PHARMAC'S Operating Policies and Procedures review

Next steps

PHARMAC's Operating Policies and Procedures (OPP) outline how we go about fulfilling our statutory objective and other key functions. The OPP is intended to help our stakeholders know what to expect when working with us. The current OPP document is available on the PHARMAC website at: http://www.pharmac.govt.nz/procedures.

Summary

- Our OPP Review began with group discussions at the PHARMAC Forum in February 2012. Subsequently, in April 2012, we sought submissions on what subjects stakeholders wanted to see in PHARMAC's OPP. The summary of submissions can be found on our website at http://www.pharmac.govt.nz/oppreview.

- Following those responses to consultation, this document outlines:

  - the list of topics to be included in a revised PHARMAC OPP;
  - our re-development of the OPP as a web-based guide, which is intended to make it easier to update sections as our functions or activities change over time; and
  - that we intend to begin a review of the descriptive content of OPP topics (and thus PHARMAC practice) with our Decision Criteria. We will be consulting on this in the early part of 2013.

- Many comments provided in response to the discussion document earlier this year focused on the descriptive content of the OPP. The next steps of this review will allow for more detailed discussions of these matters. Not all topic-specific reviews will require public consultation, though we will keep stakeholders informed throughout.

- PHARMAC's OPP 3rd Edition, dated January 2006, will remain in place until the revised OPP is available online.

OPP topics

Following consideration of all the feedback from the discussion phase of this review, we intend to list the topics below in the revised OPP. A reference, where applicable, to the relevant section of the current OPP is included in italics. Topic specific reviews will commence in 2013, which will result in the development of content for other sections (not currently in the OPP) and updating of the current OPP content.

1. Introduction
   - 1.1. PHARMAC's objective *(current OPP section 1.1)*
     - 1.1.1. PHARMAC and the Treaty of Waitangi *(current OPP section 1.6)*
   - 1.2. PHARMAC's role *(current OPP section 1.2)*
     - 1.2.1. PHARMAC's *Framework for Success*
     - 1.2.2. What PHARMAC does not do

1.3. Purpose of the OPP *(current OPP section 1.3)*
    1.3.1. The OPP and any future new functions

2. Decision making
    2.1. Decision criteria (*current OPP section 2.2 and 4.4*)
    2.2. Consulting on proposed decisions *(current OPP section 4.2)*
    2.3. Implementation activities

3. Engagement
    3.1. Consultation *(current OPP section 4.2)*
    3.2. Communications
    3.3. Consumer Advisory Committee *(current OPP section 1.5.1)*
    3.4. Feedback

4. Submitting an application
    4.1. Pharmaceuticals (community, hospital and vaccines) *(current OPP sections 4.1, 4.4-4.5)*
    4.2. Medical devices

5. Preliminary assessment and evaluation
        5.1.1. Pharmaceuticals *(current OPP section 4.1)*
        5.1.2. Medical devices
    5.2. Receiving clinical advice
        5.2.1. Pharmaceuticals: PTAC and subcommittees *(current OPP sections 1.4-1.5)*
        5.2.2. Medical devices
    5.3. Prioritisation
        5.3.1. Pharmaceuticals
    5.4. Medical devices

6. Negotiation with suppliers

7. Targeting funding
    7.1. Pharmaceuticals
        7.1.1. Special Access Panels
    7.2. Medical devices

8. Managing expenditure
    8.1. Pharmaceutical transaction strategies *(current OPP sections 3.1-3.3)*
        8.1.1. Risk sharing
        8.1.2. Cross deal/bundling
        8.1.3. Tender
        8.1.4. Requests For Proposals/Requests For Information
    8.2. Subsidy changes (Reference Pricing and Therapeutic Grouping)
    8.3. Medical devices
    8.4. Contracting and contract management *(current OPP section 3.4)*

9. Schedule management *(current OPP section 2.1 and 4.1)*
    9.1. Amending the Schedule
    9.2. Managing a Schedule's rules and definitions
        9.2.1. Pharmaceuticals
        9.2.2. Medical devices
    9.3. Exceptions to a Schedule
        9.3.1. Pharmaceuticals (including Named Patient Pharmaceutical Assessment Policy)
        9.3.2. Medical devices

10. Influencing medicines use
    10.1. Population health activities
        10.1.1. Māori health activities

10.2. Educational initiatives

11. General statements
    11.1. Transparency and confidential information *(current OPP section 4.3)*
    11.2. Unregistered and off-label use
    11.3. Non-PHARMAC approved funding and trials
    11.4. Compassionate supply
    11.5. PHARMAC's role in research
    11.6. Retrospective funding
    11.7. Overseas patients coming to New Zealand
    11.8. Sponsorships and service contracting

We are currently consulting on the policies, rules and frameworks for our new responsibilities in managing hospital pharmaceuticals and, in the future, will also be consulting on the same issues with respect to hospital medical devices. Visit www.pharmac.govt.nz for more information and to learn how to be involved in these processes. The outcomes of these workstreams may influence the above list of topics and content, so there may be some changes as this work progresses, though not all changes will require public consultation.

OPP online

PHARMAC is currently updating its website and over the coming months we will transition the OPP to an online format. We envisage each topic of the OPP will be a separate webpage with appropriate links included to other, more detailed PHARMAC guidelines and policies and/or to other agencies websites. For example, the OPP topic on the assessment and evaluation of pharmaceuticals (section 5 above) would provide links to the *Prescription for Pharmacoeconomic Analysis*.

Webpages for topics listed above that are not currently part of the OPP, and therefore do not yet have any content as noted above, would initially have information about reviewing that section, the process for developing the content and how interested parties could get involved. There is also likely to be a downloadable OPP, and/or its different sections, available.

This planned network of linking and navigation would enable users to more quickly find the sections of the OPP of most relevance to them. An online-based OPP would also enable more efficient topic reviews and the updating of content to align with current practice, avoiding the need to review the entire OPP at one time. Feedback from respondents to the OPP discussion document expressed support for this type of approach.

Topic-specific reviews: Decision Criteria

Topic-specific reviews would develop or revise the content of each topic to the appropriate level of detail. For example, some reviews may cover an entire section (e.g. Section 1: Introduction) or individual subsections (e.g. Section 5.2 or Section 9.4, etc.). The process for and level of review would be determined by the expected resource requirements, the appropriateness of separating or combining topics and alignment with other PHARMAC work (such as establishing national management of medical devices). As we work through reviewing the descriptive content of the OPP we will continue to engage with stakeholders where appropriate to ensure the OPP remain relevant and up to date.

We are aware, based on previous feedback and responses to the OPP discussion document that many stakeholders are interested in discussing the criteria used by PHARMAC for making its funding decisions. Furthermore, we consider that our decision criteria define the outcomes that we seek to achieve in our work.

As such, we intend to begin in-depth reviews of the descriptive OPP content in the first part of 2013 with an evaluation of, and consultation on, our nine **Decision Criteria**. We are currently planning this stage of work and your feedback during this review will be important.

We anticipate there will be many inter-dependencies for OPP topic-specific reviews. Using the decision criteria as an example, careful consideration will need to be given to other sections of the OPP, such as targeting funding (section 8) and the role of managing medical devices. Where appropriate, such dependencies will be reviewed as part of that topic's review or supplementary to it.

Other topics may also be reviewed at simultaneous times where appropriate. Not all reviews will require public consultation, though we will keep stakeholders informed throughout. We are also open to hearing views about any aspects of our OPP at any time.

Feedback

PHARMAC is always open to receiving feedback from stakeholders. If you have any thoughts or concerns about the approach we intend to take to the next stages of our OPP review please feel free to contact us by:

- email: opp@pharmac.govt.nz or
- post:

  OPP review team
  PHARMAC
  PO Box 10-254
  Wellington 6143

You can also contact us via the above methods if you would like to meet with us, in person or by tele/videoconference. Please visit http://www.pharmac.govt.nz/haveyoursay for information on how we would treat your correspondence in the event of a relevant Official Information Act request.

More information about the OPP review is available on our website at www.pharmac.govt.nz/oppreview.