

Pharmaceutical Management Agency
Review of the Operating Policies and Procedures

Summary of Submissions to *PHARMAC's*
Operating Policies and Procedures: What's in?
What's out?

August 2012



Executive Summary

- PHARMAC's Operating Policies and Procedures (OPP) function as a guideline for PHARMAC staff and stakeholders about PHARMAC's functions and how it performs the work it does. PHARMAC's OPP were first developed in 1993, when PHARMAC was established, and has been reviewed and updated three times, most recently in 2006. This is the fourth review.
- Public discussion of this review began at the PHARMAC Forum in February 2012 with table discussions about what areas of PHARMAC's work would be appropriate for the OPP. Following this, in April 2012, PHARMAC's Acting Chief Executive sent an invitation to stakeholders to read and respond to the OPP review discussion document, *Operating Policies and Procedures: What's in? What's out?* The period for submissions closed on 1 June 2012.
- PHARMAC received 23 submissions and had one meeting with a stakeholder group in response to this discussion document. Submissions were provided by a wide range of stakeholder groups, including representatives from the pharmaceutical industry, consumer groups, individual health professionals and professional health groups.
- A wide range of topics was discussed by respondents. At a general level, many respondents commented on the structure, style, language and flexibility of the OPP.
- A subject of significant interest amongst respondents was the pharmaceutical funding application process. Submitters provided feedback on a number of steps in this process, including making a submission, providing a decision review process, PHARMAC's decision criteria, providing timeframes for responses and decisions, receiving clinical advice, and the negotiation and contracting process.
- Another common theme for respondents was stakeholder engagement. In addition to discussing the consultation phase of decision making, submitters commented on a desire for more frequent and earlier engagement throughout PHARMAC's activities, especially in the decision making process. Feedback was also provided on PHARMAC's Consumer Advisory Committee and PHARMAC's work in promoting the access and optimal use of medicines.
- Some respondents discussed the Pharmaceutical Schedule, including its administration, maintenance and management of listings within it.
- The subject of transparency was another common topic of discussion for respondents. Many provided comment suggesting PHARMAC improve its transparency, accounting and reporting practices. However, most respondents on this subject noted a degree of confidentiality may still be required.
- Some respondents commented on, or sought more information in the OPP, about PHARMAC's new responsibilities in regards to managing hospital medicines and medical devices.
- Other considerations for decision making were raised by a number of respondents, including non-health related factors and environmental sustainability factors.
- Feedback received on the OPP from the PHARMAC Forum is included. Generally, Forum delegates discussed PHARMAC work appropriate for the OPP and issues around the timing of this review.

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Introduction

PHARMAC is the New Zealand government's medicines funding agency. On behalf of District Health Boards (DHBs), PHARMAC assesses what medicines and some related medical devices the New Zealand government will subsidise for patients.

This Summary of Submissions reflects the views of stakeholders who responded to PHARMAC's discussion document *PHARMAC's Operating Policies and Procedures: What's in? What's out?* Gathering feedback on this document follows a discussion on reviewing PHARMAC's Operating Policies and Procedures (OPP) at the February 2012 PHARMAC Forum. Feedback from the Forum on the OPP is included in this Summary, and in the *Analysis of PHARMAC Forum Feedback* available at <http://www.pharmac.govt.nz/haveyoursay/PHARMACforum>.

PHARMAC's OPP serve as the guiding framework for how PHARMAC operates. It provides a general outline of what steps PHARMAC takes when going about its work, including assessing medicines funding applications and maintaining the Pharmaceutical Schedule. The current OPP are available online at <http://www.pharmac.govt.nz/procedures>.

The last review of PHARMAC's OPP concluded in 2006. Recognising that things change over time and stakeholders' needs change, a review of the OPP was considered appropriate. The OPP discussion at the PHARMAC Forum and this discussion document were intended to identify the appropriate areas of PHARMAC's work to be included in the OPP and other necessary updates that may be required.

Methodology

A letter and email from PHARMAC's Acting Chief Executive, Steffan Crausaz, was sent on 3 April 2012 to over 900 stakeholders inviting comment on the discussion document *PHARMAC's Operating Policies and Procedures: What's in? What's out?* This letter referred stakeholders to the discussion document on PHARMAC's website at <http://www.pharmac.govt.nz/haveyoursay/OPPreview>. Stakeholders were also able to request an electronic or hard copy by contacting PHARMAC.

Those receiving the Acting Chief Executive's letter were stakeholders on any of a number of our stakeholder contact lists and many others whom we have ongoing working relationships with. These included individual clinicians from a variety of medical fields, pharmacists, health service providers, professional organisations, District Health Boards (DHBs) and DHB hospitals, pharmaceutical suppliers, consumer groups and individual consumers, and government agencies.

Stakeholders were also able to request to meet with PHARMAC to provide verbal feedback on the discussion document. These meetings provided a chance to either present submissions verbally or to expand on written submissions. The content of these meetings is reflected in this summary.

The closing date for submissions was 1 June 2012. There were no late submissions.

PHARMAC received 23 written submissions and had one face-to-face meeting (with a respondent that also provided a written submission) during this consultation period. There was a wide variety of respondents, with public interest/consumer group being the largest category.

The submissions received, both written and verbal, are grouped in the following table. Some respondents communicated with PHARMAC on more than one occasion about this review during the consultation. In these circumstances, all comments received from a stakeholder were counted as one submission, regardless of when during this phase they were received.

Code	Group	Number
A	Pharmaceutical industry	5
B	Public interest/consumer group	6
C	DHB (funding and planning authority)	1
D	Individual health professional	5
E	Health professional organisation	4
F	Other	2
Total number of submissions		23

All submissions received were reviewed and considered in their entirety.

Groups of respondents were categorised from A to F as in the table above and submissions were numbered in the order in which they were received. Submissions were thus given a code indicating their category and the order received, such as B2 for a public interest/consumer group whose submission was the second received overall. One submission was provided that represented the views of both consumer groups and pharmaceutical industry representatives. This submission is considered here as “Other” (category F). Codes are used throughout this summary to place comments in context while protecting submitters’ anonymity.

Structure of the Summary

PHARMAC’s Operating Policies and Procedures: What’s in? What’s out? contained nine questions to help guide submitters’ responses. These were:

1. What do your primary interactions with PHARMAC involve?
2. What part of PHARMAC’s work would you like further guidance on (e.g. medicines funding proposals, the clinical assessment process, consumer relationships, funding contracts, AOU activities, etc.)?
3. What is your experience of using our OPP?
4. What, if any, topics currently included in our OPP would you like kept, and why?
5. Reflecting on your answer to question 4, are there any changes you would like to see to what you suggest keeping in our OPP? What is this change and why should it be made?
6. What, if any, topics currently in the OPP do you think could be removed, and why?
7. What, if any, areas of PHARMAC’s work would you like to see included in our OPP that are not currently, and why?
8. Aside from specific topics and content, how do you think the OPP could be improved (e.g. language, accessibility, formatting, etc.)?
9. What other comments do you have regarding PHARMAC’s OPP?

However, submitters were encouraged to provide comments beyond these questions if they wished, and most chose to do so. This provided PHARMAC with a broad range of comments and subjects to consider as part of this review. Given this, this Summary is structured to best reflect submitters’ comments and does not directly follow the nine questions posed by PHARMAC.

Also included in this Summary is a separate section summarising the feedback PHARMAC received about its OPPs from the PHARMAC Forum, held in February 2012.

The OPP

Some submitters made general comments about their experience with using PHARMAC's Operating Policies and Procedures. One respondent specifically noted it "generally supports" the OPP (E8). Four respondents noted referencing the OPP as a "guidance" document outlining "governing principles" to help "understand PHARMAC principles and priorities" (B7, B10, F13, A16).

Four submitters stated that the OPP are in "need of revision" and there are "a great many areas of the current OPPs which are of common concern to the industry...and consumer groups" (B7, A15, A16, A18). One of these continued on to state that the OPP "does not help with understanding how PHARMAC decisions are made" (A18).

Two public interest/consumer groups suggested reviewing the OPP more frequently, "at least bi-annually to account for any significant changes" and to be "more responsive to the management requirements of disease" (B7, B11).

Flexibility of the OPP

Four respondents commented that PHARMAC's OPP should be kept at a "general" and "broad" level (E8, B10, F13, A16). However, one of these elaborated that the OPP "do not keep pace with developments in the general health and prescriber sector," so "further amplification of the information" in the OPP would be useful (E8). Agreeing that a "topic-level" is appropriate, another of these submitters responded that the OPP are, however, too flexible and in some cases provide "explicit statements that allow PHARMAC to deviate from policies or practices" (A16). Two submitters commented that "there may be aspects that are explicitly considered a firm commitment under the OPP...and others that may be more flexible" (F13, A15).

OPP grammar

Many respondents took the time to comment on how the OPP document could be structured, worded and generally improved. Three submitters noted the importance of using "plain English" to make the OPP document readable and useful (B7, E8, A18).

Three respondents commented that the language of the current OPP is "defensive sounding" and should be "positive and inclusive" (F13, A15, A18). For example, one of these respondents referred to section 3.3.4 of the OPP, which states "PHARMAC is not bound to apply reference pricing", and suggested that "having statements that define what PHARMAC should do is more appropriate than what PHARMAC is not likely to do" (F13).

Some submitters provided suggestions for structuring the OPP, including linking to other PHARMAC documents and policies, the different sections that could be covered and elaborating on definitions of "policies", "procedures" and actors in the system (F13, A15, A18).

Six submitters provided a number of suggestions for the structure of the OPP document and the purpose of each part of the structure (B7, B10, F13, A15, A16, A18). Some suggestions included:

- expressing the Procedures "using lists" (F13)
- creating a "Key Deliverables" section, including, for example, the Pharmaceutical Schedule as a deliverable (A15)
- providing purpose statements – "to whom does this policy/procedure relate" (A18)
- providing a background section – "the context" (A18)
- providing definitions for key terms (A18), and

- outlining the governance and relevant legislation (A18).

One submitter noted that the current OPP is “inconsistent in ensuring that each topic area includes both the goal and the procedure to support it” (A15).

Some submitters also provided comment that an updated OPP may be best structured as a document that links to or references relevant separate guidance documents, whereby more “appropriate cycles of updates could be managed more efficiently” (B7, B10, F 13, A15, A16).

Some respondents stressed the importance of outlining PHARMAC’s role within the New Zealand health sector. Three suggested the OPP incorporate and reflect “existing national medicines policy documents”, such as the Ministry of Health’s Medicines New Zealand strategy and *Actioning Medicines New Zealand* (F13, A15, A18). Similarly, three submitters also suggested the OPP outline PHARMAC’s role in relation to other agencies, such as the Ministry of Health, Medsafe, the National Health Committee or the National Advisory Committee on Health and Disability (F13, A17, A18).

General topics to keep or remove

Two respondents stated they felt there was nothing in the current OPP that warrants removal (E8, B23). Alternatively, two respondents noted some topics currently in the OPP that could be removed for a number of reasons. These include:

- “the sections referred to as requiring separate, but linked guidelines” (F13)
- section 2.1(h) referring to the publishing of information related to the assessment of hospital pharmaceuticals as “it appears that PHARMAC no longer publishes” this information (A16), and
- section 4.1.4(a) referring to pharmaceutical funding applicants supplying “non-biased information” as this is a “matter of opinion” (A16).

One pharmaceutical industry respondent suggested that “supplier guidelines and obligations on the supplier should be removed to a separate document” (A18).

In the discussion document, *PHARMAC’s Operating Policies and Procedures: What’s in? What’s out?*, there was a list of possible areas of PHARMAC’s work that are not currently in the OPP but could be. A public interest/consumer group considered some of these suggestions to be unnecessary as they were more operational in nature or “should be covered elsewhere” (B23). These include advisory committees’ terms of reference, pharmacoeconomic analysis, medicines distribution, how to request information and contract management. However, this group did suggest that as “some would be skeptical”, there should be a “robust description of the breadth (and limitations of) Pharmac’s research role” included in the OPP (B23).

The pharmaceutical funding application process

Most respondents to this discussion document provided comments about the different phases of the pharmaceutical funding application process, in particular matters related to submitting an application and considering it for funding.

Making an application

Many submitters took the opportunity to comment on the medicines funding application process. Comments about, and suggestions for improvements to, the application process included:

- “who decides when and whether an application goes to PTAC or its subcommittee?” (F13)
- how “ethics, fairness and community values” are taken into account (F13)
- providing information and/or flowchart detailing the procedures taken for “each pathway or schedule amendment” (F13)
- “clear guidance on how PTAC recommendations and PHARMAC Board decisions are made” and how each body’s role adds “unique value to the process” (F13, A15, A18)
- outlining separate application processes depending on who is making the application – pharmaceutical companies, clinicians, patient groups, etc. (F13, A15, A18)
- a comprehensive list of the information required to be submitted with an application (F13, A16, A18)
- a description of the activities undertaken by PHARMAC to assess an application (A15)
- details about the process followed for PHARMAC-initiated applications, tenders and requests for proposals (RFPs) (A15)
- providing detail about why certain steps in the process are or are not taken (such as whether to receive PTAC advice or whether a decision is made by the PHARMAC Board or the Chief Executive under delegated authority) (A18)
- additional detail about the evaluation process (A18)
- how the decision criteria are applied (A18)
- what information sources are available and used for pharmacoeconomic data (A18)
- the cost-utility models developed (A18)
- how applications are prioritised (A18)
- clarification on the “rules that will be followed and those that are flexible” (A18)
- specific requirement for PHARMAC to “contact the applicant to discuss any concerns with the quality of the application” (A18)
- using international guidelines “as a source of reliable independent evidence” (A18), and
- why some applications with a positive PTAC recommendation do not progress to Board decision or some without a positive recommendation do get funded (A18).

Four respondents also commented that there should be a decision review or appeals process established outside of Judicial Review for funding decisions and this should not be limited to a review of process (B11, F13, A18, B20).

One respondent group elaborated on this, writing that “PHARMAC decisions should be open to independent review...There is the potential to use the various Colleges and Societies to provide independent, peer review of decisions reached. It is likely that the process would substantially enhance the trust that stakeholders have in the funding process” (F13).

One respondent requested more information about how to progress a funding application for a registered and unfunded product where there may be stock issues for pharmacies and the product’s sponsor company will not yet support an application because it “has not reached critical financial significance for the supplier” (E8).

Several submitters commented on the possibility of providing an alternative application process for “relatively cheap medicines” (D5) or “for some older products contracted some time ago, [where] the SA and systems surrounding it become obsolete over time but there is no new data or interest in furnishing new applications” (A4, A15).

Similarly, some submitters suggested a different process for, and more information about, funding products not registered by Medsafe (F13, A16, A18, B20). One of these submitters noted “the OPPs should consider and align with Medsafe evaluations and approval of pharmaceuticals and devices” (A18).

One respondent discussed the issue of previously available but unfunded treatments that subsequently become funded. This submitter commented on the opportunity for patients to be reimbursed for such treatments that were previously “accessed... through private purchase, clinical trial or an early access program” (F13). This respondent stated that “PHARMAC Therapeutic Group Managers state there is no policy on this; however currently suggest contacting them to discuss the likely number of early access patients which should be incorporated into listing negotiations if this is a ‘large’ number” (F13).

Decision criteria

Several submitters discussed PHARMAC’s nine decision criteria and its role in the OPP. Two pharmaceutical industry submitters commented on the general structure of outlining the decision criteria in the OPP, including that they should be listed in a section on “decision-making inputs” and “should precede the amendments to the pharmaceutical schedule section” (A15, A18).

Two respondents commented on the need for more information about “how other formal and informal decision criteria link into or complement the nine Decision Criteria” (F13, A15). One of these respondents elaborated on possible amendments to the decision criteria:

- *The budgetary impact (in terms of the pharmaceutical budget and the Government’s overall health and social welfare budget) of any changes to the Schedule*
- *The health impacts (positive or negative) of any decision. The aim of this decision criterion is that it would ensure explicit consideration of the negative impacts of denying access to the product under consideration*
- *The impacts of any decision (positive or negative) on the cost to society of the treatment or illness being considered (including for example impact on government expenditure outside the health sector or impact on individuals). (F13)*

Two respondents expressed concern about the apparent inconsistency in PHARMAC’s application of the decision criteria. One noted their observance that not all applications are assessed against the decision criteria and the other stated it is “difficult to determine” if the “decision criteria apply consistently to all applications” (A16, A18).

A health professional organisation stated it “would like to see more transparency so that funding outcomes can be easily linked back to assessment against the decision criteria” (E9).

Two submitters requested more information about whether any weighting was given to each decision criteria and how this is determined and applied (F13, A18).

Two respondents discussed the practicality of the decision criteria, noting that “their application must be practical and accessible” and “it is difficult to see how Pharmac takes account of or is even aware of these health needs,” for example, “from the perspective of those affected.”

Timeframes

Discussions of timeframes for different parts of the PHARMAC process were a common theme amongst respondents. Two respondents commented on the timeframe for PHARMAC's review of its OPP, with one querying what the timeframe is for "reviewing each sub-document" sitting within the OPP (F13). The other submitter to comment on this stated that the lack of a clear timeframe for the OPP review "may afford PHARMAC even greater fluidity and flexibility in its practices and activities" and that "a new version of the OPPs" needs to be the outcome of this review, within an "explicit" timeframe (A16).

Four submitters expressed their belief in the importance of having clear and specific timeframes for considering an application (F13, A16, A17, A18, B20). One of these pharmaceutical industry respondents stated:

All applications should progress through to their conclusion; that is, once a recommendation has been made by the PTAC (and subcommittee as appropriate) either PHARMAC negotiates with the supplier and the product proceeds to listing or a decision is made not to pursue. In both instances the recommendation from PHARMAC is consulted on and the feedback and PHARMAC recommendation is then considered by the Board. (A18)

In addition to the application process, some respondents also stated the desirability of having clear timeframes for:

- re-review of listed products (B7)
- completing the tender process (F13, A16, A18)
- notifications (F13, A18, E21)
- consultations (A16, A18)
- general communication with an application about their submission (A16, A18), and
- negotiations (A18).

PTAC

Several respondents commented on the role of the Pharmacology and Therapeutics Advisory Committee (PTAC) in the medicines funding decision making process. Discussing references to PTAC in the OPP, two submitters commented that there are out-of-date documents referred to (such as PTAC's administration manual) and that the OPP could provide reference links to relevant PTAC administration documents, like its Terms of Reference (F13, A18).

Two pharmaceutical industry representatives expressed a desire for more information in the OPP about PTAC's subcommittees, such as their purpose, how they operate, how they fit in the PHARMAC decision making system and how members are appointed (A15, A18).

Two submitters emphasised the need to clarify the status of PTAC in terms of its independence or otherwise from PHARMAC (F13, A18).

Two respondents also discussed the importance of clarity and transparency about how PTAC members are appointed and the need for the right expertise on the Committee (F13, A18). This pharmaceutical industry submitter noted this would be particularly important "as products become more complex.. [because] there are going to be fewer people in NZ with the expertise to provide meaningful evaluations of products" (A18).

While they were appreciative, three respondents commented on the need to further improve the detail and availability of PTAC minutes (F13, A18, E21).

Negotiations and contracting

Some submitters commented on the negotiating and contracting phase of the pharmaceutical funding process. Three submitters provided suggestions for improving the terminology and definitions of relevant terms in the OPP (F13, A16, A18). These included clarifying that “strategies” appears to refer more to “implementation tools or negotiating tactics” (F13, A18), and the “definition of cross deals under Section 3.2.1(c)” (A16).

Four submitters discussed the specific content of pharmaceutical supply contracts (F13, A15, A16, A18). Two critiqued the “evergreen nature” of these contracts because “PHARMAC does appear to permit” discontinuation or subsidy changes of contracted products where this is “not explicitly permitted within the contracts” (A16, A18). One of these submitters also noted that the OPP section on contracting and tenders “is extremely brief relative to the complexity of the area of PHARMAC’s operational activity it represents” (A16). Two submitters suggested that “the standard terms and conditions of pharmaceutical supply contracts” should be provided in a separate, “regularly updated” guidance document (F13, A15).

One submitter added that “it is also important to consider health outcomes at all times and not just financial implications of such discussions and negotiations” and recommended a “proviso” stating “as long as such negotiations and agreements have minimal negative impact on patients” (A18).

Stakeholder engagement

In addition to comments about the pharmaceutical funding application process, PHARMAC's communications and consultations were a frequent subject for comment by respondents. Two respondents stated their "support...to facilitate better communications between consumers, providers and PHARMAC" (B7, E8). One of these respondents also encouraged a "greater consideration given to not only consultation processes but communication" (B7).

Several respondents suggested, at a high level, that the OPP should provide:

- reference to an "ongoing principle" of engagement with Māori and consumers (B10)
- clear and transparent communications on its recommendations and decisions (B11, F13, B20)
- an outline of how PHARMAC "intends to communicate the value of the decisions it has made, the value left on the table of the decisions it cannot make because of lack of funding and exactly where and how it would spend extra money if given it" (B11, A15)
- information about "how PHARMAC will include stakeholder input into decisions" (F13)
- a "standard process that will be followed" for all interactions between PHARMAC and a stakeholder (A18), and
- "detail on how PHARMAC consult with stakeholders, how PHARMAC engage with stakeholders" (A18, B23).

Two respondents commented that, to improve "dialogue" and timelines, the OPP should "define how PHARMAC shares feedback about its perspectives on the cost effectiveness evidence provided by applicants" (F13, A17).

One respondent suggested developing and including a "clearer flow chart of decision process and then identify where stakeholder input can occur" (F13).

Engagement in decision making

Some submitters commented on the possibility of increasing stakeholder input into the evaluation and decision making process for funding applications. Respondents suggested that during the consideration process, PHARMAC engage "with stakeholder groups during the development stage of proposals in addition to consulting on the final proposal" (B7, A15, A18). Other comments on this subject included:

- discussing "with specific health sector professionals on a regular basis the needs of specific client groups" (B7)
- co-opting patient representatives or specialist clinicians onto advisory committees (F13)
- allowing stakeholder input "at the stage of PHARMAC receiving clinical advice from its internal resources (PTAC, Subcommittees, Medical Director, etc.)" (F13)
- allowing stakeholders to input via both written submissions and appearing "in front of the clinical committees to share their perspective and expertise" (F13, A18, B20)
- "allowing pharmaceutical companies the opportunity of presenting to PTAC and its various subcommittees clinical evidence and health economic assessment data" (A17), and
- record and make evident the input of stakeholders engaged throughout the process (B20).

One respondent commented that "the opportunity for experts to change a proposal once it has already been substantially negotiated is insufficient to allow meaningful input. The inclusion of expert clinical input into Pharmac's processes would increase stakeholder confidence that decisions are soundly evidence based and have taken health outcomes into account" (B20).

Consultation process

One submitter made the general comment that the consultation process should include developing the process to be “constructive” and to “keep momentum, but maintain enough time for real input” (F13). Another submitter stated that “PHARMAC appears to operate within more tightly defined rules around consultation than are reflected in the OPPs. For instance, PHARMAC staff frequently refer to minimum consultation timelines of 10 working days. There also appear to be definable points in each Schedule amendment process where consultation occurs”, so this submitter suggested that “consultation procedures (timing and timelines) should be reflected in its OPPs” (A16). Two respondents suggested PHARMAC should “incorporate consultation earlier into the process” (F13, A15).

Some respondents commented on the apparent flexibility afforded to PHARMAC regarding its consultation procedures, with one stating “the reference to consultation ‘when it [PHARMAC] considers appropriate’ seems intended only to give PHARMAC an out clause should it fail to consult” (F13, A16). Another submitter suggested PHARMAC should consult on “ALL proposals” [emphasis in original], and, if necessary, could add “except where it considers it inappropriate with the Board’s approval” (A18).

One public interest/consumer respondent suggested that “the consultation process should be adapted according to the portfolio concerned” (B7).

Two pharmaceutical industry respondents commented on the timing of consultation in relation to PHARMAC’s requests for information (RFIs) or tenders (A16, A18). One suggested the “RFI always precede the issuing of an RFP intended to award a sole supply agreement of a product” (A18).

One submitter, stating that consulting is “a critical part of many processes” conducted by PHARMAC, “instead of being one stand alone paragraph [in the OPP], it actually needs to be incorporated directly into the processes, with descriptions of what the purpose of the consultation is at that point in the process, how feedback will be incorporated into decisions and how feedback will – or will not – be communicated back to stakeholders” (A15).

One respondent suggested PHARMAC develop “criteria that will ensure consideration with a patient focus in mind” (A18). This respondent added that “all feedback should be included in the notification letter including comment on how it was used, or not used” (A18). Similarly, another respondent stated “it would be useful to have a set of criteria on which PHARMAC intends to evaluate and respond to submissions” (F13).

CAC and health consumers

Several respondents took the opportunity to discuss PHARMAC’s Consumer Advisory Committee (CAC) and similar consumer engagement topics. Two respondents suggested the CAC’s Terms of Reference be linked within the OPP (B10, A15). These and other respondents also noted that the OPP does “not reflect that CAC is mainly an advisory committee...not an entity representing patient views in the decision-making process” (F13, A15). It was also noted that the CAC “does not take the place of appropriate consumer input into the decision process” (A15). One public interest/consumer group stated that as the CAC “has no discernible input into decision making” this indicates that “the ‘needs of eligible people’ are not assessed with reference to those affected most by the decision-making” (B20).

Three public interest/consumer groups stated the importance of keeping, “and perhaps strengthening the commitment to the Treaty of Waitangi” within the OPP (B7, B10, B23). One of these submitters stated both PHARMAC’s Māori and Pacific Responsiveness Strategies should be referenced “everywhere” within the OPP (B23).

Respondents also expressed their wish for more direct and earlier consumer engagement in the decision making process. Some suggestions from submitters included:

- “more direct consumer involvement on Draft Proposals before putting them out for consultation” (B2)
- enabling earlier opportunities for patient or consumer representatives, such as “through electronic or written feedback mechanisms and potentially through direct representation” on committees assessing applications (B10), and
- developing similar process for consumer input as that used by NICE in the UK and the PBS in Australia (F13, B20).

Noting that “consumers are often poorly informed about the recommendations and decisions made at various stages of the Pharmac process”, one public interest/consumer group stated the influence consumer input has on funding “considerations, recommendations and decisions should be recorded and made evident to stakeholders” (B20).

Access and optimal use

Some respondents commented on PHARMAC’s role in promoting the access and optimal use of medicines, including PHARMAC’s Access and Optimal Use (AOU) work. There was general support from respondents on this subject for PHARMAC’s work in this area, though it was suggested that more detail be provided in the OPP. Suggestions for this included:

- specifically, reviewing the impact of PHARMAC’s work in meeting the high needs of mental health patients (E6)
- formalising “the education of both providers and consumers in the optimal use of medicines” (E8)
- “guidance about where the PHARMAC role crosses with the population health work inside the Ministry of Health” (F13)
- clearly describing “any additional activities that PHARMAC engages in” (F13)
- information about “how PHARMAC communicates and ensures a brand switch, what PHARMAC’s role is (and is not) in educating physicians...how PHARMAC will engage with DHBs on broader health topics...and its role in BPAC” (A15, A16)
- guidelines about “when and how PHARMAC are involved in the area of the appropriate use of medicine” (A18), and
- information about the “implementation of Access and Optimal Use programs” (A18, B23).

Pharmaceutical Schedule maintenance and listings

Some respondents took the opportunity to discuss the Pharmaceutical Schedule, such as how it is organised and maintained, and how listings within it are managed.

Schedule administration

One respondent suggested PHARMAC continuously evaluate the “resource cost of administering the schedule” to “enhance the administrative process” (A4).

Discussing the organisation of the relevant section of the OPP (2.1 Amendments to the Pharmaceutical Schedule), one respondent suggested clarifying that the Schedule is “a key deliverable of PHARMAC’s work” (A15). Elaborating further, this respondent stated that this section “should also outline under what circumstances the activities are performed and then link to documents that describe processes in more detail” (A15).

Five respondents discussed the need to clarify and detail how therapeutic groups and sub-groups are established, particularly given its impact on reference pricing products to each other (B7, F13, A15, A16, A18).

Prescribing and dispensing rules

Some respondents commented on matters relating to prescribing and dispensing rules as established by PHARMAC. One individual health professional noted the need to specify and clarify the conflicts of interests of PHARMAC’s clinical advisors, particularly between specialists and general practitioners (D5). This respondent also stated “there is no clarity on SA [Special Authority] form what is meant by ‘up to date knowledge of treatment groups’”, querying what is meant by “competent” prescribing and who determines this (D5).

Another respondent stated PHARMAC’s “operations should extend to giving consideration to, and having input into, practices that enable accuracy in prescribing, robust Special Authority processes and inputs into software vendor processes to ensure accuracy and efficiency. Greater efficiencies in dispensing, such as monthly medicine pack production and the use of bulk packs for robotics, are other areas for streamlining distribution” (E6).

Related to prescribing and dispensing rules, three respondents commented on PHARMAC’s management of exceptions to the Pharmaceutical Schedule – Named Patient Pharmaceutical Assessment (NPPA). One respondent noted their support for “the funding of medicines under the NPPA process” (E8). Another respondent stated that NPPA should be covered in the OPPs both in terms of PHARMAC’s role and guidance as to how it operates in this regard” (A16). The third respondent on this subject queried whether NPPA needs to be included in the OPP as it is “operational”, but it is “necessary if the OPP is to contain an explanation of the formula assessment as this [NPPA] provides an alternative pathway for funding” (B23).

Transparency

The issue of transparency in PHARMAC's work was a common theme among submissions. One pharmaceutical industry respondent stated "it should be possible to hold PHARMAC accountable to processes...based on these OPPs" (A18). Another submitter requested more information on "how PHARMAC is improving the consultation process and its transparency (recognising the inherent commercial conflicts and tensions that exist)" (B7).

One respondent critiqued that the legislative framework protects PHARMAC whereby it is effectively protected from scrutiny by the courts (F13). This then means that it is "incumbent" on PHARMAC to make an extra effort to be transparent to give confidence to its systems (F13).

One submitter stated that "the inclusion of greater detail around procedures might help to eliminate some of the observed procedural inconsistencies" and improve transparency (A16).

A health professional organisation stated it is "particularly keen to see greater transparency in the decision making process" (E9).

Reporting and accountability

Many respondents commented on the reporting and accountability of PHARMAC. One submitter stated "people should be able to find the information they require through the PHARMAC website" rather having to go through a formal information request process (B7). Another respondent stated it was "pleased with recent developments made by PHARMAC to improve transparency. However, many of these activities currently sit outside of the OPP. [This submitter] believe[s] there is an opportunity to build upon these recent developments by ensuring greater transparency is embedded in the OPP" (A17).

Three respondents noted that PHARMAC "no longer reports on the status of applications received" and other similar measures (F13, A15, A18). One of these respondents stated that "currently there is almost no information about performance measurement and reporting in the OPP, other than a brief indirect reference" in section 3.2.4(d) (F13). Several respondents provided suggestions of the types of measures PHARMAC can report on to improve its transparency, including:

- "where PHARMAC decisions differ from international guidance" (B11, F13, A18)
- "benchmarking health outcomes" (B11, A18)
- reporting on the cost per QALY of medicines that are funded (F13)
- "goals that refer to the measurement of health impacts achieved by PHARMAC decisions" (F13)
- "performance according to pre-specified timeframes for assessments and decisions" (F13)
- "where PHARMAC actions taken differ from the OPP" (F13)
- "how many applications were received and not progressed, or were declined" (F13, A18)
- "where PHARMAC decisions differ from registered indications" (F13, A18)
- "priorities for unmet need which align with Government Health Priorities" (A18)
- "performance according to pre-specified timeframes for assessment and decision including time to PTAC meeting/subcommittee meeting/approval of minutes/publication of minutes on web" (A18)
- "reporting on PTAC recommendations and implementation" (A18), and
- "reporting on Board decisions, including number of applications approved, deferred and declined" (A18).

Confidentiality

The confidentiality of PHARMAC's processes was discussed by some stakeholder respondents. Most acknowledged a need for some confidentiality to be maintained. One respondent suggested "PHARMAC review ways to provide more information about decision-making via its OPP" while maintaining appropriate confidentiality" (E21). Another stated PHARMAC "should clearly define what it considers 'commercial sensitive' information" as this will improve stakeholder confidence (A18). Another pharmaceutical industry respondent suggested the current OPP section on confidentiality (4.3) "be fleshed out to include why it [confidentiality] is important as well" (A15).

Two public interest/consumer groups stated that, in general, it should be "obligatory" for all of PHARMAC's processes to be transparent, "with the only exception being" truly confidential material (B7, B10).

One pharmaceutical industry respondent discussed confidentiality as it relates to PHARMAC seeking commercial proposals, stating "it is not uncommon for PHARMAC to continue to protect details about the true price of a pharmaceutical (i.e. one that has been the subject of a confidential rebate while on patent) after its patent has expired. This practice results in the originator having a commercial advantage" (A16).

Budget setting process

Several submitters discussed the pharmaceutical budget setting process. One submitter noted "stakeholders would still benefit from a greater understanding of the prioritisation process that determines what, if any provision is made within the pharmaceutical funding bid for new investments and how that money is spent" (A16). Another respondent stated "it is not clear how this value [pharmaceutical funding decisions] is communicated to the DHBs and Ministry... [and] there is no reason why the process, including the format and the structure of the discussion cannot be transparent" (A15). Another submitter recommended "the addition of a section outlining the procedure for annual budget setting" (A18). One group noted that such a description could include detail on "how PHARMAC prioritises applications for new technologies, and how it attempts to provide for preferred investments in its budget bids" (F13).

Several respondents commented that detailed information should be provided about "PHARMAC's role in bidding for funding for pharmaceuticals in the wider health funding context, including prioritisation of applications as well as forecasting" (A16). Others noted that "operating within a fixed budget does not remove the responsibility to provide input into a budget setting process" (F13, B20). To ensure the appropriate pharmaceuticals budget, several respondents stated "PHARMAC should be involved in discussions to promote the value of pharmaceuticals and consider the potential savings to other areas of healthcare in New Zealand" (A18).

Two respondents commented that the budget setting process should include adequate "forward planning" and a "long term procurement plan based on global therapeutic directions" (A18, B20).

Specifically, one respondent discussed more targeted "socio-economic" budgeting (E6). This respondent stated it is "in favour of some form of socio-economic targeting of government funding that flows through community pharmacy" as untargeted funding is "inequitable and unsustainable" (E6).

PHARMAC's new responsibilities

Many respondents briefly discussed PHARMAC's OPP in terms of PHARMAC's new roles in managing funding for hospital medicines and medical devices, and any other new responsibilities PHARMAC may receive in future. A common sentiment was that "expanded portfolios need to be reflected, along with expanded assessment criteria able to better cover off the diverse products coming under PHARMAC's umbrella" (B7, A16, A18). One of these respondents stated that the OPP "should, therefore, not only permit PHARMAC to acquire new roles but [the OPP] should apply" to those new roles (A16). Two respondents elaborated, seeking "understanding on how the decision criteria will change" with PHARMAC's new responsibilities (B7, F13).

Five respondents commented specifically that PHARMAC's OPP should reflect and provide detail about PHARMAC's new role in managing some medical devices (C1, B7, A16, A18, B23). One of these respondents expressed its belief that "the existing [decision] criteria which relate to pharmaceutical and therapeutic interventions are inadequate for the evaluation of medical devices. In our opinion, qualitative social impacts on individuals and their families need to be accorded a value rating to enable consideration in the assessment of the cost of a medical device" (B7).

Five respondents also commented specifically on including PHARMAC's new role in managing hospital pharmaceuticals into the OPP (F13, A15, A16, A18, B23). Two respondents made similar comments that "it would be helpful to define any policy or process that differs from the community pharmaceuticals policy or processes. Also include information on how the hospital pharmaceuticals committee or any subcommittees will function and fit within the existing evaluation and funding decision processes" (F13, A18).

Other considerations

Several respondents suggested PHARMAC take the opportunity to include non-health related considerations into its assessments and decision making framework. Specific suggestions included:

- taking “into account wider potential gains in its [PHARMAC’s] utility assessments of proposed medications...[for example] in opioid substitution, changes in criminal activity, employment and financial status are identified treatment goals and subject to outcome measurement” (D3)
- “a holistic view should be taken of all spending that contributes to patient outcomes. Such a view would go beyond the cost of the given pharmaceutical, to include the costs of distribution, dispensing, professional pharmacy services” (E6)
- “the impact that Pharmaceutical Schedule listings have on DHB payments for pharmacy services” (E6)
- “factoring in the cost of change: In making changes to the preferred pharmaceutical and other products, it is clear that some will require more extensive change management interventions than others (depending on the complexity of the therapy/intervention or the number of users). In the decision making process this cost of change should be considered and built into the equation and timetable, along with meaningful consultation with communities to ensure understanding” (B7)
- “qualitative social impacts on individuals and their families” (B7)
- “the impact of decisions on the wider community” (B7, F13)
- “consideration of ethics, fairness and community values” (F13)
- “the health impact (both positive and negative) of any decision taken i.e. the cost to society of the illness being untreated along with consideration as to whether or not the decision aligns with international guidelines” (A18), and
- “consideration of the budgetary impact of the decision not only on the Pharmaceutical Budget but also on the overall government healthcare expenditure including ACC, Social Welfare and other related budgets” (A18).

Environmental sustainability

Five respondents discussed the OPP review as an opportunity for PHARMAC to consider and include environmental factors and sustainability into its decision criteria and general operations (D12, D14, D19, E21, F22). Two respondents stated, based on “international data that the healthcare industry has an enormous environmental impact through its consumption of virgin resources and its high levels of generated waste” (D12, F22).

Respondents on this topic all raised similar issues and considerations, including:

- giving extra consideration to Māori and Pacific peoples health, as part of PHARMAC’s decision criteria two, as they are “particularly vulnerable to early impacts of climate change due to their lower average socio-economic status, and poorer health outcomes” (D12, F22)
- developing a new decision criteria “with regard to the environmental impact of pharmaceuticals purchasing decisions” (D12, D14, D19, D21, F22)
- aligning PHARMAC’s policies and procedures “with the pre-existing statutory objectives of DHBs. The NZ Public Health and Disability Act 2000 states there are 11 statutory objectives of District Health Boards and one of these is ‘to exhibit responsibility to the environment in regards to its operations’” as PHARMAC will begin working closer with DHBs (D12, D14, F22), and
- reducing “the significant adverse impacts on human health caused by inefficient resource use and climate change (D19).

Four respondents provided significant lists of what “factors need to be accounted for” when considering environmental impact, including:

- “the manufacture (including packaging) of a medication/device” (D12, D14, D19)
- the carbon cost (D12, D14, F22)
- “the environmental degradation costs of manufacture” (D12, D14, D19, F22)
- “the full lifecycle of the product – its energy efficiency and whole-life energy costs, its ability to be repaired or refitted and whether the product can be safely disposed of or appropriately recycled (D12, D14, D19, F22), and
- “the transport of that medication/device” (D12, D14, D19, F22).

Noting a benefit of careful environmental consideration, one respondent noted that “medical products could then be compared on a level playing field, rather than allowing suppliers with poor environmental practices and high-carbon production lines to offer a marginally cheaper product than a company that is acting in an environmentally responsible manner” (D12). Another respondent commented that such procedures would “align well with PHARMAC’s aims of achieving the best possible health outcomes, and responsible use of pharmaceuticals” (D19).

OPP feedback from the PHARMAC Forum

At PHARMAC's Forum in February 2012, delegates in attendance discussed PHARMAC's OPP in small groups. In general, discussions were focused on aspects of PHARMAC's work that were relevant for inclusion in the OPP, whether it currently was or not. A short list of PHARMAC workstreams that attendees felt should be part of the OPP included:

- Access and Optimal Use activities
- clarification of PHARMAC's role in research
- NPPA
- PHARMAC's role in educating clinicians & patients
- trial periods for drugs/risk sharing to be included in list of procurement strategies
- stakeholder engagement
- the scope of advisory committees, e.g. whether they include nurses, physiotherapists, other prescribers or health professionals
- timeliness of PTAC advice and PHARMAC decisions, and
- statements as to the way decision criteria are 'weighted' (if they are).

Some delegates noted that this OPP review is an opportunity for PHARMAC to review and define its decision criteria, particularly for medical devices. Some stated medical devices may require different decision-making criteria from pharmaceuticals.

Some delegates queried the timing of this OPP review given PHARMAC is beginning its expanded role in hospital medicines and medical devices. Other questions arose about what influence external factors may have on PHARMAC's OPP, such as the trans-Tasman therapeutic agency (ANZTPA) or the trans-Pacific Partnership (TPP) trade negotiations.

Delegates expressed their opinion that the OPP should not be too prescriptive, as this could limit how PHARMAC operates and prevent more innovative ways of working from being adopted. Delegates did say that PHARMAC's OPP should align with the Government's Medicines New Zealand national medicines strategy.

Delegates also felt that PHARMAC's thinking and learnings should be adopted by other departments and agencies. In particular, PHARMAC's use of cost-utility analysis meant that other less cost-effective interventions were funded while more cost-effective pharmaceuticals were not.