Applying the PHARMAC model to hospital medical devices management

Consultation document

October 2013

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

Informing establishment of national hospital medical devices management

Message from Sarah Fitt, Acting Chief Executive, PHARMAC

In broad terms, a medical device is considered to be anything used on, in or by a person for a therapeutic purpose, but which is not a medicine. This includes is a huge range of items – anything from a cotton swab to an MRI machine – and hospitals use a lot of them. Most people will have interactions with a hospital medical device at some time in their life.

When the Government asked PHARMAC to apply its successful model to management of hospital medical devices, we knew this would be a significant expansion of our role but were prepared for the challenge. We also knew we needed significant input from the health sector to help us work out the best way to achieve this.

We've already begun work towards management and have initiated some interim activity to procure specific items for DHBs on a national basis. Now we are looking for input from all those with knowledge and expertise relating to medical devices, to help inform our next steps.

It's important to note that in taking on management of hospital medical devices, PHARMAC does not intend to make any changes to our community medical device operating principles and policies (OPPs), but we will consider whether any of the feedback relating to hospital medical devices is relevant to our OPPs in other areas – such as community medical devices.

PHARMAC's aim is to improve national consistency in access to hospital medical devices, provide for appropriate variation where needed, and free up health spending that can then be re-invested in health.

The quality of the devices and patient safety is critical and underpins our approach to this work. It's vital that we take sector experience into account as we decide how we will apply the model.

I want to acknowledge the feedback we've received so far and note that all the feedback we gather will be considered. There is no need to repeat information you have already sent us.

I recognise there is a lot of change occurring in the health sector at the moment and we appreciate you taking the time to respond and add your expertise to this work.

Following this consultation, there will be another opportunity for people to provide input early next year. PHARMAC will consider all the information we have and form a proposal for how we plan to carry out management, which we will then seek your comment on.

Sarah Fitt
Acting Chief Executive

Contents of this consultation document

1. Introduction

PHARMAC is a Crown entity under the New Zealand Public Health and Disability Act 2000 responsible for securing:
'The best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided'.

In the 2010/11 financial year, District Health Boards (DHBs) spent approximately $880 million on hospital devices, expenditure which has been rising at a rate that is faster than DHBs' funding increases. Whatever the drivers for this are, this is unsustainable for the sector.

PHARMAC's expertise and success in managing medicines was a feature of the 2009 Ministerial Review Group's report to the Minister of Health. The report recommended a greater role for PHARMAC and 'PHARMAC-like' procurement.

The Government has determined that PHARMAC will manage vaccines and hospital medicines within a fixed budget on behalf of DHBs.

In 2012, the Government also agreed to a phased plan for PHARMAC to progressively take on management of hospital medical devices, while also undertaking some immediate interim procurement activity. This builds on PHARMAC's previous involvement in managing some medical devices; items include asthma inhalers and spacers, pen needles and some syringes, insulin pumps and diabetes meters.

PHARMAC's management of hospital medical devices will increase over time, as the organisation gradually picks up activity that has previously been managed by the sector.

PHARMAC has started development of its processes and policies to support this expanded role and this consultation document seeks to gather further information from the health sector (and others) about how we best apply the PHARMAC model to take on management of hospital medical devices. Some guiding questions to provoke thought on key elements of this work have been included.

In broad terms, a medical device can be considered to be anything that is used for a therapeutic purpose that is not a medicine. PHARMAC acknowledges that a very broad range of people (clinical, non-clinical and consumers) have interactions with hospital medical devices. Therefore, this document is also designed to provide sufficient background and links to other information about PHARMAC to help inform responses.

Whatever your understanding of PHARMAC's work, and/or knowledge of the use of medical devices in hospitals, PHARMAC wants to hear about your experience and what you see as important issues for consideration for the organisation.

2. Why PHARMAC needs your input

This is an important opportunity to influence the policies and procedures that are established to support medical device management and PHARMAC encourages anyone with particular expertise and knowledge, or just an interest, in hospital medical devices to put forward a submission.

PHARMAC recognises that a very wide range of people interact with medical devices in hospitals and that these interactions are different to medicines. This consultation seeks to gain a greater understanding of how medical devices are obtained and used, what considerations DHBs take into account when deciding which ones to use and what the implications are for managing these on a nationally consistent basis.

PHARMAC is seeking to understand further how it will need to further adapt PHARMAC operating policies and procedures to be suitable for managing hospital medical devices.

In a variety of obvious and less obvious ways, devices are different to pharmaceuticals. For example, PHARMAC has been told that there is much less data available, as a result of fewer randomised controlled trials being undertaken, to clearly determine how effective particular devices are.

Other considerations are particularly relevant for medical devices, such as whether significant and/or on-going technical support, or user training for patients or clinicians, is required. It may also be much more difficult to attribute direct health gains to a particular device.

Further considerations could include whether the device would require PHARMAC to purchase a number of other 'accessories' and the expected lifespan of the device. Some questions PHARMAC might need to consider are:

- how quickly might technology advances make this device obsolete?
- does the lifespan of similar devices differ?
- what interfaces and/or interactions with other medical devices are involved?

The key purpose of this consultation is to seek information from the sector and interested groups to inform PHARMAC's thinking on the above issues – and any other issues you think are relevant to taking on the management role.

3. Next steps

After the consultation period on this document closes on 29 November 2013, PHARMAC will consider all submissions and use this information to help form a proposal for how it might apply the PHARMAC model for management of medical devices. Consultation on that proposal will be held in the early part of next year and we will invite you to participate.

A summary of all submissions received in the current consultation will also be published.

The aim is to have a functional framework for medical devices management in place by mid-2015, with management activity taking place on an incremental, category by category basis.

This will be working towards full budget management, with a capped budget agreed by the Minister of Health and DHBs sometime in the future.

4. Guiding Questions

The following questions aim to provoke thought on key elements of PHARMAC's work. They are arranged to roughly follow the order of the decision making process that PHARMAC follows for medicines (http://pharmac.govt.nz/2009/09/01/DecisionMakingGraph.pdf).

These questions are prompts only – PHARMAC invites you to comment on those relevant to your submission. You do not have to stick to the questions and you do not have to answer all the questions in your submission. All information provided will be considered.

If you feel that there are specific cultural aspects to be addressed at any point please also highlight those in your response.

Some of you may have provided input on medical devices into previous consultations. It is not necessary to repeat information you have already given – all feedback provided in any of our consultations will be considered together to help inform PHARMAC's next step towards hospital medical devices management.

General questions

The Medicines Act 1981 provides a definition of a medical device. This definition focuses on medical devices having a therapeutic purpose.

1. How would you define the products that fall within PHARMAC's scope of hospital medical devices?
    a. Why?
    b. Which, if any, related services should be included e.g. repairs and maintenance, training?

    You might refer to the characteristics of medical devices or give specific examples.

2. What do you think falls outside the scope of a funded medical device?

3. What makes a medical device a "new" medical device?

4. What are the features that PHARMAC needs to consider when determining if one medical device is interchangeable with another?

Listing on the Pharmaceutical Schedule

The Pharmaceutical Schedule will list medical devices available for use in public hospitals. It provides a nationally consistent list of medical devices that DHBs can use.

5. In what circumstances would variation in DHBs' purchasing and use of medical devices be needed and/or reasonable?

6. What benefits and risks, if any, might be associated with greater national consistency of DHBs' purchasing and use of medical devices?

For some medicines, the Pharmaceutical Schedule requires that their use be restricted to certain clinical circumstances and the prescribing of those medicines be authorised by a clinician recognised as a specialist in treating those clinical circumstances.

7. In what circumstances should the use of some medical devices be limited and who should be involved in setting those limits?

8. In what circumstances might DHB management be involved?

Application for a new medical device to be listed for use in a public hospital

There needs to be an application process to list medical devices on the Pharmaceutical Schedule. This process will set out who can make an application and what information PHARMAC needs to consider the application.

In accordance with its governing legislation, PHARMAC will also operate a scheme for DHBs to access medical devices not listed on the Pharmaceutical Schedule in exceptional circumstances. We currently manage this through our Named Patient Pharmaceutical Assessment process for hospital pharmaceuticals and community devices and pharmaceuticals.

9. What do we need to consider when creating an application process for medical devices?

10. In what situations might decisions need to be made urgently about whether to provide access to a medical device?

Quality Assurance of Medical Devices

PHARMAC needs to carefully consider how we will gain a reasonable level of confidence about the quality and safety of the medical devices we list for use, especially before the Australia New Zealand Therapeutic Products Agency (ANZTPA) takes on pre-market approvals for medical devices in July 2016.

Currently Medsafe is New Zealand's 'Medical Devices Safety Authority', and is responsible for the regulation of therapeutic products in New Zealand, including medical devices. It is a mandatory requirement for importers, exporters and New Zealand manufacturers to advise the Director-General of Health, via the WAND database, of the devices that are supplied here. There is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand.

11. What do you see as the strengths and weaknesses in the way that the safety and quality of medical devices used in public hospitals is assessed now?

12. What approaches might we look at for a nationally consistent quality assurance process until ANZTPA starts operations in 2016?

13. What factors do we need to consider when assessing whether a medical device is safe for use and effective?

14. What information is needed to demonstrate this?

Clinical Input

PHARMAC undertook an initial consultation, *PHARMAC and hospital medical devices – Obtaining clinical input*, to help inform thinking around a framework for clinical engagement for management of medical devices.

The consultation sought information about how PHARMAC should engage clinicians to make sure clinical views are taken into account when developing the policies and processes used for medical devices management from 2015, and what kind of framework needs to be established to get appropriate clinical advice for PHARMAC's funding activities from this point onwards.

If you did not respond to this consultation at the time and would like to do so now, the questions asked and the responses received are here - http://www.pharmac.health.nz/medicines/hospital-devices/consultations

Economic Assessment

PHARMAC uses cost-utility analysis (CUA) in deciding whether funding a new medicine or medical device will make the best contribution to New Zealand's health. You can read the document *Cost-Utility Analysis (CUA) Explained* at http://www.pharmac.health.nz/ckeditor_assets/attachments/8/economic_assessment_guide.pdf .

PHARMAC understand from other consultations and research that medical devices differ from medicines in a range of ways e.g. availability and quality of clinical evidence, length of life-cycle, learning curve, one device for many uses, sheer number and complexity.

15. When assessing the benefits of using a new device, what should we consider? How would we measure these?

16. When working out the costs/savings from initial and ongoing use of a medical device, what should we take into account? Retraining, repairs and maintenance, consumables, cost of capital?

17. What are the best sources of information for this assessment?

Decision Criteria

PHARMAC uses its decision criteria to prioritise pharmaceuticals (medicines, vaccines and medical devices) for funding within the funding available.

As part of the broader review of operating policies and procedures, PHARMAC will be asking questions around how the decision criteria are applied. This will come after the decision criteria review is completed.

PHARMAC has recently concluded a consultation on whether the decision criteria PHARMAC uses for determining which pharmaceuticals are available for public funding still reflect the things that the public feel are important.

The consultation has now closed and a second phase of consultation is expected in early 2014. If you would like to view the questions asked in the first round these are online - http://www.pharmac.health.nz/about/operating-policies-and-procedures/decision-criteria-consultation

Purchasing Strategies and Contract Management

In the process of determining what is listed on the schedule PHARMAC uses a range of commercial tools to achieve better pricing.

18. Do you think there are some medical devices more suited to certain tools? What are the attributes of these devices that lead you to this conclusion?

With medicines there are some market drivers that mean PHARMAC is able to get a better price if it uses confidential rebates.

19. Are there circumstances in medical devices markets that would lend themselves to these sort of arrangements as well? What are some of the challenges of rebates vs transparent pricing?

PHARMAC monitors analyses and manages its contracts with the suppliers of pharmaceuticals listed on the Pharmaceutical Schedule.

20. What do you like about the way medical devices contracts are managed now in public hospitals and what improvements would you like to see?

Integrating new devices into hospital processes

21. What are the strengths and weaknesses of how a medical device gets approved for use in a public hospital now? What is done to ensure a smooth implementation?

22. What role should PHARMAC have in ensuring that a newly listed hospital medical device can be used?

5. Submission process

Some of you may have provided input into other consultations PHARMAC has held. It is not necessary to repeat information you have already given – all feedback provided in any of our consultations will be considered together to help inform PHARMAC's next step towards medical devices management.

You do not have to adhere to the guiding questions provided and you do not have to answer all questions in your submission. All information provided will be considered.

Deadline:
Submissions may be made until **5pm, 29 November 2013**.

How to make a submission:
Find PHARMAC's **consultation document online here**:
http://www.pharmac.health.nz/medicines/hospital-devices/consultations

Email:
devices@pharmac.govt.nz

Fax:
(04) 460 4995

Letter:
Medical Devices Establishment Consultation
PHARMAC
PO Box 10-254
Wellington 6143

In person:
We will be holding open forums as part of our medical devices consultation.
Details of the open forums:
Auckland
22 October 12 – 2pm
Clinical Education Centre Auditorium
Auckland Hospital

Auckland
25 October 12 – 2pm
Ko Awatea Centre
Middlemore Hospital

Palmerston North
30 October 2 – 4pm
Medical Lecture Theatre
Palmerston North Hospital

Wellington
4 November 12 – 2pm
Small lecture theatre, Conference Centre
University of Otago Wellington School of Medicine

Christchurch
11 November 2 pm – 4 pm
Oncology Lecture Theatre
Ground Floor, Oncology
Christchurch Public Hospital

Dunedin
12 November 10am – 12pm
Colquhoun Lecture Theatre
Dunedin Hospital

Hamilton
15 November 12 – 2pm
Bryant Education Centre
Waikato Hospital

PHARMAC will also be inviting specific groups to meet to present their views in response to this consultation. Please contact Megan Whittleston on (04) 901 3208 if you would like to arrange a time to meet with PHARMAC. If a range of groups are interested in meeting we may organise larger group meetings.

Please email devices@pharmac.govt.nz if you require any further information about any other aspects of this consultation.

Information requested under the Official Information Act
Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld. PHARMAC will give due consideration to any such request.

6. Appendix 1: PHARMAC's role in hospital medical devices

What does PHARMAC do?

The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown entity that decides, on behalf of District Health Boards (DHBs), which pharmaceuticals and related products are subsidised for use in the community and which are available for use in public hospitals.

The term 'pharmaceuticals' includes medical devices. The legislation under which PHARMAC operates already provides a mandate to take on medical device management.

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

- Maintain and manage a Pharmaceutical Schedule that applies consistently throughout New Zealand.
- Manage in exceptional circumstances the provision for subsidies for the supply of pharmaceuticals not on the Schedule.
- Engage in research as we see fit, but within our operating budget
- To promote the responsible use of pharmaceuticals
- Any other functions as directed by the Minister

As a Crown entity, PHARMAC has a commitment to upholding the principles of the Treaty of Waitangi. PHARMAC's Māori Responsiveness Strategy, *Te Whaioranga*, provides a framework for ensuring that PHARMAC responds to the particular needs of Māori in relation to pharmaceuticals.

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

PHARMAC does not decide which pharmaceuticals are safe for use in New Zealand. This is the role of Medsafe. PHARMAC is responsible for deciding which pharmaceuticals should be subsidised for use in the community and available for use in hospitals in New Zealand.

Brief history of PHARMAC and hospital medical devices

2009
The Ministerial Review Group suggested that further savings could be made in the health sector by extending PHARMAC's role with hospital medicines. It also suggested the possibility of benefits from a national procurement approach to medical devices.

- The Cabinet Social Policy Committee agreed in principle to expand PHARMAC's role, initially in a limited way with respect to medical devices, and subject to sector consultation.

2010
Dr David Sage (CMO ADHB) led consultation with clinicians, which revealed support for national procurement. You can read David Sage's report here: http://www.health.govt.nz/publication/report-consultation-period-proposal-expand-functions-pharmac

The consultation also found there were some concerns from the sector, including PHARMAC's ability to take on such extensive additional responsibilities all at once (hospital medicines already having been agreed), and the possibility of unreasonably restricting clinicians' choice.

Cabinet agreed that PHARMAC should start groundwork for assuming responsibility for managing the prioritisation, assessment, standardisation and procurement of medical devices over several years, to give PHARMAC time to properly develop its processes. It also asked Health Benefits Limited to take on some national procurement while PHARMAC got ready to take over management. (for more information about Health Benefits Limited's role in the health sector, visit: http://www.healthbenefits.co.nz/)

- The Minister of Health invited PHARMAC to consider assessment, standardisation, prioritisation and procurement of insulin pumps in the interim.

- The newly re-constituted National Health Committee began taking an active role in health technology assessments and intended to extend this to medical devices. PHARMAC has worked closely with the committee to assist them with their thinking in this area.

2012
Cabinet confirmed PHARMAC expansion into management of hospital medical devices.
Cabinet also asked PHARMAC to:

- Undertake some initial procurement activities immediately (beginning in the 2013/14 financial year)
- Consultation with clinicians (held in 2012)
- Work towards taking on management from about mid-2015
- Work towards management within a fixed budget

It's important to note that information provided to PHARMAC in any of these previous stages of work will be taken into account when PHARMAC develops its proposal for adapting the model for medical devices.

Applying the core elements of the PHARMAC model

While PHARMAC is not looking for comment on the model itself, it is important to get input on how to develop the suitable Operating principles and policies to enable the organisation to give effect to its expanded role. PHARMAC is looking at how to apply the model to this area of business, rather than how to change the model.

PHARMAC is guided by a number of laws, regulations and Government guidelines, and Medicines New Zealand – the strategy for the medicines system.

Both DHBs' and PHARMAC's objectives and functions are set out in the New Zealand Public Health and Disability Act 2000 (NZPHD), and, for PHARMAC, also in a Ministerial direction made on 4 September 2001. DHBs and PHARMAC are each accountable to Parliament and the Minister of Health for the performance of their objectives and functions.

More detail on PHARMAC's role in the health system, key functions, what the Schedule is and how funding decisions are made, is in *Your guide to PHARMAC*, which you can find here:

http://www.pharmac.health.nz/about/your-guide-to-pharmac

PHARMAC will give effect to its medical devices role through the Pharmaceutical Schedule.

Objectives and what success might look like

PHARMAC's objective is to achieve the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. To assist in achieving this and to make sure we're on track, PHARMAC may develop some goals in taking on management of hospital medical devices, for example:

- Improving national consistency in access to medical devices
- Providing for appropriate variation where needed
- Freeing up health spending that can then be re-invested
- Maintaining patient safety.

PHARMAC is mindful that a one-size-fits-all approach won't be appropriate for medical devices and that flexibility to meet the needs of the sector will be essential.

Clinicians, consumers and suppliers may experience PHARMAC's approach as:

- High-quality, transparent, justifiable decisions that consider a range of views, including those of consumers
- A nationally consistent approach
- Balancing access with evidence of health gain and cost-effectiveness
- Prioritising the next best investment
- Sustainable expenditure growth – and re-investment of savings
- Improved and consistent consumer access to medical devices
- Consideration given to alternatives where there is a need

We would be interested in your thoughts on what goals might usefully signpost that we are on track to achieving our legislative objective.

How do all of PHARMAC's consultations fit together?

Clinical Engagement in hospital medical devices management

We undertook an initial consultation, *PHARMAC and hospital medical devices – Obtaining clinical input*, to help inform our thinking around a framework for clinical engagement for management of medical devices.

The consultation sought information about how we should engage clinicians to make sure we take clinical views into account when developing the policies and processes we will use for medical devices management from 2015, and what kind of framework we will need to get appropriate clinical advice for our funding activities from this point onwards.

PHARMAC received 81 submissions to this consultation, from a range of clinicians, nurses, allied health practitioners and their representative organisations, as well as device suppliers and industry representatives.

The consultation responses have been analysed by PHARMAC and a summary of the submissions received was publicly released in July. You can read the summary of submissions here: http://www.pharmac.health.nz/medicines/hospital-devices/consultations.

While this consultation was targeted largely at clinicians, we did receive some helpful, more general information, about the management role. We will continue to reflect on this feedback when considering our processes over the coming months – there is no need to resubmit information you have already provided to PHARMAC in previous consultations.

Interim Procurement Project consultation

Alongside our work to develop our approach to medical devices management, PHARMAC is beginning procurement of selected groups of medical device products in this financial year.

One of the expectations from the Cabinet decision in 2012 was for PHARMAC to undertake interim procurement while it establishes its processes for management. The basis of this is to achieve some early savings for DHBs, through national procurement of a small group of items, before full management can begin. Essentially PHARMAC will be looking to get the best price, on the best item, for all DHBs, for particular items they are already using. Any learnings PHARMAC gains from this process will help inform its approach to management.

PHARMAC held a consultation around 11 initial categories where we will look to procure items for DHBs and has now chosen three groups for initial procurement activity.
PHARMAC chose a range of categories where it knew there will be challenges, but this will help to develop a robust approach to management.

These first categories chosen for activity are: **Wound care, Orthopaedic Implants and Sutures.**

PHARMAC will be negotiating national agreements for particular items, which will then be added to the Pharmaceutical Schedule for DHBs to buy under the terms and pricing in agreements reached between PHARMAC and the suppliers.

The clinical advice and decision criteria framework will be that which PHARMAC currently uses for community and hospital pharmaceuticals. We consider this framework to be flexible enough to enable PHARMAC to consider factors relevant to devices but not applicable to pharmaceuticals.

Operating Policies and Procedures (OPPs) and decision criteria

In 2012, PHARMAC launched a review of its OPPs with a period of public consultation. The feedback received indicated that people were interested in having a say about how PHARMAC works, particularly with respect to our decision criteria, what they take into account and how we use them.

PHARMAC has recently concluded a consultation on whether the decision criteria PHARMAC uses for determining which pharmaceuticals are available for public funding are fit-for-purpose and reflect the things that the public feel are important.

This is relevant to the hospital medical devices management work, which falls outside PHARMAC's traditional focus on medical devices and medicines used in the community, cancer medicines used in hospitals and more recently, vaccines and hospital medicines.

The OPP consultation sought to make sure that, as a result of these changes to what PHARMAC does, how we do these things remains relevant. This consultation will contribute to PHARMAC's work on management of medical devices.

This current medical devices-specific consultation seeks input on how to develop the suitable operating principles and policies to enable the organisation to give effect to its expanded role. PHARMAC is looking at how to apply the model to this area of business, rather than how to change the model.

Previous feedback received

Some of you may have provided input into the consultations above and it is not necessary to repeat information you have already given – all feedback provided in any of our consultations will be considered to help inform PHARMAC's next step towards medical devices management.

PHARMAC does welcome additional thoughts on hospital medical devices and considerations for how to apply the model.

7. Appendix 2: Relationship with other entities; enablers

Health Benefits Limited (HBL)

Cabinet acknowledged that, in order for PHARMAC to assume responsibility for medical devices, it would need comprehensive and consistent data regarding hospital medical devices from all 20 DHBs and the means for managing compliance with the Pharmaceutical Schedule and the adoption of new device technologies.

HBL is currently working with DHBs to build a DHB National Catalogue and a single financial management information system for the sector.

The financial management system and the Catalogue will, amongst other things, provide PHARMAC with the data and tools to carry out its role.

Shared Services (including healthAlliance)

HBL is establishing new arrangements for DHBs' shared services – including procurement activity. These arrangements are outlined in HBL's Finance Procurement and Supply Chain shared services operating model.

The arrangements will apply to medical device procurement in areas that PHARMAC isn't undertaking activity in yet. healthAlliance has been chosen by HBL as the organisation that can ensure procurement activity for DHBs continues between now and when PHARMAC can begin management in 2015.

Even after this, PHARMAC's activity will be carried out incrementally, on a category by category basis and will take time, so shared services will continue to have a medical device procurement role after PHARMAC takes over management.

Once PHARMAC is managing all medical devices, some procurement activity for medical devices – such as purchasing – may remain within the scope of the shared services and will not be undertaken by PHARMAC.

Medical devices will only ever be a sub-set of all procurement activity undertaken in DHB hospitals.

Medsafe

PHARMAC does not decide which pharmaceuticals are safe for use in New Zealand: this is the role of Medsafe. PHARMAC works closely with MedSafe and will continue to hold responsibility for deciding which pharmaceuticals (including medical devices) should be subsidised for use in the community, or available for use in DHB hospitals in New Zealand.

National Health Committee

NHC has a mandate to provide the Minister with advice on which services and procedures should be publicly funded, including on new technologies. Where there is an overlap with PHARMAC's medical devices role, PHARMAC will work closely with the NHC to ensure alignment of decisions and advice

8. Appendix 3: Additional resources

For any questions related to this consultation, please email: devices@pharmac.govt.nz or call 04 460 4990.

You can find further information about the PHARMAC operating model in *Your guide to PHARMAC*, which is available at: http://www.pharmac.health.nz/about/your-guide-to-pharmac

General information about the medical devices work programme can be found at: http://www.pharmac.health.nz/medicines/hospital-devices

More information about Health Benefits Limited and their work in the public health sector can be found at: http://www.healthbenefits.co.nz

Information about the National Health Committee can be found at: http://nhc.health.govt.nz/

Information about MedSafe can be found at: http://www.medsafe.govt.nz/

Pharmaceutical Management Agency
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