PHARMAC's Operating Policies and Procedures

What's in? What's out?

Discussion document

April 2012

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

3 April 2012

An invitation from the Acting Chief Executive

Thank you for taking the time to read and respond to this discussion document seeking your views on our Operating Policies and Procedures (OPP).

PHARMAC's OPP are the framework for how we carry out our objective of achieving the best health outcomes we can from pharmaceutical treatment and from within the funding provided. They are intended to provide guidance to our stakeholders about what to expect when working with us and what information we need to do our work. They also guide us internally as we consider funding proposals and policy changes. Our OPP are available online at http://www.pharmac.govt.nz/procedures.

We last reviewed our OPP six years ago and recognise the need for regular refreshing of such an important document. We are aware of some updates that may be needed to our OPP and, during the past several years, have received a number of comments from stakeholders about what updates they would like to see.

To date, our OPP have focused on the medicines funding assessment and Pharmaceutical Schedule listing processes. However, we carry out many other functions not currently reflected in our OPP, for example, our work in promoting the responsible use of medicines or arranging distribution of some higher cost medicines.

Our formal review of the OPP began at the PHARMAC Forum on 20 February 2012. We greatly appreciate the feedback from those who attended this Forum and contributed to the discussions on our OPP. Your input will be considered alongside the comments we receive in response to this discussion document and will help us to develop a revised OPP framework.

The PHARMAC Forum and this discussion document will not be your only chance to provide your feedback. This first phase of the review is aimed at helping us determine the appropriate scope of our OPP. We are seeking your thoughts on what should be covered in the OPP and what you need to know about how we operate to help your work with us. We are open to all views.

After we consider responses to this discussion document we will develop an updated OPP framework that we will consult with you on to make sure we have addressed your feedback appropriately and developed the best framework we can. We expect to complete this stage of the review by the end of 2012. Then, over time we will be able to isolate specific activities and functions that sit within the revised framework, consult with you further on these and update them as appropriate. We are, of course, also open to meeting with you to discuss your views further at any time during the review process.

We recognise the importance of this review for many of our stakeholders. As such, we intend to provide ample time for you to develop your response. We are also aware that many groups hold regular meetings on a monthly basis, or less frequently, and hope that our timeframe for responses enables these groups to provide a comprehensive submission they are satisfied with.

We look forward to hearing your views and continuing to work with you as we update our OPP.

Kind regards

Steffan Crausaz
Acting Chief Executive

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Making your submission

This discussion document is also available on our website at www.pharmac.govt.nz/haveyoursay/oppreview.

There are questions provided throughout this document to help your thinking when developing a response. These are collated in Appendix 1. However, we encourage you to also provide comment beyond these questions if you have any.

To make your submission, provide your comments via an email, fax or letter to:

PHARMAC
PO Box 10-254
Wellington 6143

Email: opp@pharmac.govt.nz
Fax: (04) 460 4995

All responses should be submitted by **5 pm Friday 1 June 2012.**

We also invite interested stakeholders to meet with us, in person or by teleconference/Skype, to present their views in response to this discussion document. Contact us at the above details by Friday 4 May if you would like to meet. If a range of stakeholder groups are interested in meeting, we may organise larger group meetings.

Please contact us at opp@pharmac.govt.nz if you require further information about any aspects of this review.

Information requested under the Official Information Act

Please note that your response and all correspondence you have with PHARMAC may be the subject of requests under the Official Information Act 1982 (the OIA). PHARMAC will generally omit your personal details (name, contact details and any other personally identifying information) from your response, before making it available as part of any request under the OIA, if you make it clear that you wish such information to be withheld.

If there is any other part of your response 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 provisions setting out reasons for withholding information under the OIA are attached in Appendix 2 for your information.

Introduction to PHARMAC

PHARMAC is the New Zealand Crown Agency that decides, on behalf of District Health Boards (DHB), what medicines are subsidised by the government for use in the community and in public (DHB) hospitals.

Our obligations are set out in the New Zealand Public Health and Disability Act 2000 (NZPHD), which states that our objective is:

> *to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.*
>
> (NZPHD section 47(a))

Our key statutory functions are, within the funding available to us, to:

> *a) maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies;*
>
> *b) manage incidental matters arising out of paragraph (a), including in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule;*
>
> *c) engage as we see fit, but within our operational budget, in research to meet our objective;*
>
> *d) promote the responsible use of pharmaceuticals; and*
>
> *e) as directed by the Minister of Health in 2001, manage the purchasing of pharmaceuticals, whether used in hospitals or outside it, on behalf of DHBs.*
>
> (NZPHD section 48)

We carry out these responsibilities through a wide range of activities, including, among others, the clinical and pharmacoeconomic assessment of medicines, commercial purchasing strategies, negotiations with pharmaceutical suppliers, access and optimal use of medicines activities, and contributing to advice to the government on relevant matters.

1. What do your primary interactions with PHARMAC involve?

2. What part of PHARMAC's work would you like further guidance on (e.g. further information, medicines funding proposals, the clinical assessment processes, consumer relationships, funding contracts, AOU activities, interacting with us, etc.)?

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Our OPP outline how we go about fulfilling some of our statutory obligations. We seek to provide as much information as we can about our processes and outcomes and the OPP is intended, in part, to help us achieve this.

For our stakeholders, the OPP provides guidance for working with us. The OPP generally outlines what steps we take when doing our work, what stakeholders can expect during implementation of our processes and what factors we consider when making a medicines funding decision.

For PHARMAC, our OPP are a key reference document for how we go about considering medicines funding proposals, managing the Pharmaceutical Schedule, making changes to our processes and our other work.

Our OPP currently recognise the need for flexibility, as no single method will be suitable for all circumstances. It does not currently detail every aspect of our work; some particular aspects of what we do are detailed in other topic specific guidelines.

Our OPP are available on the PHARMAC website at http://www.pharmac.govt.nz/procedures. Currently, they focus primarily on the medicines assessment and Schedule listing process. The general content of the current OPP includes an outline of:

- our advisory committees (the Pharmacology and Therapeutics Advisory Committee (PTAC), the Consumer Advisory Committee (CAC), a hospital pharmaceuticals advisory committee and others as established by the PHARMAC Board),
- PHARMAC's role as a partner in the Treaty of Waitangi,
- managing the Pharmaceutical Schedule,
- PHARMAC's nine decision criteria for medicines funding,
- strategies to assist in the pricing or subsidy determination of medicines,
- relevant definitions,
- the contract and tender process,
- the funding application process,
- the medicines funding consultation process,
- identifying the need for confidentiality, and
- a brief explanation of the cost-effectiveness criterion.

3. What is your experience of using our OPP?

4. What, if any, topics currently included in our OPP would 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?

Reviewing our OPP

PHARMAC last reviewed its OPP in 2006. In the interests of best practice, we seek to regularly review our work and respond to stakeholder feedback. At this time, we are looking for a better understanding of what stakeholders would like to see included in the OPP in order to bring together PHARMAC's different activities under a central framework.

We began this review with table discussions at our PHARMAC Forum on 20 February 2012 of what stakeholders wanted to see included in the OPP. This feedback is being considered and will be included with responses to this discussion document in helping to develop an OPP framework. Later this year, we will consult on this framework to obtain feedback on whether it is structured appropriately. This will then enable us to progress to reviewing and consulting where appropriate on the individual policies and procedures that constitute the OPP.

There are many facets of PHARMAC's work not currently included in the OPP. This initial phase of the review aims to identify which, if any, of these you think should be integrated into the OPP. Below we have set out a shortlist of examples of such activities. However, we encourage you to think broader than this list and identify any and all aspects of PHARMAC's work you think should be included in our OPP. This could include areas of our work that you are aware of, are particularly interested in or are directly involved in.

- Prescription for Pharmacoeconomic Analysis (PFPA)
- Advisory committees' Terms of References and other documents
- Discretionary Pharmaceutical Fund (DPF)
- Descriptions of our function related to responsible use of medicines (e.g. Access and Optimal Use activities)
- Research involvement
- Hospital medicines and medical devices purchasing
- Medicines distribution activities
- Stakeholder engagement activities
- Named Patient Pharmaceutical Assessment (NPPA) policy
- Te Whaioranga (Māori Responsiveness) and Pacific Responsiveness Strategies
- How to request information from us
- Contract management.

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?

Appendix 1: Collated questions

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?

Appendix 2: Relevant provisions of the OIA 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.