

Pharmaceutical Management Agency
Consumer Participation Discussion Document
Seeking Your Views



Discussion Document on PHARMAC's Consumer Participation

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1. Introduction

PHARMAC's role

PHARMAC is the New Zealand government agency that decides which medicines are subsidised by public funding. Its primary objective is to ensure New Zealanders get the best possible health outcomes from the budget the Government allocates for medicines funding. PHARMAC is also one of many players in the medicines system that works towards ensuring funded medicines are used to best effect. Further information on PHARMAC's role is included in the information sheet attached in Appendix 1.

Origins and purpose of the review

This review is an opportunity to consider in greater depth, and seek a broad range of stakeholder views on, all our current consumer participation activities and our early thoughts on potential options for increasing these activities.

Information gained in response to this discussion document will assist our thorough assessment of options to improve our consumer participation activities. We are not committing at this point to implementing any new activities – such decisions will need to further consider the value of additional activities over those we currently do, and the best use of PHARMAC resources across all its work. However, identification of all options, and robust assessment of their pros and cons, is essential to inform the choices we ultimately make.

PHARMAC's Consumer Advisory Committee (CAC) is one mechanism we use for advice from a consumer or patient perspective. We are currently reviewing CAC's Terms of Reference, as required in the action plan accompanying *Medicines New Zealand*, the Government's medicines strategy. We began the Terms of Reference review with the release of an information-seeking document earlier this year.

This discussion document discusses some of the information we collected in that earlier process and seeks views on how CAC's role can best complement PHARMAC's other consumer participation activities.

Review process to date

In addition to the information gathering work for the CAC Terms of Reference review noted above, PHARMAC commissioned a literature review of approaches to consumer engagement used in other agencies - both internationally and in New Zealand. That literature review has underpinned our own work. The report is available on PHARMAC's website www.pharmac.govt.nz and in hard-copy from PHARMAC.

Process for providing feedback

This discussion document seeks feedback on PHARMAC's current consumer participation activities and options for improvements. Discussion questions are included throughout the document and a complete list is provided in Section 6. To assist our consideration of submissions, we encourage you to provide reasons supporting your views.

We will consider all submissions received by 4 December 2009. Submissions will also be considered prior to our drafting revised CAC Terms of Reference for consultation in early 2010.

To provide comment, please submit an email, fax or letter by 4 December to:

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Email: cherie.jacobson@pharmac.govt.nz

Fax: (04) 460 4995

PHARMAC
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We would be pleased to receive feedback on this document face-to-face. Please contact Cherie Jacobson by 6 November 2009 to arrange a suitable time.

We encourage you to advise us of any other groups or individuals who would be interested in receiving this document.

Please include the following information in your submission:

- Your name
- The organisation the submission is from (if appropriate)
- Contact email or postal address

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 2.

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.'

2. Background on consumer participation

Drivers and aims

PHARMAC's consumer participation activities sit in the broader context of good government practice to build strong and respectful relationships with community, voluntary and Māori/iwi organisations.

The four key drivers that generally motivate government agencies to implement consumer participation activities are:

- strengthening democracy – increasing citizens' opportunities to participate in government decision-making and service delivery;
- developing better and more responsive services – using citizen participation to inform the development or redesign of government services (this overlaps with the first driver but relates more to specific services than to strategy and policy direction);
- developing social capital – increasing citizens' confidence and capability in participating in government decision-making processes and activities. An increase in responsibility for individual actions may also result.
- community development – involving citizens' in activities to improve communities – common in developing economies but also used in developed nations to inform urban planning and community sustainability programmes.^{1,2}

Of these, the first two are particularly relevant to all PHARMAC's operations and are reflected by one of our key organisational aims of 'understanding and being understood', meaning:

- understanding – ensuring we understand and appropriately consider the perspectives and experiences of others, including consumers; and
- being understood – clearly explaining our work and decisions, so that stakeholders, including consumers, understand and have confidence in our role, operations, and funding decisions.

Developing social capital is a further driver for consumer (among other stakeholder) participation in PHARMAC's Access and Optimal Use (AOU) campaigns. Empowering individuals to take ownership of programmes supports the behaviour change required to improve medicines use, and improves the sustainability of programmes. Consumer participation is central to such empowerment and supports consumers to act as agents of change within their own communities.

Consumer participation and PHARMAC's statutory objective

The drivers for PHARMAC's consumer participation ultimately relate to our statutory objective - to secure the best health outcomes from pharmaceutical treatments within the funding available. In addition to our statutory objective, PHARMAC must align its activities with the strategic direction and goals for the medicines system, including reducing inequalities.

Our ability to fulfill our objective, and to act consistently with medicines system aims, relies on the quality and effectiveness of all of our work and, importantly to the present task, our consumer participation. In order to best satisfy our statutory objective, we need to adopt the right mix of consumer participation activities, and ensure these are appropriate for all sub-population groups, particularly Māori and Pacific communities.

Both too little and too much consumer participation, or the wrong sorts of participation, risk making PHARMAC less effective than it

could be. With too little, we may miss opportunities to be properly informed of consumer views. However, with too much, resources may be devoted to something that adds limited, or no, value over existing activities – using resources that could be put to a more productive use. A careful assessment is therefore required – taking into account both costs and benefits of consumer participation activities (whether existing or new) – so that the right mix is adopted.

Measuring outcomes

Many approaches to participation in decision-making have been used by different organisations but formal evaluation of the outcome of these is rare. However, we routinely evaluate our Access and Optimal Use campaigns to determine their effect in contributing to our primary objective, and whether they warrant continued funding.

Given limited information on the effect that consumer participation in decision-making has on outcomes, we need to make careful judgments about the resources we commit to such activities. We also need to undertake, as well as we can, our own evaluations to learn from the activities we do undertake.

Limitations

Many consumers understandably want PHARMAC's decisions to provide increased access to medicines. However, PHARMAC's decisions will never keep all consumers happy – because we have to make choices about which pharmaceuticals to fund from limited resources.

Understanding how and on what grounds we make our choices may provide consumers with some confidence that we are making the best decisions – particularly if we make a decision not to fund a pharmaceutical. Understanding that our role is to make decisions that consider the interests of all people wanting pharmaceuticals may also balance some individuals' sense of missing out. Consumers also want to know that we have taken into account the information they consider to be important.

Through focusing on our organisational aim of understanding and being understood, and improving on our activities to achieve these aims, we will continue work to further increase consumer confidence that we make the best decisions within our given circumstances.

Who is a consumer?

Who do we mean when we refer to 'consumers'?

In our experience, the groups that interact with PHARMAC can be described according to the nature of their interest in our activities. The following categories provide one way of understanding these groups.

The public – individuals who may not be aware of PHARMAC's role and activities, or who want to better understand the context for, or express a view on, an event that has an effect on them or someone close to them. Interaction is usually fleeting as it relates to a single event.

Consumers – individuals or (more commonly) groups with a sustained interest in the context for events that affect their specific sphere of concern, which may be:

- disease-specific – a particular condition or group of conditions; or
- sub-population group specific – e.g. the elderly, Māori, Pacific peoples, women, men.

Both the public and consumers may wish to influence PHARMAC's policies and processes, although consumer groups are more likely to have a continued role in commenting on the organisation's activities.

For ease of reference, we have chosen to use the word 'consumer' throughout this document to describe anyone with an interest in PHARMAC.

¹ Ipsos-Eureka. Consumer/Citizen Engagement in Decision-Making Final Report Prepared for PHARMAC. 30 June 2009.

² Harding, Elishia – Ipsos-Eureka. Personal communication. September 22 2009.

Who should participate?

We want to enable anyone with an interest in PHARMAC's role and operations to access information and provide consultation responses. For this reason, much of our communication material (including our website) is designed for a general audience, and activities around specific funding decisions (such as our consultation and notification letters described in Section 3) are targeted to individuals and organisations who have indicated an interest in a specific therapeutic group.

However, when considering increasing consumer participation in the decision-making process (beyond considering consultation responses), identifying who would most appropriately be involved (given the need to limit numbers to manage the process and costs) is not clear cut.

Given PHARMAC's role is to make decisions on behalf of all who use medicines, those involved in the decision-making process need to be able to consider the broader 'public good'. However, there is no clearly identifiable group of individuals who can be said to have the mandate to reflect the 'public good'. Ensuring we have input from a representative sample of the New Zealand population might be considered a desirable solution, but would be expensive and may pose recruitment problems. Ultimately there are no fixed rules about who would most appropriately reflect the public's view.

The appropriate target group for consumer participation activities depends to a large extent on the specific activity being proposed and its purpose. We therefore discuss, and seek your views on, the appropriate target group for each of the potential participation activities in Section 4.

Spectrum of consumer participation

There are different categories of consumer participation. Each has different goals, is achieved through different techniques, and provides consumers with different levels of influence. One classification of different categories, from the International Association for Public Participation (IAP2), is included on the following page. The examples provided in the table are for illustrative purposes only and do not necessarily reflect PHARMAC's use of these activities. The categories should also be regarded as fluid, rather than fixed or separate.

PHARMAC's current consumer participation activities, and the location of these on the spectrum, are described in detail in Section 3.

Generally our activities involve informing and consulting consumers (among other stakeholders). This is because the PHARMAC Board is the ultimate decision-maker and cannot delegate its powers outside of the organisation without the consent of the Minister of Health. There are also limits (including PHARMAC's legislative functions) to PHARMAC's ability to act in the "empowering" section. In addition, agreements to protect the confidentiality of commercially sensitive information restrict PHARMAC's ability to share information that may be required for 'collaboration' or 'empowerment'.

Some of the options for additional consumer participation would involve a shift along the spectrum of participation. As noted above, any change in activities brings the potential for increased benefits and costs and risks, for both PHARMAC and consumers. These benefits and risks are reflected in the range of factors (described below) that we need to consider when determining which, if any, improvements we will make.


Increasing level of public impact 				
INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
Public participation goal:				
To provide the public with balanced and objective information to assist them in understanding the problems, alternatives and solutions	To obtain public feedback on analysis, alternatives and/or decisions	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered	To partner with the public in each aspect of the decision, including the development of alternatives and the identification of the preferred solution	To place final decision-making in the hands of the public
Promise to public:				
We will keep you informed	We will keep you informed, listen to and acknowledge your concerns and provide feedback on how public input has influenced the decision	We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision	We will look to you for direct advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible	We will implement what you decide
Example techniques to consider:				
Fact sheets Websites Open houses	Public comment Focus groups Surveys Public meetings	Workshops Deliberative polling	Citizen Advisory Committees Consensus-building Participatory decision-making	Citizen's juries Ballots Delegated decisions

Figure 1: IAP2 Public Participation Spectrum (© 2004 International Association for Public Participation)

Factors relevant to participation activities

We have used the framework below to assess options for improvements to consumer participation activities. We welcome your comments on the framework – questions are included at the end of the section.

- **Purpose - what and why?**
 - What is the activity intended to achieve and how?
 - How does this purpose fit with PHARMAC's primary objective and governance requirements?
- **Target group - for who?**
 - Who is the activity intended for and why?
- **Pros**
 - What are the key benefits of the activity to PHARMAC?
To consumers?
 - How would PHARMAC measure these benefits to provide confidence that the activity is having an effect?
- **Cons**
 - What are the potential risks of the activity for PHARMAC, and for consumer groups? These could include:
 - confidentiality breaches
 - perception of capture by PHARMAC
 - perception of exclusion of certain groups
 - costs of delayed decisions
 - What could PHARMAC do to manage these cons?
 - What are the direct and indirect financial and resource implications for PHARMAC and for consumers?
 - What could PHARMAC do to manage these costs?

Discussion questions:

1. Are there any factors listed above that you consider are not relevant to assessing potential consumer participation activities? Please identify these and provide reasons for your view.
2. Are there any additional factors, not listed above, that you think PHARMAC should consider when assessing potential consumer participation activities? Please describe these factors and explain why you think they should be considered.

3. PHARMAC's current consumer participation

PHARMAC has four main roles. These are:

- managing the Pharmaceutical Schedule, the list of subsidised medicines
- promoting the optimal use of medicines
- managing pricing negotiations for medicines and related products for public hospitals
- managing funding for non-subsidised medicines in exceptional circumstances

PHARMAC can also engage in research relevant to its work.

The majority of PHARMAC's consumer interaction relates to the first two roles. Managing the Pharmaceutical Schedule involves making decisions about which medications are subsidised by public funds, including inviting consumer input as part of the decision making process. Promoting the optimal use of medicines involves direct-to-consumer education campaigns and programmes in which PHARMAC has face-to-face contact with consumers.

Funding decisions

The diagram in the Making funding decisions information sheet attached as Appendix 3 of this document sets out PHARMAC's decision making process. The current opportunities for consumer involvement in this process are described in more detail below.

Funding applications

Anyone can make a pharmaceutical funding application to PHARMAC. The document *Having Your Say in Our Decisions*, which is available on our website, outlines the process for making a funding application and gives information about PHARMAC's decision making process.

Most pharmaceutical funding applications come from pharmaceutical companies and a list of applications received for new investments is updated quarterly and published on the PHARMAC website.

PTAC and subcommittee minutes

The Pharmacology and Therapeutics Advisory Committee (PTAC) reviews funding applications and makes recommendations to PHARMAC about each one. PTAC can request more specialised advice from a specialised subcommittee or experts as required. The PTAC and subcommittee minutes are made available on the PHARMAC website and we often send relevant excerpts to people who write to us with queries about particular funding decisions.

Consultations

When it considers it is appropriate, PHARMAC consults with any sections of the public, groups, or individuals that it believes may be affected by its proposals to fund or change access to medicines. The consultation process ensures that anyone interested in, or potentially affected by, a decision PHARMAC is making is able to express their views.

Consultations on funding proposals are published on the PHARMAC website and anyone can respond – *Having Your Say in Our Decisions* provides information about how to make a submission. People can join PHARMAC's consultation database and specify the therapeutic areas they would like to receive consultations about funding proposals on (such as Mental Health, Diabetes, and Respiratory Medicines), or they can sign up to receive all consultations that PHARMAC issues; they can also sign up to electronic web feeds.

While PHARMAC prefers to receive submissions in writing, as a clear record of the points the submitter wishes to make, it is possible to discuss a submission with us face-to-face.

Notification letters

We issue notification letters advising of PHARMAC's funding decisions. For decisions that were consulted on, the notification letters include a summary of the submissions PHARMAC received and PHARMAC's responses to them. With some decisions, however, it may not be possible to respond to every point raised in consultation, because of issues like privacy or commercial confidentiality. The notification letters are published on the PHARMAC website and are sent to everyone who made a submission.

Access and Optimal Use activities

Promoting the responsible use of medicines (otherwise known as 'access and optimal use' (AOU)) is one of PHARMAC's statutory functions. Working to reduce the overuse, underuse and misuse of medicines is an important way to get the best health outcomes from medicines that are funded.

PHARMAC's AOU campaigns aim to improve health professional and consumer behaviour around medicines prescribing and use. AOU activities often focus strongly on provision of consumer education resources to ensure the safe and effective use of pharmaceutical treatments. Recently PHARMAC has moved to make all consumer-oriented resources freely available on line through a resource centre, www.pharmaonline.co.nz.

Consumers are often closely involved in campaign and resource development through participation on steering groups, surveys and focus groups. In early development phases of campaigns, consumer's attitudes and perceptions are often surveyed to identify key issues from the patient's perspective. In instances where consumer resources are developed or for campaigns seeking behaviour change among consumers, PHARMAC will actively test key messages and channels with the target audience.

Some campaigns (such as *One Heart Many Lives*) also involve consumer 'champions' who are responsible for modelling and encouraging positive behaviour change within their own communities.

Other organisational activities

In addition to consumer participation in funding decisions and AOU activities, PHARMAC provides information about its role and how it operates, corresponds with individual consumers and consumer groups, and also seeks consumer feedback on some operational and policy changes.

PHARMAC has been focussing on improving its communication and stakeholder participation, and believes improvements have been made. Given how critical effective communication and participation is to our performance, this remains an important area for further improvement.

Website

The PHARMAC website www.pharmac.govt.nz provides comprehensive, up-to-date information about PHARMAC – and has dedicated areas for patients and consumers, along with health professionals, District Health Boards, and pharmaceutical suppliers.

The patient and consumer section contains a wide range of information that may be useful to anyone wanting to learn more about PHARMAC's role, how it operates and aspects such as Māori health, medicines information and frequently asked questions. All consultation documents, notifications, committee minutes, media releases and a wide range of other information is published on the website. We also have a 'what's new' area for new developments, and links to other websites set up for specific purposes (mostly AOU campaigns).

Information sheets

Available as individual sheets or as a complete set in a booklet, the Information Sheets are designed to answer some of the most commonly-asked questions about PHARMAC and the work we do. They range from general information about the structure and roles of PHARMAC, to how PHARMAC goes about economic analysis and the work we do to manage pharmaceutical supplies. These sheets are available on the PHARMAC website, PHARMAC Online, or by contacting PHARMAC to request a copy.

Pharmaceutical Schedule and Updates

The New Zealand Pharmaceutical Schedule (the "Schedule") is a list of the approximately 2000 prescription medicines and therapeutic products subsidised by the Government. The Schedule is published three times a year and updated monthly. Schedule information on the PHARMAC website is updated monthly.

The printed Schedule is distributed free to about 11,000 medical practitioners, pharmacists, medical libraries, professional bodies and support groups, and can also be requested by other users, including pharmaceutical suppliers, by contacting PHARMAC via their 0800 line (details below).

Correspondence

PHARMAC receives hundreds of letters and emails every year from consumers with questions, observations and concerns. We reply to all correspondence and seek to substantively comment on the issues raised and, where useful, provide additional information such as information sheets, resources or minutes from PTAC or subcommittee meetings.

PHARMAC 0800 line and general PHARMAC switchboard

In addition to its general switchboard (04 460 4990), PHARMAC operates a toll-free phone line (0800 66 00 50) between 9am and 5pm on weekdays, to enable consumers and other stakeholders to speak to us about any questions or concerns they have.

PHARMAC Online

The PHARMAC Online website (www.pharmaonline.co.nz) enables people to order PHARMAC information and resources. As well as browsing publications and resources available for order, people can sign up to receive information on topics of interest in the future.

Inpharmation

PHARMAC produces a bi-annual newsletter, Inpharmation, which is sent to a wide range of consumer groups, DHBs, pharmaceutical companies and is published on the PHARMAC website. It contains updates on recent funding decisions, new resources and articles of interest.

Consultation on operational policy development and implementation

PHARMAC also seeks stakeholder views on operational changes. A recent example of an operational change is the review of the PTAC Terms of Reference; a current example is the CAC Terms of Reference review.

Like funding decision consultations, these general consultations are published on the PHARMAC website and sent to those who have registered with us to receive consultations of this nature, along with any other stakeholders, including consumer groups or individuals, that we think would be interested in the consultation.

PHARMAC has also publicly consulted on its policy development and implementation. During the development of the Māori Responsiveness Strategy, PHARMAC undertook significant consultation with key Māori health stakeholders throughout the country, at hui held on marae. Stakeholder involvement has been, and continues to be, an integral component for the implementation of PHARMAC's Māori Responsiveness Strategy Action Plan: Te Whaioranga.

PHARMAC Forum

The first PHARMAC Forum was held in December 2007. More than 100 stakeholders including consumer groups, clinicians, pharmacists, the pharmaceutical industry and Government sector attended to talk about PHARMAC and its work. PHARMAC captured all the feedback people provided, analysed it and then formed an action plan in response. The action plan also reflected actions PHARMAC was taking in response to the Government's Medicine Strategy, *Medicines New Zealand*.

A second PHARMAC Forum is being held in October 2009, providing a further opportunity for wide-ranging discussion about our work.

Attending/presenting at conferences

PHARMAC staff regularly attend conferences to learn about developments in the health sector and make themselves available to speak to stakeholders, including through operating PHARMAC information stands when appropriate. Staff also present at conferences on PHARMAC's role and operations and any issues of interest.

Recognising the importance of PHARMAC's relationships with consumers, PHARMAC sponsored and attended two conferences to establish a national health consumer entity that aims to work collaboratively with consumer organisations for the purpose of strengthening consumer voice and raising the profile of consumer perspectives on health issues.

Face to face meetings

PHARMAC is always open to meeting with anyone who wishes to provide feedback on our work or learn more about PHARMAC's role. We also make effort to proactively meet with consumer groups and other stakeholders to keep abreast, and increase our understanding, of their views.

Consumer Advisory Committee

The Consumer Advisory Committee (CAC) is an advisory committee to the PHARMAC Board. CAC's role is to provide input from a consumer or patient perspective. CAC makes recommendations to the Board on a number of issues. The CAC Chair also attends Board meetings as an observer. In formulating its advice and recommendations to the Board, CAC seeks, reviews and debates a wide range of papers and topics presented to it by PHARMAC staff, including:

- educational information to assist patients;
- initiatives to promote the responsible use of medicines;
- how access to medicines could be improved;
- use of medicines by Māori, Pacific Peoples and other groups that are identified as experiencing inequalities in relation to medicines; and
- implementation of PHARMAC's decisions.

The Committee is made up of people from a range of backgrounds and interests including the health of Māori people, Pacific peoples, older people, women and mental health. CAC members developed the following vision statement to describe the Committee's aim:

To ensure the voice of consumers is effectively represented in PHARMAC decision making in order to achieve optimal health outcomes

Consumers can contact CAC via email or letter. Depending on the nature of the query, a response may come from CAC or from PHARMAC. Minutes from CAC's meetings are published on the PHARMAC website. CAC has met with a small number of consumer groups face-to-face, but tends to rely on its members' links with networks within their particular area of interest in the health sector in order to remain informed of consumer views.

The CAC Terms of Reference are currently undergoing a review following a public information seeking document that asked for input into developing a new draft Terms of Reference. This will be discussed in greater depth in Section 5.

PHARMAC's current consumer activities on the participation spectrum

PHARMAC's current consumer participation activities					
Participation level	Inform	Consult	Involve	Collaborate	Empower
	Provide consumers with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions.	Obtain consumer feedback on analysis, alternatives and/or decisions.	Work directly with consumers throughout the process to ensure that consumer concerns and aspirations are consistently understood and considered.	Partner with consumers in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	Place final decision-making in the hands of the consumers.
PHARMAC's current activity	PTAC and Subcommittee minutes Information sheets PHARMAC website Notification letters Correspondence Publications (annual report, annual review) PHARMAC Forum 0800 number AOU resources PHARMAC Online Inpharmation Face-to-face meetings	Funding decision consultations Operational policy consultations CAC (though not currently on funding decisions) PHARMAC Forum	AOU campaign development (including CAC)	AOU campaign implementation	
<p>Discussion questions:</p> <p>3. Do you have any comments on PHARMAC's current consumer participation as described above?</p> <p>4. Are there any improvements you think should be made to PHARMAC's consumer participation activities?</p> <p>Please describe and give reasons for your answers.</p>					

4. Building on our consumer participation activities

Capability development

In order for all consumer participation activities to be carried out effectively, the right level of organisational capability is required. In particular, effective skills and competencies in both oral and written communication are important (including the ability to convey information in easy-to-understand language), as are skills in building effective relationships and handling, at times, sensitive or difficult discussions. Another important set of skills and competencies is in participation activities that must be delivered in a culturally appropriate way – particularly in our work related to engagement with Māori and Pacific communities.

While all of these skills are used in everyday life, no organisation can assume it has the right level of skills to carry out the desired level of consumer participation effectively. Instead, organisations must assess what types and levels of capability are required, and set about planning, building and maintaining the desired levels over time.

As part of professional development of our staff, we provide training opportunities in areas particularly relevant to consumer participation - for example, effective writing, presentation, interpersonal skills, tikanga Māori, negotiation - all areas that can make a positive contribution to our work in this area.

As our internal capability is a key determinant of the success of our consumer participation, and in addition to our own further work around capability assessment, we welcome feedback on any areas that you believe require development.

Discussion questions:

5. Are there any areas of capability development you consider PHARMAC should focus on? Please explain.

Options for improvement

We are in the early stages of identifying and considering potential options for additional consumer participation activities and would benefit from your feedback. Some of the potential options have been suggested by consumers, others have been identified by PHARMAC staff in response to consumer and other stakeholder comments. We welcome your feedback on the potential options described below as well as other ideas for new participation activities.

PHARMAC cannot guarantee that any new consumer participation activities will be undertaken. As described above, PHARMAC already undertakes extensive consumer participation activity and – like all government agencies and organisations – is very mindful of using its funding to best effect. Some new activities may also require a funding increase, something that cannot be guaranteed in the current economic climate with significant pressure on government resources.

What should be clear, however, is that we want to do a thorough assessment of potential options for changing or adding to consumer participation activities. By identifying potential options, and robustly assessing their pros and cons, we can then make more informed judgements about the future direction of our consumer participation activity.

Any additional potential options you identify will be assessed against the factors described in Section 2. It would, therefore, be helpful for you to include an analysis of your suggestions against these factors in your submission.

Scope of potential options

The majority of the activities described below relate to the medicines funding component of our role. Based on our engagements to date, including the PHARMAC Forum, this is the area where consumer groups have indicated additional activities should be explored.

We are largely satisfied that our involvement of consumers in the design and delivery of access and optimal use (AOU) programmes is supporting us achieving our legislative objective. We also benefit from feedback on consumer involvement in AOU activities directly from the groups involved and through process evaluations of these programmes.

Potential new activities

(a) Patient reference guide

What?

- A two sided reference guide for patients about:
 - pharmaceutical subsidies;
 - the funding system and principles that underpin it;
 - questions about medicines that may be useful to ask doctors; and
 - who to contact for information about subsidised medicines.

Why?

A reference guide would provide consumers with easily accessible information about PHARMAC's role and responsibilities and those of other agencies in the medicines system (particularly Medsafe), and raise awareness of who consumers should contact if they have concerns about medicines safety or funding issues. Providing this information to help consumers better understand how the medicines system works may also increase confidence in PHARMAC's decisions.

For who?

The information would be produced for anyone likely to use prescription medicines and could be distributed to patients through service channels, in particular GP surgeries, pharmacies, the Citizens Advice Bureau, and advocacy groups.

Pros?

An information card would be an efficient way for people to gain basic information about the medicines system and PHARMAC's role, and doesn't rely on people having internet access. However, it may also be argued that the incremental benefit of this is relatively low, considered alongside PHARMAC's Information Sheets and other resources which we could distribute more widely as an alternative to creating an additional source of information.

It is also not clear what the level of uptake of information would be and the extent to which this would translate to increased consumer understanding and confidence in PHARMAC.

Cons?

While not automatically a 'con', we would need to be clear what the specific need for this resource was, over-and-above other resources we currently publish for consumers, including our Information Sheets. If that need is not well defined, there is a risk that this material may constitute additional cost without additional benefits.

The distribution of information through a range of organisations (e.g. GP surgeries and pharmacies) also has some risks, including that information is superseded and we are reliant on others to replace the out-dated with up-to-date information. In addition, the availability of a range of different consumer publications may create confusion about the 'correct' or most appropriate source to refer to.

Writing the patient reference guide would not be very time intensive. The printing and distribution of the document is likely to be of moderate-high cost, depending on demand.

Discussion questions:

6. Do you think consumers need more information on the topics proposed for the patient reference guide?
7. What, if any, benefit do you think the patient reference guide would provide over existing PHARMAC publications such as the Information Sheets and Having Your Say in Our Decisions, and the consumer section of PHARMAC's website.
8. Are there better/alternative ways PHARMAC can provide this information to consumers? If so, please describe these and their benefits.
9. Is there other information that would be better included in such a document?

(b) Quarterly consumer-specific newsletter

What?

A newsletter (in electronic and hard-copy format) for consumers that would:

provide links to relevant information and documents on PHARMAC's website (including Having Your Say in Our Decisions, consultations and notification letters, and PTAC minutes);

explain, in a consumer-friendly format, concepts at the heart of PHARMAC's role; and

raise awareness of other PHARMAC activities of relevance to consumers (organisational policy reviews, CAC meeting minutes, AOU campaign events, PHARMAC Forum information).

Why?

To provide consumers with relevant information, increase understanding of PHARMAC's role, and highlight opportunities for consumer involvement in PHARMAC's processes. While all the information contained in the newsletter is currently available on PHARMAC's website and can be subscribed to via RSS feeds, a newsletter would highlight the points of interest and opportunities for participation consumers would be interested in.

For who?

Anyone with an interest in PHARMAC would be able to access the newsletter. It would be distributed to groups and individuals on PHARMAC's consumer consultation database, and would be posted on the consumer section of the website.

Pros?

A newsletter would be an efficient mechanism for PHARMAC to deliver key information to large numbers of consumers, and would reduce the time imposition of searching for the latest information on our website.

PHARMAC is not clear about the level of demand for the information that would be included in the newsletter. If demand is low, the newsletter may not be read (especially given the volume of mail people receive).

Cons?

There would be a moderate time and financial cost to PHARMAC of producing and distributing the document to consumers.

Low resource requirements on consumers who would just need to sign-up to receive the newsletter.

Low-moderate PHARMAC resource required to prepare, produce and distribute the publication.

Discussion questions:

10. Do you think consumers would be interested in receiving the newsletter described above?
11. What additional or alternative information would you like to receive from PHARMAC?
12. Are there better alternative ways PHARMAC could provide this information to consumers? If so, please describe these and their benefits.

(c) Occasional papers

What?

Occasional papers would provide more information and in-depth analysis on medicines funding topics, some of which would be of interest to consumers. PHARMAC could seek stakeholders' (including consumers) views on the topics they would like to see papers focus on.

Why?

For consumers interested in medicines funding issues, the occasional papers would be a good source of information for consumers beyond that which is currently provided. To the extent that the papers provide further insights into PHARMAC's role and operations, the papers may also increase understanding of PHARMAC.

For who?

Anyone with an interest in PHARMAC would be able to access the occasional papers which would be posted on the consumer section of the website and advertised via RSS feeds.

Pros?

Occasional papers would be a further efficient mechanism for providing information to large numbers of consumers, although some paper topics may not be of interest to consumers, or may relate to technical or analytical parts of PHARMAC's work that require a grounding in a topic or area that many consumers would not have.

As with the newsletter, PHARMAC is not clear about the level of demand for the information that would be included in the occasional papers and whether these would be read. We would have greater confidence that we are providing information of interest if responding to topics suggested by consumers.

Cons?

Moderate-high PHARMAC resource in time and cost would be required to seek suggestions for, and prepare, produce, and distribute occasional papers.

Discussion questions:

13. Do you think occasional papers would provide additional value to consumers over and above the information already available through the Information Sheets and on the PHARMAC website?
14. Are there specific topics you are interested in that you would like more information on in this form? What are these?
15. Are there better alternative ways PHARMAC could provide this information to consumers? If so, please describe these and their benefits.

(d) Formalisation of regular meetings with consumers and consumer groups

What?

PHARMAC would identify and proactively arrange a face-to-face meeting with consumer groups to discuss medicines funding issues. We currently hold such meetings, but a programme of meetings could potentially be formalised and advertised.

Why?

Face-to-face meetings are a good way for PHARMAC to hear consumers' perspectives and concerns and discuss the funding process and common misconceptions. They also provide a good opportunity for consumers to raise, and receive a direct response to, concerns about funding process or other issues.

PHARMAC already has ad-hoc meetings with many special interest groups to discuss specific funding proposals, PHARMAC's operations and AOU campaign development, and consumers also have the opportunity to attend the PHARMAC Forum. However, there may be benefits from a more structured approach to regular meeting with groups or individuals for broader discussions.

For who?

PHARMAC would be willing to meet with anyone with an interest in the organisation's activities. We anticipate that disease-specific or sub-population group specific consumer groups or individuals would be most likely to take up the offer.

Pros?

Face-to-face discussions can enable parties to reach a deeper understanding of each other's views, and are a good format for responding to questions.

Cons?

Meetings are time intensive and this would limit the number of regular meetings PHARMAC could hold. It is also not clear how PHARMAC would choose which individuals or groups to meet with – there is a risk that some individuals or groups may feel excluded.

Discussion questions:

16. Do you think consumers would be interested in regular face-to-face meetings with PHARMAC? Please explain your view.

17. How do you think PHARMAC should identify those groups it should offer to meet with regularly?

(e) Consumer comment on PTAC recommendation

What?

We would formally seek stakeholders' (including consumers) comments on PTAC's recommendations once these have been published on the PHARMAC website.

Why?

Stakeholders can currently comment on proposals at the formal consultation stage of the process. Information provided on PTAC recommendations can be considered earlier in the process as funding proposals are developed.

For who?

Anyone with an interest in commenting on PTAC recommendations could provide comment. PHARMAC would advise of opportunities to provide comments on PTAC minutes through the consultation database.

Pros?

Seeking views on the PTAC minutes would enable interested parties to comment early in the process. This would help ensure that PHARMAC is aware of all potentially relevant information as early as possible in the assessment process.

Cons?

PTAC provides its view early in the decision process. In addition, PTAC provides recommendations and PHARMAC may decide not to fund a pharmaceutical recommended for funding by PTAC. Through seeking views on the PTAC minute, PHARMAC may raise expectations of rapid funding decisions which in some circumstances will not eventuate.

A low level of PHARMAC resource would be required for distribution of PTAC recommendations for comment. The level of resource required for considering the implications of comments on the minute will depend on the volume and nature of responses but could be high.

There is a risk that individual consumers or consumer groups, some of whom are relatively poorly-resourced, would expend significant resource preparing comments on PTAC recommendations. PHARMAC would seek to minimise this risk by encouraging those commenting to provide only information relevant to the 9 decision criteria on which funding decisions are based. However, groups may consider this a poor use of resource if they don't see immediate evidence of PHARMAC action on PTAC minutes, which is possible given the number of pharmaceuticals PHARMAC prioritises for funding.

Discussion questions:

18. What is your view on PHARMAC seeking views on PTAC minutes? Do you think it offers benefits over and above PHARMAC's current consultation process?

19. Would you be likely to respond to an invitation for feedback on PTAC minutes?

(f) Retrospective consumer 'audit' of PHARMAC's performance

What?

PHARMAC would ask a group of consumers to review PHARMAC's decisions over the previous year, and advise whether, on the basis of the information PHARMAC had available at the time, the group would have made different choices.

Why?

A consumer audit would provide PHARMAC with information about how consumers value different choices. While retrospective, PHARMAC would take this information about consumer preferences into account when making future decisions. Knowing that PHARMAC is considering the outcomes of the retrospective audit may also increase consumers' confidence in PHARMAC's decisions.

For who?

Disease-specific and sub-population group specific consumer groups are likely to have the greatest interest in participating. Given PHARMAC's role of making decisions on behalf of the government for all New Zealanders the group would be considering PHARMAC's choices from the 'public good' perspective rather than a specific interest-group point of view.

We are not clear how we would identify the people who would best be able to undertake this role. Involving members of the Consumer Advisory Committee is one option that could be considered as part of its Terms of Reference review.

Pros?

This activity would enable PHARMAC to receive information about consumer views of funding decisions without the risks of sharing commercial-in-confidence information and pressure on consumer participants to disclose confidential information.

Cons?

There is a risk that some consumers would feel excluded from the process and/or perceive that PHARMAC has 'captured' the participants.

While PHARMAC seeks to simplify the information it presents, decisions are based on significant amounts of complex clinical and economic assessment. While consumers could be asked to verify parts of that assessment, or the overall process integrity, there would be areas that require a higher degree of technical training than most consumers could bring.

In short, the issue just noted is whether the audit would be based on sufficient capability. The cost of bringing consumers up to speed on all the information necessary for them to provide comment on PHARMAC's funding decisions would be significant for both PHARMAC, and for the consumer participants.

Further, any audit – to be fair to PHARMAC – would need to be based on the information that was available at the time – drawing into question whether the results, after the fact, were meaningful or useful. While some stakeholders would welcome a "merits appeal" of PHARMAC's decisions, there are significant downsides to such appeals, and PHARMAC would need to feel assured that an audit undertaken after the decision is made was not a merits appeal by another name.

This potential option fundamentally relates to the integrity of PHARMAC's processes and systems that underpin decisions. PHARMAC is always trying to demonstrate, and build confidence in, the integrity of its process and systems. We would welcome ideas on how such confidence could be further enhanced.

Discussion questions:

20. Do you think a retrospective audit will increase consumer confidence in the prioritisation process?
21. Do you agree that the participants would need to consider PHARMAC's choices from the public good perspective? If so, why? If not, why not?
22. How would PHARMAC identify the participants described in your response to question 21?
23. What, if any, role do you think CAC should have in the consumer audit of performance?
24. What are your suggestions for how PHARMAC can manage the risk of perception of 'capture' of the participants?

(g) Consumer involvement in PHARMAC's funding decision prioritisation process

What?

We would directly involve a small number of consumers in our prioritisation meetings. The consumer participation currently provided for is through the provision of consultation responses.

A diagram of PHARMAC's decision process, including the prioritisation process, is included in Appendix 1.

Why?

Involvement of consumer participants would ensure that consumer values are reflected in the prioritisation process, prior to a funding decision being made. Such involvement may also increase consumer confidence in PHARMAC's decision. This confidence is currently limited by the necessarily confidential nature of our prioritisation process.

However, before it could be determined that there is a valid reason for this option, PHARMAC needs to understand what information is currently not being factored in by PHARMAC itself, including on the basis of significant consumer participation activities?

For who?

As with the audit option we would be seeking input from the 'public good' perspective rather than specific consumer group perspectives. The question of how PHARMAC would identify the best people to participate is raised again.

Involving members of the Consumer Advisory Committee is one option that could be considered as part of its Terms of Reference review.

Pros?

Including consumers in PHARMAC's prioritisation process is one way of getting consumer views into, and increasing consumer confidence of, the prioritisation process while maintaining confidentiality of our prioritisation list - essential to getting the greatest value from pharmaceutical funding.

Cons?

Commercial confidentiality may be breached with significant consequences for PHARMAC's budget management and the health outcomes that can be achieved from funding. Confidentially agreements would reduce but not remove this risk.

Participants would not be able to feed back to other consumers on details of the prioritisation process, or ranking of individual applications but may come under significant pressure to do so.

Given there is no set of individuals with a mandate to represent the 'public good', consumers who are not involved in the process may feel that their perspective is not being reflected. Other stakeholder groups may also believe they should be involved.

The perception may also develop that PHARMAC has 'captured' the participants. These scenarios would negate some of the anticipated benefits of consumer involvement.

The information considered in the prioritisation process is complex, and participants may feel poorly equipped to comment. This can be mitigated by a thorough induction process and ongoing investment in participants' development.

A low level of financial resource would be required to cover meeting fees and any travel and accommodation costs for the participants.

A medium-high level of resource would be required for induction and development of Panel members and to prepare accessible information for the participants.

A medium level of resource requirement for the participants – including reading materials, attending meetings and ongoing development.

Discussion questions:

25. Do you think consumer participation will increase consumer confidence in the prioritisation process?
26. Do you agree that the participants would need to contribute to the prioritisation process from the public good perspective? If so, why? If not, why not?
27. How would PHARMAC identify the participants described in your response to question 26?
28. What, if any, role do you think CAC should have in the prioritisation process?
29. What are your suggestions for how PHARMAC could support participants to manage the pressure they are likely to experience to disclose commercial in confidence information?
30. What are your suggestions for how PHARMAC can manage the risk of perception of 'capture' of the participants?

Additional suggestions

PHARMAC invites you to provide your suggestions for other consumer participation activities that you think would improve PHARMAC's understanding of consumers' views and/or consumers' understanding of PHARMAC.

Discussion questions:

30. Do you have any suggestions for consumer activities? If so, please describe using the following questions when describing your suggestion (What? Why? For who? Pros? Cons?).

5. Role of the Consumer Advisory Committee

Earlier this year, PHARMAC sought views on issues and information that should be considered as part of the CAC Terms of Reference (ToR) review. The responses reflected a range of views about the optimal role for CAC, which raised further questions we are seeking your views on.

CAC, PHARMAC and consumers

CAC members have established consumer networks that keep them up-to-date with a range of views on medicines and broader health issues. However, no consumer group with only a few members can be an authority on, nor representative of all, consumer views. CAC is a very valuable source of information and advice, but additional consumer participation remains critical – something CAC also helps with through advice on how PHARMAC could improve its own relationships and participation activities with consumers.

Many respondents to the information-seeking phase of the CAC ToR review said CAC should increase its interactions with consumer groups so it is better able to communicate and represent consumer views, and report information back to consumers. Some respondents also thought CAC should undertake consultation processes. At the extreme, this could see CAC acting as a representative of all consumer groups as well as undertaking activities that PHARMAC is obliged to do, in effect it could see CAC acting as a conduit for the flow of information from consumers to PHARMAC, and for reporting the PHARMAC view back to consumer groups.

The advantages of CAC acting as a conduit for consumer views could be that CAC would develop a thorough understanding of a range of consumer views which it could then feed into PHARMAC's processes. In addition consumers may be reassured that because CAC reports to the PHARMAC Board, concerns expressed to CAC would ultimately end up being considered by the Board.

Arguably, however, it may be preferable for PHARMAC to continue to directly develop its own understanding of consumer views through increased interaction with consumers so that PHARMAC staff could bring this knowledge and experience to bear in their work. This approach also makes clear that it is PHARMAC's task (not CAC's) to consider conflicting stakeholder (including consumer) views when these arise, and determine how best to proceed. Consumers' views expressed in submissions on funding decisions and operational changes are ultimately considered by the Board. Perspectives that consumers share on broader issues at the PHARMAC Forum are also considered by the Board as part of the Forum summary and report-back process.

While responsibility for obtaining consumer views will never solely rest with PHARMAC or CAC, we do want to better understand if and why stakeholders consider that CAC, rather than PHARMAC should be responsible for gaining consumer views and for reporting PHARMAC views back to consumers.

Discussion questions:

31. Do you think PHARMAC or the Consumer Advisory Committee should have primary responsibility for developing relationships with consumer groups to better understand consumer views? Please explain the advantages of the approach you suggest.

6. Summary

Next steps

PHARMAC will consider all submissions when deciding on which, if any, improvements to existing consumer participation activities or new consumer participation activities we will implement. As already noted, the options discussed in this paper are described for the purposes of collecting views and are not intended to indicate a commitment by PHARMAC to undertake any of the activities described. Further assessment of pros and cons, with the benefit of your feedback, is required to determine what, if any, additional activities would contribute to PHARMAC achieving its statutory objective.

We will let stakeholders know of our decisions through responses to submissions, our website and via email to our consumer consultation database.

We will also be consulting on a revised version of the Consumer Advisory Committee Terms of Reference in early 2009 and will distribute this broadly to our consumer consultation database.

If you want to check whether you are included on our database, please contact Jessica Dougherty (jessica.dougherty@pharmac.govt.nz or (04) 916 7518).

Discussion questions

The full set of discussion questions are provided below:

Discussion questions:

1. Are there any factors listed above that you consider are not relevant to assessing potential consumer participation activities? Please identify these and provide reasons for your view.
2. Are there any additional factors, not listed above, that you think PHARMAC should consider when assessing potential consumer participation activities? Please describe these factors and explain why you think they should be considered.
3. Do you have any comments on PHARMAC's current consumer participation as described above?
4. Are there any improvements you think should be made to PHARMAC's consumer participation activities? Please describe and give reasons for your answers.
5. Are there any areas of capability development you consider PHARMAC should focus on? Please explain.
6. Do you think consumers need more information on the topics proposed for the patient reference guide?
7. What, if any, benefit do you think the patient reference guide would provide over existing PHARMAC publications such as the Information Sheets and Having Your Say in Our Decisions, and the consumer section of PHARMAC's website.
8. Are there better/alternative ways PHARMAC can provide this information to consumers? If so, please describe these and their benefits.
9. Is there other information that would be better included in such a document?
10. Do you think consumers would be interested in receiving the newsletter described above?
11. What additional or alternative information would you like to receive from PHARMAC?
12. Are there better alternative ways PHARMAC could provide this information to consumers? If so, please describe these and their benefits.
13. Do you think occasional papers would provide additional value to consumers over and above the information already available through the Information Sheets and on the PHARMAC website?
14. Are there specific topics you are interested in that you would like more information on in this form? What are these?
15. Are there better alternative ways PHARMAC could provide this information to consumers? If so, please describe these and their benefits.
16. Do you think consumers would be interested in regular face-to-face meetings with PHARMAC? Please explain your view.
17. How do you think PHARMAC should identify those groups it should offer to meet with regularly?
18. What is your view on PHARMAC seeking feedback on PTAC minutes? Do you think it offers benefits over and above PHARMAC's current consultation process?
19. Would you be likely to respond to an invitation for feedback on PTAC minutes?
20. Do you think a retrospective audit will increase consumer confidence in the prioritisation process?
21. Do you agree that the participants would need to consider PHARMAC's choices from the public good perspective? If so, why? If not, why not?
22. How would PHARMAC identify the participants described in your response to question 21?
23. What, if any, role do you think CAC should have in the consumer audit of performance?
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27. How would PHARMAC identify the participants described in your response to question 26?
28. What, if any, role do you think CAC should have in the prioritisation process?
29. What are your suggestions for how PHARMAC could support participants to manage the pressure they are likely to experience to disclose commercial in confidence information?
30. Do you have any suggestions for consumer activities? If so, please describe using the following questions when describing your suggestion (What? Why? For who? Pros? Cons? Costs?).
31. Do you think PHARMAC or the Consumer Advisory Committee should have primary responsibility for developing relationships with consumer groups to better understand consumer views? Please explain the advantages of the approach you suggest.

7. Appendices

Appendix 1

Introduction to PHARMAC

What is PHARMAC?

PHARMAC is the New Zealand Government agency that decides, on behalf of District Health Boards, which medicines are subsidised.

PHARMAC, a Crown Entity, was created in 1993 to ensure that New Zealanders get the best possible health outcomes from money the Government spends on medicines. Trying to meet the public's growing demand for new medicines within a defined budget is a challenging and important job. Since its establishment, PHARMAC has made a wider range of subsidised medicines available, while staying within an agreed budget each year.

What does PHARMAC do?

PHARMAC has four main roles:

- managing the Pharmaceutical Schedule of over 2000 Government-subsidised community medicines (those medicines that your doctor prescribes)
- promoting the best possible (or 'optimal') use of medicines
- managing the subsidy of some medicines and products for public hospitals
- managing Exceptional Circumstance schemes (medicines funding for people with rare conditions) and other special access programmes.

We are guided by a number of laws and Government guidelines, and *Medicines New Zealand* – the strategy for the medicines system.

Managing the medicines budget

The budget for medicines that people take when they are not in hospital - the Community Pharmaceutical Budget - is set each year by the Minister of Health, on the advice of District Health Boards and PHARMAC. District Health Boards hold that money and PHARMAC works on their behalf to manage the spending. PHARMAC decides what medicines to fund, negotiates prices, sets subsidy levels and conditions, and ensures spending stays within budget. The list of subsidised medicines is called the Pharmaceutical Schedule.

Legislation requires that PHARMAC does not spend more than the budgeted amount. PHARMAC tries to keep spending as close as possible to the target figure, while remaining under it.

Optimal use of medicines

As well as making medicines available, an important part of PHARMAC's role is to ensure that medicines are used appropriately, and not overused, underused or misused. We do this by developing campaigns, such as Wise Use of Antibiotics (encouraging appropriate use of antibiotics) and One Heart Many Lives (encouraging men to improve their heart health).

Hospital medicines

PHARMAC negotiates prices (and other supply terms) for some hospital medicines on behalf of District Health Boards. These are listed in Section H of the Pharmaceutical Schedule. District Health Boards may also use PHARMAC's expertise to manage the purchasing of other products used in hospitals.

We also negotiate annual supply contracts for the influenza vaccine - on behalf of the Ministry of Health.

Pharmaceutical Cancer Treatments (PCTs)

PHARMAC manages the cancer treatments 'basket', a list of pharmaceutical cancer treatments which all District Health Boards must fund. PHARMAC decides which medicines to add to the list. Funding is currently held by District Health Boards, and this may be transferred to PHARMAC in future.

Advisory committees

PTAC, the Pharmacology and Therapeutics Advisory Committee, gives PHARMAC advice on whether new medicines should be subsidised and, if so, what priority they should be given. PTAC is made up of practising clinicians with expertise in general and specialist medical practice, clinical pharmacology, and examination of data from clinical trials. The committee generally meets four times a year.

Members are appointed by the Director General of the Ministry of Health. PTAC has subcommittees for specialised advice, such as on cancer and diabetes treatments, when necessary. Together these committees provide PHARMAC with a resource of more than 50 clinicians helping us to make the right decisions.

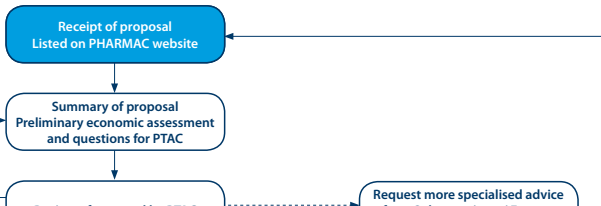
The Consumer Advisory Committee provides PHARMAC with an important patient or health consumer point of view. Its members are appointed by the PHARMAC Board. Members bring a wide range of consumer perspectives, such as gender, age, ethnicity and geographical location.

Decision making process

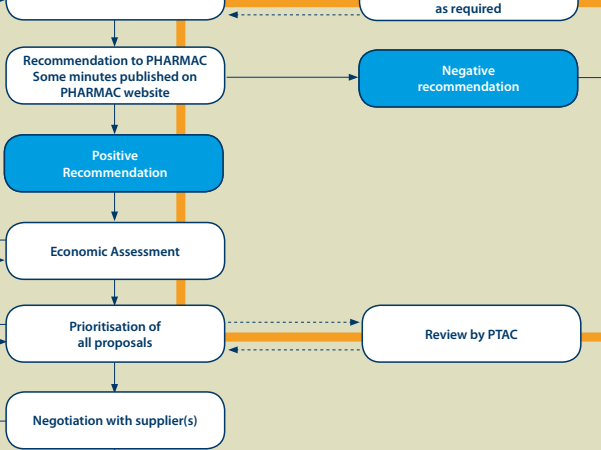


The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funded on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process (for example, decisions on whether or not it is appropriate to undertake consultation are made on a case-by-case basis).

Considering evidence

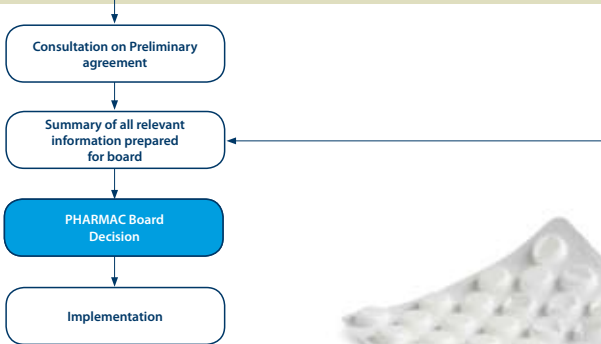


Assessing Relative Value



PTAC

Reaching a Decision



Decision-making

There are nine Decision Criteria that PHARMAC considers when making funding decisions. A wide range of information is considered under these criteria, including patients' needs, whether there are other existing treatments, the amount of health gained for each dollar spent on the medicine (value for money), and the Government's health priorities. In assessing these factors PHARMAC seeks advice from the Pharmacology and Therapeutics Advisory Committee (PTAC - a committee of expert doctors).

PHARMAC's people

PHARMAC employees undertake a wide variety of roles including analysing proposals to subsidise medicines, negotiating with pharmaceutical companies, economic and clinical assessment and developing optimal use initiatives. A range of skills and expertise enables this work to be done effectively. Our office is based in Wellington, with approximately 60 staff.

7. Appendices

Appendix 2

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.

7. Appendices

Appendix 3

Making funding decisions

The medicine funding environment

None of us can have everything we want; our personal resources only stretch so far. The same is true of healthcare, and medicines. There will always be a greater demand for funded medicines than the available resources allow.

Rapid sharing of information leads to heightened public desire for new medicines to be funded. Further, when a new medicine becomes available, it is often presented as doing the job better than older medicines. But newer isn't necessarily better and part of our job is to assess all medicines and fund those that make the most improvement in the health of New Zealanders.

All New Zealanders are, in some way and at some time, affected by the decisions we make. To ensure that the funding of medicines is as fair and robust as possible, we use nine Decision Criteria and an established process that includes expert clinical advice, and internal analysis by PHARMAC of clinical, economic and commercial issues. We also seek the views of the wider community through consultation.

The job of assessing the potential health outcomes and then allocating a subsidy to a medicine is challenging and complex. The decision making process is shown in the diagram on the right.

The "Decision Criteria"

The Decision Criteria are not weighted or applied rigidly as the situation for one assessment may require quite different considerations compared with another. Decisions are made relative to other options, and the context within which decisions are made is constantly changing. These criteria are:

- the health needs of all eligible people within New Zealand;
- the particular health needs of Māori and Pacific peoples;
- the availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- the clinical benefits and risks of pharmaceuticals;
- the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
- the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule;
- the direct cost to health service users;
- the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

How does PHARMAC decide which medicines should be funded?

We undertake a range of work for each funding decision, which falls into three broad areas: clinical, economic and commercial assessment.

Clinical Assessment

- What are the existing treatments/alternatives in the area?
- Is this medicine any better than what is available already?
- How do we know it is better?
- How reliable is the clinical trial data, what time period does it cover?
- Is something "proven" or is evidence still emerging?
- Has all available evidence been provided?
- Are there any side effects that need to be considered?
- How big a population will it treat?
- Does access need to be targeted for the medicine to work well?

Our main clinical advice comes from an expert committee of clinicians - the Pharmacology and Therapeutics Advisory Committee (PTAC). In addition, there is a network of Subcommittees providing specialised advice on a range of medical areas. Overall, these committees provide us with a considerable resource of over 50 practicing clinicians to call upon for advice. Committees also consider the nine decision criteria when making recommendations.

We also employ a number of people within PHARMAC with clinical expertise – in medical practice, pharmacy, public health or the science of pharmacology – and with links to other health professionals. This expertise is crucial in helping us manage the funding process.

Economic Assessment

Economic assessment looks at the costs and benefits of a proposed course of action. It's based on three fundamental concepts that summarise the issues PHARMAC faces daily:

- scarcity - resources will always be insufficient to support all possible activities;
- choices - due to scarce resources, decisions must be made regarding how best to use them; and
- opportunity cost - by choosing to use resources one way, we forgo other opportunities to use the same resources.

The way that PHARMAC assesses pharmaceuticals is described in the Prescription for Pharmacoeconomic Analysis (PFPA). Most funding decisions involve spending more for the additional health gains. "Cost utility analysis" enables us to compare these potential funding options on a more-or-less equal basis, and rank them in order of priority. Cost-utility analysis includes consideration of:

- effects on quality of life (e.g. ability to work/perform usual activities, pain/anxiety, mobility) as well as effects on the duration of life
- short and long-term effects
- changes to the cost of pharmaceuticals
- changes to other health sector costs (e.g hospitalisations, doctor visits)
- the risk and uncertainties of the evidence available.

Assuming that the impact on the other decision criteria is identical, the more cost-effective an intervention is the more likely it is to be funded.

Commercial Assessment

We all like to get the best deal we can when making a purchase and as a medicine funder, PHARMAC is no different.

We encourage price competition through the use of competitive processes such as tendering for supply (asking for quotes in effect), and reference pricing (applying the same subsidy to all medicines with same or similar effects). PHARMAC does not "regulate" prices by requiring that pharmaceutical companies supply at a particular price.

Commercial assessment means establishing whether funding proposals from pharmaceutical companies represent a good deal. There are many aspects to this such as using our economic assessment, comparing prices for existing subsidised medicines in the same therapeutic group and with those that other countries are paying (see our Purchasing Medicines information sheet for further information).

When we think we have reached a good agreement, the next step is to consult with our stakeholders.

Consultation

Before we make a medicine funding decision or make a change to our policies, we want to be sure that we have considered all the possible reasons for and against a decision, and any likely implications. One way we do this is to consult with anyone who is interested in the decision or who may be affected by the decision, to get feedback on our proposed approach and hear their views. We welcome all the views we receive whether from health professionals, the pharmaceutical industry, consumer and patient groups, Government agencies or the general public.

See the Getting Involved in PHARMAC Decision Making information sheet to find out how you can let us know your views.

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PHARMAC is the Government agency responsible for deciding which medicines are subsidised for New Zealanders. It manages spending on pharmaceuticals for the District Health Boards, and ensures that a comprehensive list of medicines (the Pharmaceutical Schedule) is subsidised for New Zealanders, and that the list of medicines continues to grow to meet the needs of patients.

