

PHARMAC and hospital medical devices: Obtaining clinical input

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices. In August 2012, Cabinet approved the plan for transitioning this work to PHARMAC.

The goal of this decision is to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into health.

For us to be successful in this role, it is critical to include clinicians and other DHB staff in the decision making process. To help achieve this, we are beginning our formal consultation¹ on this work. This document seeks your feedback on how we can best work with you and what sorts of information we need to consider to ensure sensible funding decisions for medical devices (including consumables).

We seek input on clinical matters from all users of medical devices in the clinical setting – clinicians and non-clinicians alike. If you are not a clinician but have clinically-related advice to give, we are keen to hear your views also. We recognise there are other important areas to consider when managing medical devices and will seek stakeholder views on these in future activities.

Summary

- We will develop a list of devices (including consumables) over time. Changes to this list will be communicated to the sector. We will seek your input into the detail of the listing arrangements for these products when appropriate in the development process.
- We appreciate there are differences between pharmaceutical and medical devices management. We need to develop processes for ensuring our funding decisions are informed by robust clinical advice. Some of the issues we have already identified that will need careful consideration include:
 - how we will clinically assess new health technologies
 - what information we need to know prior to deciding on whether to fund
 - how we approach choice management in any tendering-type process
 - what the clinical issues are in funding exceptions to the approved list
 - how we determine the scope of medical devices PHARMAC will manage
 - local decision making
 - the risks of potentially limiting clinicians' choices on the medical devices they use, and
 - how we approach and encourage innovation and the ability to trial new technology.
- Below is a list of questions we are seeking your feedback on. An outline of the next steps and background of this work is also provided.
- The deadline for responses is **5 pm Thursday, 28 March 2013**. If you would like to meet with us to discuss your views, please contact us by Friday 15 February 2013.

¹ This consultation informs PHARMAC's devices establishment work. It should not be confused with the Health Benefits Ltd's coordinated consultation on change resulting from the implementation of the Finance, Procurement and Supply Chain Business Case.

Questions

The questions below are divided into three broad categories of focus. A template for your response is provided on page 6 should you wish to use it.

Considering clinical input into medical devices management

1. What sources and types of clinical information should PHARMAC consider when making medical devices funding decisions? How will we best be able to obtain this information for the group of devices of particular relevance to you?
2. From a clinical perspective, what is essential when developing a national medical devices management system?
3. What other comments do you wish to make regarding clinical input into medical devices decision making?

Your current systems and processes

4. What are the clinical aspects of the system in place at your organisation for assessing and procuring medical devices? For example, how does a new product currently get introduced, how does this process take account of clinical advice, how are changes to clinical equipment managed, etc.?
5. What role do clinical staff play in this system, and in your view how well does this work?
6. What aspects of the system that you work in do you like? What do you think could be improved upon?

Engaging with you

7. What is the best way for PHARMAC to obtain your input as its work on medical devices management progresses?
8. What are the key clinical groups, meetings or publications we should consider becoming involved in to help develop national management of medical devices?
9. Please identify which one category best describes who your submission is on behalf of.

Individual clinician (please specify area of practice: _____)

Individual nurse (please specify area of practice: _____)

Individual Allied Health practitioner (please specify area of practice: _____)

Clinical college

Clinical society

Medical union group

DHB procurement professional (please specify area of practice: _____)

Industry company

Industry representative group

DHB funder group

DHB provider group (please specify: _____)

Patient/consumer group

Government agency

Other (please specify: _____)

Providing your views

You can provide your responses to the topics and questions in this document in one of the following ways:

1. Email: devices@pharmac.govt.nz
2. Fax: (04) 460 4995
3. Post:

Medical Devices Establishment Team
PHARMAC
PO Box 10-254
Wellington 6143

The deadline for responses is **5 pm Thursday, 28 March 2013**.

We also invite you to meet with us to discuss how we can best get clinical input into our medical devices work. Please contact us by Friday 15 February 2013 to arrange a meeting.

This discussion document, and more information about our expanded role in managing medical devices, is available on our website at www.pharmac.govt.nz/HospitalMedicalDevices. Contact us at devices@pharmac.govt.nz if you require further information about any aspects of this work.

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 Two for your information.

Next steps

Once we understand the best way to work with you, we will continue to seek your input to progress development of the framework, policies and processes for national management of medical devices. This includes on a broader range of devices management issues, such as regulation, procurement and contracting considerations, devices maintenance and disposal, and more. Regular updates will be provided throughout the health sector and via our website (www.pharmac.govt.nz).

Background

PHARMAC's expanded work on managing medical devices is integral to projects being undertaken by Health Benefits Limited (HBL) to implement the Finance, Procurement and

Supply Chain (FPSC) Business Case, developed by HBL alongside District Health Boards (DHBs). Work with the health sector on the wider FPSC is currently underway and consultation on business models and organisational design will begin in mid-2013.

We recognise that working closely with clinicians, procurement staff, the medical devices industry and others will be critical to a successful national system of medical device management. There will be multiple opportunities for you to be involved in, and provide your views on, different aspects of work in this area.

Over the long term, we will be working to develop a catalogue of funded hospital medical devices, including the rules, policies and framework for the catalogue. In the short term, we will be undertaking some discrete procurement projects for which clinical input will be crucial.

Included in the appendix is a brief summary of some of the feedback we have received so far. This includes that provided to the Ministry of Health in response to its draft Cabinet paper *Update on a plan for PHARMAC to assume responsibility for medical devices* and the 2010 *Report on the consultation period for the proposal to expand the functions of PHARMAC* (Dr David Sage, report to the Minister of Health). This summary encapsulates a wide range of issues related to medical devices management, many of which are not the subject of this specific consultation but may be consulted on as this work progresses.

Below is an indicative, high level timeline of the key dates for our progress towards national management of medical devices. Please note that timelines are subject to change as information becomes available. PHARMAC and HBL will keep you informed of changes.

- **31 August 2012:** PHARMAC, HBL and the New Zealand health sector commenced work on specific national procurement initiatives. These initiatives will be rolled out between now and June 2015.
- **27 November 2012:** PHARMAC begins clinical engagement to develop a framework for clinical input into our hospital devices activity.
- **30 September 2013:** HBL completes the National Product Catalogue, a comprehensive list of hospital devices available in New Zealand.
- **31 December 2014:** A single Financial Management Information System (FMIS) rollout will be completed. This FMIS will provide detailed information on what hospitals are purchasing nationwide.
- **30 June 2015:** PHARMAC assumes management of most hospital devices
- **30 June 2017:** PHARMAC begins management of hospital devices within a budget agreed with DHBs and the Minister of Health.

Health sector context for this review

Other national health sector agencies are also engaged in various aspects of medical devices management; in particular, HBL and the National Health Committee (NHC). In the short term, PHARMAC, HBL, DHBs, and the NHC are working to identify areas for immediate procurement activity where savings and service improvements can be made.

Established by the Government in 2010 to help DHBs save money by reducing their administrative, support and procurement costs, HBL is tasked with identifying and leading initiatives to implement the following programmes:

- Finance, Procurement & Supply Chain Shared Systems and Services (people, processes and technology)
- Collective procurement

- Facilities Management and Support Services (led by food and laundry service initiatives)
- Information Services
- Human Resources and workforce management

HBL is already working closely with PHARMAC and DHB managers to build shared support services, including the financial and administrative tools, systems and processes which will support PHARMAC's future management of hospital medical devices.

The NHC's role is to assist the health and disability sector to use sector funding in the most effective way and enable continued improvement of the health of New Zealanders within the available financial resources. Providing independent advice to the Minister of Health on value for money and prioritisation, the NHC's work includes assessing new and existing health and disability technologies, services, models of care and programmes.

Alongside our work to establish national management of medical devices, PHARMAC is also undertaking other substantial consultations, including on the rules and framework for hospital medicines purchasing and our Operating Policies and Procedures (OPP). Wherever possible, we will ensure that these consultations align and that providing your feedback is manageable.

Response template

If you choose, you may provide your responses to the questions posed above in the spaces below. The deadline for responses is **5 pm Friday 28 March 2013**. If you would like to meet with us about this work, please contact us by Friday 15 February 2013.

Considering clinical input into medical devices management

- 1. What sources and types of clinical information should PHARMAC consider when making medical devices funding decisions? How will we best be able to obtain this information for the group of devices of particular relevance to you?

- 2. From a clinical perspective, what is essential when developing a national medical devices management system?

- 3. What other comments do you wish to make regarding clinical input into medical devices decision making?

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_____)

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DHB procurement professional (please specific area of practice:
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Industry company

Industry representative group

DHB funder group

DHB provider group (please specify: _____)

Patient/consumer group

Government agency

Other (please specify: _____)

Appendix: Summary of feedback about national medical devices management

PHARMAC has obtained feedback from some stakeholders about national management of medical devices, given in response to a number of pieces of work (including recent PHARMAC meetings with stakeholders, the Ministry of Health's 2012 Cabinet paper on this subject and Dr David Sage's report to the Minister of Health). The below information provides a brief summary of this feedback, categorising by theme some of the issues we are now aware of that require careful consideration as we develop a national medical devices system. This summary is not intended to be comprehensive and the scope of this information is larger than the scope of the current consultation.

Definition and scope

1. What is the definition of a medical device?
2. What about the compatibility and interactivity of a single medical device with other processes, pharmaceuticals and other medical devices?
3. Is it realistic to include large items that individually cost millions of dollars?
4. Who will decide what is in and out of scope for inclusion into the devices that PHARMAC will manage in due course?

Clinical engagement

5. Broad clinical input and the role of clinicians in both designing and building the new system, and in relation to its ongoing management, is critically important.
6. The process of obtaining clinical input will need to involve colleges, societies and a wide range of clinical networks.
7. It will be important to take account of the impact of consultation processes on clinicians' time and general availability when undertaking consultation processes.
8. Who and which clinical groups will be involved in both the establishment phase of the new model and in its ongoing management?
9. Who and how will groups or individuals be mandated to 'sign-off' on decisions? Who will decide this?

Evaluation criteria

10. Cost considerations
 - a. Cost must not be the sole or principal driver of procurement processes.
 - b. Face value cost versus hidden costs/ongoing operational costs must be considered. Account must be taken of the whole-of-life cost of devices.
 - c. Account must be taken of the cost of switching out devices that are already in use.
 - d. Consider the implementation costs for devices which may only have 18 month life cycles, noting that new processes may cost more than current practice.
 - e. On-site support and education/training and capacity for upgrades – how will this be costed? Who will cost this? Who measures total cost of time involved? Will this be different to current practice?
11. Measures of quality
 - a. This needs to consider both the short and long term performance of a device.
 - b. How will the acceptability of a device by clinicians and patients be sought and considered?
 - c. Will on-site support always be provided by the company, or will it be provided by the intermediary, i.e. PHARMAC or the DHB?

Procurement and contracting

12. Market impacts – there is may be an undesirable potential to shrink the pool of suppliers in New Zealand and/or push existing suppliers out of New Zealand.
13. Considerations must be given to the contracting process and conflicts of interest since New Zealand is a relatively small country.
14. Will PHARMAC use the same current contracting methods or consider new ones, which might include contracting models not currently used in pharmaceuticals?

Safety and supply

15. Allowing local variation – what if there is a high demand for a particular device in one region? How will this be managed?
16. Will adequate supplies of medical devices be assured?
17. Who will regulate the safety of medical devices? Will this be the role of Medsafe?

Use of savings obtained

18. Will savings be reinvested into provision of medical devices? Or both pharmaceuticals and medical devices?
19. Will savings be reinvested in secondary care?

Evaluation and monitoring

20. How will evaluation and monitoring occur? What factors will be measured?
21. Beyond savings, how will the change from hospital management to PHARMAC management be evaluated?

Capability and relative role of PHARMAC

22. How will this work impact on PHARMAC's pharmaceutical management role?
23. In the shift to PHARMAC-managed medical devices, what other agencies will be involved and what will they have responsibility for? How will this be decided?
24. What is the role of PHARMAC in relation to other agencies, such the NHC, HBL, or Medsafe?