such brands would remain fully funded for at least the duration of the relevant subsidy protection applying to each*". This immediately raises questions for consumers about what may or will happen when subsidy protection ends.

In contrast, consultation on the listing generic letrozole clearly spells out the effect of the end of subsidy protection on other aromatase inhibitors (in this case reference pricing).

The lack of clarity associated with risperidone and topiramate may have been intentional (i.e. belying indecision about the next steps) or simply the result of PHARMAC assuming consumers would somehow know what these statements mean. However, the fact remains that consumers are frequently being asked to comment on proposals from a position of incomplete and/or insufficient understanding.

The possibility that the subsidy for an existing brand could be reduced (whether immediately or later) as a result of the listing of another, it is clearly relevant to consumers. Subsequent consultation may not be sufficient since, once the lower

priced generic is listed on the Pharmaceutical Schedule, PHARMAC's subsequent decision about the application of reference pricing may be more significantly influenced by the prospect of greater fiscal gains associated with reference pricing. Furthermore, once the generic is listed, it is possible that PHARMAC could point to existing use of that product as a counter argument to any clinically based objection to the application of reference pricing.

The RMI also considers that the amount of discretion and flexibility PHARMAC has over when it consults and what it discloses remains, at times, problematic. Herceptin is a very public example of where PHARMAC's judgment about when to consult was found wanting by the High Court. This is unlikely to be an isolated case. We are aware of other examples of proposals which have changed significantly after, but not as a result of, initial consultation but have not been the subject of further consultation.

- In the case of the request for proposals (RFP) for fentanyl, PHARMAC consulted on awarding Sole Supply Status (SSS) to a generic brand. The original proposal included a full range of strengths of the generic, including a strength that is critical for dose titration. However, acceptance of the proposal without that strength was subsequently notified without further consultation.

- Similarly, the results of the RFP for sumatriptan consulted on included a new, generic supplier of both the tablet and injection presentations. More recently, the dossier for the injection was subsequently withdrawn from Medsafe. No further consultation has taken place to date.

We consider that failure to re-consult in these instances has denied consumers, particularly clinicians and patients, an opportunity to comment on potentially clinically significant issues. The costs of delayed savings could not be a reason for the lack of further consultation in these cases because none of the products to which SSS was awarded in these RFPs were approved by Medsafe at the time the decision was taken.

The RMI considers that these two issues and the Herceptin error could have been prevented if PHARMAC had clear internal policies and procedures which required it to:

- consult on any proposal to decline a funding application; and
- re-consult in the event of a clinically material change to a proposal that has not resulted from the initial consultation.

The RMI considers that PHARMAC needs to introduce measures to ensure issues that are of key importance to consumers are recognized, addressed and properly managed in its consultation processes.

5. We note that PHARMAC's Annual Review is listed on Page 8 among its current consumer activities which are used to inform, but is not discussed in detail. This

publication is currently the most comprehensive source of information about decisions PHARMAC has made in any given year. The Annual Report provides some of the information but without the commentary that is contained within the Annual Review. Whichever medium or publication is used, it is vital that PHARMAC reports its activities honestly and accurately. The RMI considers that the figures currently presented in these reports are sometimes less than satisfactory.

For example, in the Annual Report for the year ending June 2009, PHARMAC reported that it widened access to 55 medicines. While it acknowledged that 29 of these related to the removal of specialist restrictions, the details of only 5 others are provided.

The RMI considers that PHARMAC should publish annually or maintain throughout the year, a comprehensive list of its new investment decisions it has made. It should also be easier for consumers to determine what has been recommended by PTAC but remains unfunded. Ideally, it should be possible for consumers to determine what PHARMAC is considering for funding (whether by a published List of Need or by virtue of PHARMAC declining any applications that it is unlikely to progress).

6. The last of PHARMAC's current consumer participation activities on which we wish to comment is the PHARMAC Forum. In our view, the material presented at your last forum in October 2009 was oversimplified. Comments from the floor appeared to endorse this view.

   The last two forums have involved PHARMAC presenting information and seeking feedback. The time allowed for feedback is very limited. Also, the mixed representation of discussion groups can (and is perhaps intended to) hamper progression of the discussions within such limited time.

   While the now twice-used format of the Forum worked well in 2007, *we suggest that future forums need to allow stakeholders to explore issues in more detail.* This could be achieved by holding issue-specific forums or by grouping together stakeholders at a more general forum, according to the issues of particular relevance to them, and allowing them to spend at least half the session in those groups.

   It would also be good to hear presentations of the issues from the stakeholders and have PHARMAC respond, rather than vice versa.

Comments on proposals outlined under "Building on Our Current Consumer Participation Activities"

Of the ideas put forward in your document, only three ((d), (e) and (g)) would result in improved consumer input. The rest are all aimed primarily or exclusively at promoting and promulgating PHARMAC's objectives and perspectives.

7. The RMI sees no real benefits resulting from the development of a Patient Reference Guide, *and therefore does not support Option (a)* given the likely high cost associated with it.

8. Similarly, we do not consider that a Quarterly Consumer-Specific Newsletter would add much value over what is now a reasonably well organized website. *We therefore do not support Option (b).*

9. The RMI considers that Occasional Papers would be useful if they provided a detailed insight into funding decisions (i.e. what PHARMAC thinks relative to PTAC, cost effectiveness, budget impact in the context of current budget etc.)

   We note that information of a similar nature was PHARMAC published about Herceptin. This provided consumers with very useful insights into the decision-making process in this case. The amount of information published in that instance was unprecedented and PHARMAC's decision to release so much information in this case was clearly motivated by the level of interest in the decision. PHARMAC has indicated that it could not practically make this amount of information available for every decision. However, Herceptin is not the only decision to have attracted such strong interest. The RMI considers that PHARMAC could and should provide this level of detail for other issues of similar concern.

   If PHARMAC decides to make greater use of Occasional Papers in future, it cannot expect to solicit advice on the topics at one particular point in time as it is apparently attempting to do via question 14 of the discussion document. *The RMI supports the notion of Option (c) but considers that PHARMAC needs to:*
   - *issue an open invitation for suggestions on Occasional Papers; and*
   - *provide better information about the status of applications and the strategic direction of therapeutic areas (i.e. generic entry etc) so that consumers are sufficiently informed to suggest topics.*

   We do not agree that the costs of seeking suggestions in this way would be high. We also note that publication of the papers on PHARMAC's website in the way that the Herceptin papers were published would involve minimal expense.

10. While face-to-face meetings can be engender better mutual understanding, their value can be diminished if the meetings become a matter of routine or the agenda/format of the meeting is too tightly controlled.

    The RMI considers that there is a need for consumers with common interests to have a regular opportunity to regularly discuss issues and concerns with PHARMAC. *To this extent, we support Option (d). However, we consider that this could be achieved via modification to the PHARMAC Forum (refer to section (6)) to ensure more attention is given to common issues and there is greater opportunity for dialogue with PHARMAC (as opposed to response to presentations).*

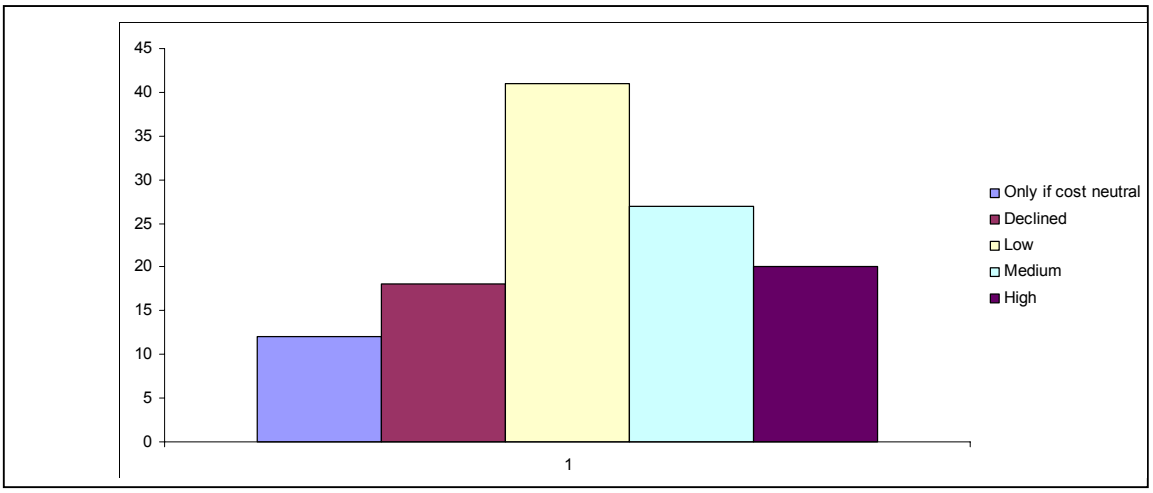
11. *The RMI supports the Option (e) of allowing Consumer comment on PTAC recommendations.* Under the current processes, consumers are only permitted to comment of PTAC's advice in the context of the provisional commercial agreement, which is highly likely to proceed regardless of their input.

    It is clear from funding decisions, that PHARMAC's views of the priority for funding of a pharmaceutical frequently differs from that of PTAC. Many of the

investments PHARMAC has made over the last three years had not been given a high priority by PTAC. Meanwhile, there are over 30 applications to which PTAC has assigned a medium to high priority for funding that have not been progressed.

This difference may also be reflected the time taken to progress applications.

Months from PTAC recommendation to listing for new listings since July 2006



The RMI is aware that funding availability, commercial factors, and PHARMAC's assessment of cost-effectiveness are factors which frequently influence the order in which pharmaceuticals are funded.

The RMI considers that the influence of commercial factors on the order in which pharmaceuticals are funded relative to PTAC's advice could and should be significantly reduced by removing PHARMAC's ability to utilize savings derived via the application of reference pricing in another therapeutic category and from another supplier to fund new medicines (i.e. cross deals).

Little else is known about the way PHARMAC prioritizes funding other than that, during this process, PHARMAC takes into account all of its decision criteria. It therefore seems appropriate that the views of consumers regarding the need, risks and benefits of each pharmaceutical should be considered in this process. Agreement or disagreement with PTAC's views would seem to be an obvious way to gather the views of consumers.

The RMI does not consider that PHARMAC has valid concerns about this proposal raising expectations of rapid funding decisions. It is unlikely that an opportunity such as this would significantly alter the understanding of consumers, so well cultivated by PHARMAC, that New Zealand cannot afford to fund everything from within a fixed budget. The opportunity proposed would, at best, make consumers feel less powerless during the inevitable wait. In any case, denying consumers access to information and/or opportunities to have input into decisions is not an acceptable means of managing expectations.

That said, the RMI does not believe that the current delays in funding decisions are acceptable, nor always justifiable. There are many pharmaceutical applications that are never likely to be progressed, but which have not been declined by PHARMAC. The RMI considers that there is no reason to delay decisions to decline applications. We consider that to make prompt decisions about these applications (as was PHARMAC's practice when it was first established) would enhance the transparency of the system.

The RMI considers that PHARMAC should be making all decisions in a finite timeframe. We are well aware that, under the current budgetary limitations, this would mean most applications would have to be declined – at least in the first instance. However, the process of doing so, especially where the reasons where made apparent, would help consumers to differentiate between pharmaceuticals that are not perceived to be good value for money and those for which there is simply not enough funding.

12. The RMI would not reject Option (f) - the idea of a Retrospective consumer "audit" of PHARMAC's performance but would regard it to be inferior to Option (g) Consumer involvement in PHARMAC's prioritization process. .

It is clear that PHARMAC considers the value of this option lies in building consumer confidence in the integrity of PHARMAC's systems and processes. However, rightly or wrongly, history shows us that the Government is likely to intervene whenever the public loses that confidence. The RMI considers that for this approach to be worthwhile, the feedback given by consumers who participated in the audit process would need to increase PHARMAC's awareness of the needs and views of consumers and ensure that it struck the right balance between its objectives/core values and public sentiment.

We do not regard the issues raised in your discussion document about this option as insurmountable but have chosen not to comment further on this option because it is not preferred by our members.

13. *The RMI considers the idea if Consumer involvement in PHARMAC's prioritization process (Option (g)) to be an interesting one and worthy of further consideration*.

You have raised many valid concerns about the practicalities of such a process including confidentiality, and selection of participants.

We also note that, for consumers to properly assess funding priorities, they would need to consider all potential investments. There are currently close to 85 positive PTAC recommendations about which investment decisions are still outstanding. Clearly, the list would need to be reduced in order to make the process manageable. This could be done if PHARMAC completed its decision making process for those applications that it regarded as unviable.

Furthermore, for consumers and/or PHARMAC to properly compare the relative merits of, and assess the possible trade-offs associated with funding one drug over

another, they would need to know exactly what the price and fiscal risk would be. In order to do this, PHARMAC really needs to have gathered that information in advance of the prioritization assessment.

The RMI considers that this could be achieved if PHARMAC ran an annual Request for Proposals (RFP) in which pharmaceuticals whose applications have been positively recommended by PTAC (potentially subject to a priority rating threshold) would bid for any funding available for new investments.

This would ensure that there is an equal opportunity for all new investments to be approved in any given year rather than the current "first come first served" approach. Consistent with PHARMAC's strategies to ensure a competitive market, suppliers would be forced to offer their absolute best prices in order to maximize their potential to secure some of the available funding.

Consumers could then assess priorities using *rankings* of all potential new investments in terms of its Decision Criteria - need (as assessed by PTAC), net budgetary impact, cost per QALY and the number of patients that will benefit - according to the best prices available. In this way, explicit prices and/or cost per QALY figures would not need to be disclosed.

Role of Consumer Advisory Committee

14. As per the RMI's submission on the Terms of Reference for CAC, we do consider that CAC should have a greater role in developing relationships with consumer groups. Here are the relevant points we made in that submission:

- 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.

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

  - Monitoring 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.

- The primary (as opposed to optional) functions of CAC should be to:

  - Engage and consult with the community and/or relevant consumer groups
  - Work with special focus/interest groups on specific issues/problem solving.

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

- CAC should 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.)

- 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.

We thank you once again for the opportunity to comment on these issues. We would welcome the opportunity to work together with PHARMAC to involve consumers in a more meaningful way in contributing to medicines funding decisions.

Yours sincerely,

Denise Wood
Chief Executive Officer