

A discussion document on

PHARMAC's proposed approach to managing hospital medical devices



Foreword

Message from PHARMAC Chief Executive, Steffan Crausaz

Over the past year and half PHARMAC has undertaken three formal consultations and met with a wide range of health care professionals to discuss how we can best manage the expansion of PHARMAC's role to include hospital medical devices.

As you probably know, this work is underway because the government has asked PHARMAC to start managing the assessment, prioritisation and procurement of hospital medical devices within a fixed budget in order to provide the best health outcomes for New Zealanders. The work has already started with optional contracting in particular areas and will build over time.

PHARMAC is grateful to all of you who have made a contribution and offered your expertise and knowledge as we have considered the issues involved. Management of such a diverse and hugely complex group of items is no simple feat. Your ideas have helped us develop this proposal.

Now we are keen to get your thoughts on how we are proposing to apply the PHARMAC model to the management of hospital medical devices. To help get the discussion started we have prepared a proposal that outlines our set of key principles and the next steps we are planning to take to implement this work.

It's important to note that this proposal does not attempt to define the exact process PHARMAC may use when we look at every medical device – we know we can't employ the same process for every decision as every device is different. We need to be flexible enough to choose the most appropriate tool to make the best decision.

Since 1 Feb 2014 PHARMAC has contracted for a range of devices worth over \$26 million as part of our initial procurement activity and have already started to generate savings for the sector. Over the next few months we expect the number of medical device line items to rapidly overtake the number of community pharmaceuticals currently listed in the Pharmaceutical Schedule.

The success of this work involves not just PHARMAC, but also our colleagues in other organisations – particularly Health Benefits Ltd and healthAlliance. However, we know that the key element for success will be those of you in DHBs who will be at the forefront of carrying out the day to day work in hospitals, as well as our supplier partners, without whom we would not have innovative products to invest in. Your input is essential in making this work successful.

Your continued engagement in this work, your support for PHARMAC and for the systems that are being put in place in DHBs, is essential to us all gaining the full benefits of a national management approach.

I look forward to your feedback on this Discussion Document by 5pm 20th June.



Steffan Crausaz
Chief Executive

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1. Introduction

What is in this document?

The main purpose of this document is to present our proposed approach to the national management of hospital medical devices. It outlines the mechanisms we propose to use to make decisions about what medical devices will be available in DHBs, once all the systems are in place to support this, and discusses some of the steps we intend to take while these systems are still being developed.

We are proposing to gradually work towards full management of hospital medical devices (i.e. assessment and prioritisation within a capped budget) across all device categories. We know that we have much to learn along the way and may need to make changes as we go. We won't be doing everything straight away; it is going to be a gradual process over a number of years. We will continue to talk to as many people as we can along the way, as things evolve and as we increase the number of device categories we manage.

What has the Government asked PHARMAC to do?

Our statutory objective states that PHARMAC is responsible for securing the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. In this context, 'pharmaceutical' includes medical devices.

PHARMAC has been asked by the Government to apply its successful model of assessment, standardisation, prioritisation and procurement within a capped budget to hospital medical devices. The aim of managing expenditure growth in this area in a sustainable way will contribute towards supporting the high level of clinical services currently provided by DHBs while still staying within our financial means. It will also help increase national consistency in access to devices across DHBs and potentially reduce inequalities that are often described as 'postcode medicine'.

In order to implement this approach, PHARMAC will need to be able to consider new technology using economic assessment, and good clinical advice. It will need to apply a range of different commercial approaches that are appropriate to the circumstances of the different medical devices, and be confident that DHBs have what they need in order to introduce any changes.

Concerns raised during our previous consultations suggested that this work may limit access to variety of devices, and the benefits of a home-grown, innovative, medical technology industry would be lost. PHARMAC's success is dependent on improving the competitive environment for medical devices, including competition for new, more efficient ways of delivering healthcare. Companies that create value and efficiency for DHBs should see opportunities in PHARMAC's activity in this area.

What we are seeking from you?

Firstly we would like to acknowledge the input we have already had from many people from our previous rounds of consultation and many informal meetings. Your feedback has helped shape our approach and guided our thinking. We appreciate the time taken to provide us with such valuable input. (For summaries of the submissions we have received to

date please see our website : <http://www.pharmac.health.nz/medicines/hospital-devices/consultations>)

Now in this document we are seeking your thoughts on how we are planning to implement our overall approach, whether you agree or disagree with what we are proposing and how we might address any issues you see as possible problems. We have a number of questions through the document that seek your thoughts on particular issues. Some sections, particularly where we have had a lot of previous feedback, we have not asked specific questions. However, you are welcome to provide any comments on any section or aspect of this document.

We will again be holding public forums around the country where you may discuss any particular aspects with members of our team (for further details see section 8 on the submission process).

2. An overview of PHARMAC

The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Government agency that decides, on behalf of District Health Boards, which pharmaceuticals are subsidised for use in the community and those listed for use in public hospitals.

PHARMAC was created in 1993 to ensure that New Zealanders get the best possible health outcomes from funding the Government allocates for pharmaceuticals. Trying to meet the public's growing demand for new and more complex treatments within a limited budget is challenging. Since its establishment, PHARMAC has made available a wider range of medicines while staying within a capped budget each year.

Over the last ten years, PHARMAC is estimated to have saved District Health Boards a cumulative total of \$3.8 billion. At the same time, the number of new medicines and the number of patients receiving them have increased.

3. Introducing our full management approach

What might it look like when PHARMAC is fully managing medical devices?

We recognise that there is no single approach that will work for all devices.

We expect that our approach for any particular device would include some or all of the following steps which have been developed with the feedback from previous consultations in mind:

- > Funding application process
- > Clinical input
- > Risk assessment
- > Economic assessment
- > Prioritisation
- > Commercial activity
- > Contract management
- > Supporting implementation

More detail on each of these steps is provided later in this document.

How will PHARMAC get to full management?

We have already started some medical device work with over 2700 hospital medical devices listed in the Pharmaceutical Schedule so far. There are national contracts available for wound care products, sutures and laparoscopic equipment to use now, that offer savings for DHBs. Other device categories currently being worked on include interventional cardiology and orthopaedic (spinal and trauma) devices.

There will be a step-by-step increase in activity as we work through different categories of devices. We do not propose to review every possible item that is currently being used within DHBs. For many items we consider that a similar approach to our initial work, where we have used a request for a proposal, along with receiving clinical advice and undertaking consultation, before awarding a contract would be how we manage those categories.

The number of categories being managed will increase as more of the wider system (particularly the DHBs' Financial, Management and Information System (FMIS)) comes on-line and where we see opportunities that will bring the most benefit for DHBs from applying our approach.

PHARMAC will consult with the appropriate people each time we look at a different category to make sure we get the right level of input into each decision we make. We will also seek advice if we are considering making changes to currently managed products that may have an impact on the end users.

In planning what to do next, we would consider what we are asking of different areas within the DHBs and what amount of change is already expected of those areas.

When will full management be in place and PHARMAC managing all categories?

This is a difficult question to answer at this stage. For PHARMAC to be able to apply all aspects of our approach, particularly managing a budget for medical devices, we will need co-ordinated information systems to be in place and fully functional across all DHBs. This is likely to take a number of years. However while these changes are being implemented we intend to build our category frameworks, and look for opportunities to improve value for money for DHBs.

How does PHARMAC's work fit with what else is happening in the sector?

There are a number of different agencies involved who are working together to ensure that as the system evolves and we are able to apply more aspects of our approach, the changes will be as seamless as possible. Some aspects of our approach are dependent on the success of work being done by other agencies, for example Health Benefits Limited and the establishment of the DHBs' Financial Management and Information System (FMIS) and National Catalogue. We will, as far as we are able, make sure that our work is in alignment with other sector work to reduce confusion and promote a streamlined approach.

We are aware of other changes occurring in the sector, which include:

- Significant changes within the finance, procurement and supply chain (FPSC) for DHBs

- Introduction of Health Alliance's national procurement role and a third party logistics supplier (procurement and supply chain changes)
- National Health Committee (will be taking a whole-of-system perspective to assessing new technologies, including systems and models of care)

We recognise that with so much change occurring across the health sector at this time it may be confusing at times as to who is responsible for what. We will wherever possible provide as much information as we can when we are looking at making any changes. We are also happy to provide specific clarification and respond to direct questions where we are able.

When can you expect to hear from PHARMAC after this?

You will hear from us when we are looking at products that may impact on your area of work. We encourage you to be a part of the decision-making process when it is relevant to your work.

PHARMAC is currently reviewing its Operating Policies and Procedures (OPPs). These are PHARMAC's framework for how we carry out our statutory role of deciding, on behalf of District Health Boards, which pharmaceuticals and related products are subsidised for use in the community and by public hospitals. They provide guidance to the people and groups with whom we work about what to expect when working with us, and they steer us internally as we consider funding proposals and policy changes. They need to reflect our expanding role in relation to medical devices and hospital medicines.

Topic specific reviews commenced in 2013, and will result in the development of content for other sections (not currently in the OPP) and updating of the current OPP content.

As we apply our approach to manage hospital medical devices we may need to consider whether any further parts of the OPPs need to be changed. At that time we would consider the information stakeholders have already provided, and seek wide feedback on any proposed changes and would welcome your thoughts and participation in that process. (Visit www.pharmac.govt.nz for more information and to learn how to be involved in these processes.)

In the meantime we are confident that for our current work the operating policies and procedures provide sufficient flexibility to carry out this initial procurement work, as well as gradually increasing this work.

We will continue to issue our Device Advice newsletter to keep you informed of what we are currently working on. (To subscribe to this newsletter contact: devices@pharmac.govt.nz)

We will seek advice from across the sector as we go. We also acknowledge that as the sector changes and as we learn from our experiences, some aspects of our approach may need to be modified. As always if this arises we will be consulting widely.

For PHARMAC the next steps are to use the advice and ideas you have provided to ensure the model works and to determine what additional resources we will need to enable us to build on the work we have already started. We will also need to continue to consider our people, our internal processes and what technology we might need to enable us to do our work.

4. How will we define a medical device?

We know that many people have been seeking clarity about what is – and perhaps more importantly – what isn't a medical device. With the passing of the Medicines Amendment Act 2013, an amended Medicines Act definition of medical device will come into force from July 2014. While the new Medicines Act definition does not apply directly to PHARMAC's statutory role (which relates to pharmaceuticals including "therapeutic medical devices") it is a good starting point for understanding the scope of PHARMAC's hospital medical devices role. This definition states that a medical device:

- a) means any device, instrument, apparatus, appliance, or other article that—
 - i. is intended to be used in, on, or for human beings for a therapeutic purpose; and
 - ii. does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and
- b) includes a material that—
 - i. is intended to be used in or on human beings for a therapeutic purpose; and
 - ii. does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and
- c) also includes—
 - i. anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and
 - ii. any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of this Act.
- d) It does not include a device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations not to be a medical device for the purposes of this Act.

We consider that this definition provides a clear explanation of what is considered a medical device and what is not which will generally be appropriate in defining PHARMAC's area of responsibility. However despite this we do acknowledge that there may still be some products that do not clearly fall into this definition. When this does occur we will provide some clarity on a case-by-case basis.

5. What is the Pharmaceutical Schedule?

Under the New Zealand Public Health and Disability Act 2000, PHARMAC is required to manage and maintain a pharmaceutical schedule. The Schedule sets out eligibility for funding of pharmaceuticals and is required to be applied consistently by DHBs throughout New Zealand. Generally the end result of all PHARMAC's decision making is a change to eligibility for funding for a pharmaceutical. This change is then reflected in the Pharmaceutical Schedule.

Schedule listings

The rules applying to an item listed in the Schedule are important for determining what the effect of a listing is.

For example, the rules applying to community pharmaceuticals, hospital medicines and, 'optional pharmaceuticals' are different:

- Community pharmaceuticals are listed with a subsidy level for a specific brand and pack size. Only these items are funded (unless a specific patient application is approved)
- Hospital medicines are listed to chemical and formulation level, but unless a specific agreement has been entered with a supplier by PHARMAC, DHBs are free to determine which brands and pack sizes they use.
- 'Optional pharmaceuticals' are items that PHARMAC has entered national agreements for, and DHBs may utilise, but they still have discretion to use other products not listed.

Currently hospital medical devices are being listed as 'optional pharmaceuticals'. We intend to continue building this section of the schedule over the next couple of years, so it is a more comprehensive section of hospital medical devices.

As the number of devices covered by the Schedule becomes more complete PHARMAC intends to look at categories where there might be some standardisation opportunities. We will also take a greater role in the decisions around funding of new technology, and reflect any such decisions in the Pharmaceutical Schedule. This would mean that DHBs will be increasingly required to apply the Schedule to their hospital medical device purchasing. At this time we would need to implement parts of our model such as an applications process that includes greater clinical input, economic assessment, and an exceptions pathway. Details of these steps are discussed later.

Question:

- **What challenges, if any, do you see with us developing the Schedule in this way? If so, how might we overcome these challenges?**

6. PHARMAC's intended approach to managing medical devices

Many people have told us over the last year or so that the biggest challenge for managing medical devices is the huge range and complexity of products we will need to consider as well as the differences we may need to make to some aspects of our decision making process. We recognise that we will not be able to take a single approach to all devices as the range is too diverse and a one-size-fits-all approach will not work. We are proposing therefore to take a flexible, 'tool-box' approach depending on what device is being considered. Some applications or schedule changes will require a more involved process due to the complexity of the device being considered. Others may need little more than a commercial proposal, with some basic assessment, and a decision to change the Pharmaceutical Schedule, that is then communicated to DHBs.

Medical Devices

Not Funded

Decision Process

If Funded

Funding Applications

Exceptions Applications

Clinical Input

Clinical Risk Assessment

Prioritisation

User Input

Assessment

Commercial Approaches

Schedule

Contract Management

DHB Implementation Support

The activities we may undertake are set out in the diagram above:

It's important to note that we may use some, or all of these steps, and they may not necessarily be carried out in this order or at the same time. These are tools we can draw on, using those most appropriate to the item(s) we are considering at the time. We expect that, once budget management is in place, technology which is more expensive than its comparative treatment options (taking account of all health sector costs relevant to each treatment), is likely to require more scrutiny. This would ensure that any new investment is being targeted at the treatments providing the greatest value.

For many devices very few of these steps would be used. For products that are already managed we might only need to make a Pharmaceutical Schedule change such as a change in price. In that instance commercial negotiation, perhaps some clinical advice and an update to the Schedule might be all that is required.

What are the key points PHARMAC is proposing for each of the tools we might use in our approach?

The Schedule

Currently hospital medical devices are being listed as optional pharmaceuticals. We intend to continue building this section of the schedule over the next couple of years, so it is a more comprehensive section of hospital medical devices.

Funding applications

An application process provides a pathway for medical devices to be listed on the Schedule or for changes to be made to current Schedule listings. The application process will need to be flexible enough to deal with a wide range of applications for different devices with varying levels of complexity. Some medical devices would go through a far more comprehensive application process than others.

Exceptions applications

The need for an exceptions pathway will only become necessary once we have started applying restrictions to what devices can be purchased by a DHB. An exceptions policy sets out how we would consider funding medical devices that are not listed on the Schedule where there are special circumstances.

Risk assessment

Before considering a listing a new product, PHARMAC would gather enough evidence to understand whether the risks associated with a particular device are outweighed by its benefits.

Clinical input

As our work with devices gradually increases, PTAC and our sub-committees will be asked for their clinical advice when it is appropriate. However we recognise we will need broader clinical advice than we seek currently and will obtain this when we need to do so. We plan to work with the existing networks of clinical and non-clinical groups within DHBs and the New Zealand Health sector.

User input

When we need clinical and non-clinical input beyond our advisory committees to consider a device's suitability, we would consult the appropriate groups at the time. It may also be appropriate on occasion, to evaluate a product in the clinical setting to ensure its suitability for use by users.

Patient/consumer input

Finding out what the impact of changes might be on patients and consumers will be part of the process we use for evaluating those devices where it is relevant.

Economic assessment

PHARMAC intends to use cost-utility analysis (CUA) for the economic assessment of medical devices. This will be mostly used when considering the possible benefits, both clinical and financial, of new technology, particularly where the reported health benefits are at a higher cost than currently used pharmaceuticals.

Prioritisation

We are proposing, eventually, to prioritise all the investment options against each other. This means that when we get to full budget management, we will have a list that includes community pharmaceuticals, vaccines, hospital medicines and hospital medical devices.

Commercial approaches

Depending on the circumstances, PHARMAC is likely to use a mixture of open competitive process such as 'Requests for Proposals', and 'Request for Information', as well as direct contracting processes as appropriate to the circumstances and Government procurement policy.

Contract management

PHARMAC is open to discussing different contracting terms that are appropriate to the circumstances, and create value for DHBs.

Introducing devices into DHBs

PHARMAC's management of this important activity would involve close engagement and co-operation between suppliers, DHB and PHARMAC staff. PHARMAC's role is to ensure this is coordinated in a nationally-consistent way.

Question:

- How do you think our overall intended approach will work for managing hospital medical devices?
- What, if any, issues do you see with PHARMAC applying the different parts of our process to medical devices?

7. The steps in detail

We will now look at each of the steps of our approach in turn and explain what we are proposing to do for each of them. It is important to remember that for many devices being considered by PHARMAC, they would not have all these steps applied to them.

Funding applications

An application could be made for a new technology to be funded or for changes to be made to a current Schedule listing. Each application would be different depending on the characteristics of the device being considered and whether it is a new piece of technology.

An application is the way we would apply our range of tools to make a funding decision. The application process will need to be flexible enough to deal with a wide range of applications for different devices with varying levels of complexity. Some medical devices would go through a far more comprehensive application process than others.

In developing a flexible application process we have a range of tools such as clinical risk assessment, user input, economic assessment (see below for more details) that can be used if they are relevant for the specific application being considered. Some applications may require many of these tools and some may be reviewed more than once. Other applications may only need one or two tools to be used before a decision is reached.

The flexible, 'toolbox' approach, would also allow us to assess the clinical, local and commercial circumstances when we are considering devices for a Schedule listing. If there is a good reason for us to list a range of devices within a category we would do so.

A flexible application process means that there would be no standard process, though there would be some elements that would be usually required. This also means that the time to assess each application would not be the same. Our assessment of applications and the process of prioritisation for funding may mean that consideration of some applications may be quicker than others.

As work progresses PHARMAC would develop a set of application guidelines for new devices that would describe the information required from an applicant. To develop these guidelines we would consult with a wide range of clinical and non-clinical stakeholders at that time.

Question:

- Can you name any medical devices that you think we would not be able to use our range of 'tools' (i.e. risk assessment, clinical input, economic assessment etc.) on if we were considering an application?
- What factors do you think should influence how the various 'tools' are applied to medical device applications?
- What 'tools' not listed here do you think should be applied when we are considering a particular device?

Exceptions applications

The need for an exceptions pathway will only become necessary once we have started applying restrictions to what devices can be purchased by a DHB. A number of submitters to previous consultations noted that we would need to offer a way of considering technologies that were not listed on the Schedule, but where the standard application approach would

not be suitable. This is what an exceptions application pathway would provide for. The purpose of an exceptions policy is to be flexible and responsive to complex and unusual clinical situations. An exceptions policy would set out how we would consider funding medical devices that are not listed on the Schedule where there are special circumstances.

After considering the different attributes of medical devices we anticipate that all medical device exception applications would be able to be categorised into two groups:

1. This is very different (Unusual Clinical Circumstances)

We are proposing that the unusual clinical circumstances pathway would be for situations in which the clinical circumstances are so unusual that the time and resource required for consideration of a Schedule listing is not warranted given the limited direct financial impact on DHBs due to the relative rarity of the unusual clinical circumstances (i.e. they are unlikely to present in the same way again).

2. This can't wait (Urgent Assessment)

We are proposing that the urgent clinical circumstances covered by this pathway would be those where a patient in serious clinical circumstances would, within a timeframe of six up to 12 months, be expected to experience either significant deterioration or miss the opportunity for a significant improvement in clinical outcomes (length or quality of life) if they didn't receive the treatment.

For medicines, we have only considered exceptions applications on behalf of named patients. However, a medical devices exception policy might need to be applied more widely to include named health practitioners or other factors.

Once we are ready to consider exceptions we would ask for input from the sector on what our final proposal would be. Until we are ready to start that work (likely to be some time away) we will not be developing our exceptions pathways in any further detail.

How will we manage risk assessment?

PHARMAC does not have statutory responsibility for regulating medical devices. This is the role of Medsafe and will continue to be so until such time as a modern regulatory framework is in place. However, we do have a responsibility to ensure that, as far as possible, when making funding decisions we carefully weigh up the benefits and risks. In New Zealand, medical devices do not currently require any pre-market scrutiny prior to marketing.

Before considering a listing a new product, PHARMAC would gather enough evidence to understand whether the risks associated with a particular device are outweighed by its benefits. This is what DHBs currently do when reviewing new or changed products.

When we are considering the risks associated with a device, we propose using a range of risk assessment tools. The tools would only be applied as it is seen necessary for the level of risk associated with the device being considered. This would be a key step of an application process when we would seek appropriate advice (including clinical advice) as to the level of assessment that might be required. The types of assessment tools we propose using are outlined:

- > All products would require WAND notification before being considered. Evidence that the product data contained within WAND was current and complete would also be required.
- > PHARMAC would internally assess whether, based on the available evidence, it appears that the appropriate risk classification based on the Regulations has been assigned for a product. Any variations would be clarified with the supplier
- > For higher risk products we could require registration in a foreign jurisdiction (e.g. Europe, the United States, Canada or Australia) with pre-market approval processes and/or evidence of a third party conformity assessment¹ demonstrating the product complies with the IMDRF² Essential Principles for Safety and Performance
- > For lower risk products, evidence of self-assessed conformity assessment could be requested
- > PHARMAC could consider relevant aspects of the conformity assessment when seeking clinical advice on a product
- > Where uncertainty exists about the level of risk with a product, PHARMAC could require an independent conformity assessment be undertaken at the expense of the supplier.
- > Where a decision is made to list a product in the Schedule, the supplier would be contractually required to maintain the WAND database with accurate, up-to-date product information.

In using this flexible approach, rather than a standard one, we hope we would not be unnecessarily increasing compliance requirements for an application. Also PHARMAC wants to ensure application processes are straightforward for suppliers and decisions are made in a timely way. However, we have to be able to give DHBs and patients confidence that we have adequately considered the benefits and risks of a particular device and are making appropriate funding decisions.

Feedback during earlier consultations noted that PHARMAC is not a regulator or safety agency and quality assurance is beyond its scope. On the other hand stakeholders also emphasised the importance of quality and safety, and clinical input into funding decisions. It is because of this that PHARMAC considers a risk assessment approach an appropriate way to address this issue. An assessment would not result in an endorsement or an approval of a product for use, but would provide information about the risks and benefits of any funding decision that PHARMAC was considering.

We have also been told that it would be important to be clear about whose responsibility it is if an issue occurs with a funded device. Medsafe has, and would continue to have, the regulatory responsibility for managing any alerts or recalls that are issued for devices. Nevertheless PHARMAC can play a role in supporting DHBs to manage such events when they happen as we do now for medicines. For example, including indemnity clauses into supplier contracts requiring DHBs to be reimbursed for the resources involved in managing hospital level recalls, supporting communication to affected end users and managing alternative products.

¹ Conformity Assessments – assessments undertaken either by a notified body or the manufacturer (depending on the risk classification of the type of product) to determine whether a manufacturer's QMS meets relevant standards and products perform as intended. Assessments are usually based on IMDRF principles. It is important to note that the relationship between an assessment and a product is not "one to one" (ie, it will relate to the type of product not the specific product)

² IMDRF - A voluntary international forum of device regulators established in 2011 to discuss the future directions for medical device regulatory harmonisation.

Question:

- Do you think there is anything we have not considered in the proposed requirement for risk assessment?
- Are there any elements that you particularly support /do not support?
- Can you identify any gaps in the proposed approach, and how would you suggest these are addressed?

How will PHARMAC obtain clinical input?

Currently our main clinical advice for medicines comes from an expert committee of medical practitioners, the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC has been part of the health system since the 1930s and, in 1993, began providing advice to PHARMAC. Members are appointed by the Director-General of the Ministry of Health. Membership terms are usually three years and may be renewed. Further specialist advice comes from a range of subcommittees that provide, along with PTAC, objective, independent clinical input and give recommendations for prioritisation of funding.

(For further advice on PTAC's terms of reference see: <http://www.pharmac.health.nz/about/committees/ptac/>)

As our work with medical devices gradually increases, PTAC and our sub-committees would initially be asked for their clinical advice when it is appropriate to do so. However PHARMAC recognises that in order to take all relevant clinical aspects into account for our assessments for devices, we would need to engage with a wider range of experts than we have done in the past for medicines.

The processes to do this would be developed over time as our work develops, to ensure we are able to get the right advice from the right people at the right time. Before making any significant changes to how our current committees are organised, our early work with devices will help inform us as to what changes we may need to make and how best to make them. This would evolve over time.

We plan to work with the existing networks of clinical and non-clinical groups within DHBs and the New Zealand Health sector. They won't only be important in providing advice on specific medical devices, but would be able to provide us with guidance around who needs to be involved to make sure we are seeking all the appropriate advice at the appropriate times. These groups could be representatives from the different medical societies, colleges or other clinical or non-clinical groups and will be seeking nominations at the appropriate time.

A key concern raised during consultation has been the possible overlap of PHARMAC's clinical input work with that of HBL's clinical engagement framework. We will be working closely with HBL to try and coordinate our activity to prevent over-burdening clinical staff.

User input

We recognise, and have been told by many submitters, that we may need to consult with a wide range of people on the

possible suitability and usability of a device when considering Schedule listings and changes. The range of possible end users for many devices means that, in these situations, we would have to have a flexible approach to seeking user input.

Some aspects of our clinical input (such as Pharmacological and Therapeutic Advisory Committee – see section on clinical input) are defined by legislation.

However we recognise that on some occasions we may need specific user input to make sure that we are able to effectively make changes. If we need specific clinical input to consider a device's suitability, we would consult the appropriate clinical and non-clinical groups at the time. It may also be appropriate on occasion, to evaluate a product in the clinical setting to ensure its suitability for use by specific clinicians. The process to do this would evolve over time as our experience, ongoing advice and the work programme develops.

Patient/consumer input

PHARMAC is legally bound to have a Consumer Advisory Committee (CAC) to provide a consumer point of view on a range of PHARMAC's activities. Our consumer advisory committee provides us with a valuable and different perspective and would continue to be involved as our work develops. (For more information on CAC see: <http://www.pharmac.health.nz/about/committees/consumer-advisory-committee-cac/>)

However CAC cannot provide advice on specific patient experience. For some hospital medical devices, a patient may use them in hospital and then may be required to use them at home. As part of the overall decision making process, information about how a patient's experience may be affected by any changes will be important to know. Making changes to a device can have a huge impact on a person's life. While it may be possible to predict with some degree of certainty which changes may impact consumers, what that impact may look like is harder to assess.

As part of the various approaches to supporting the management of medical devices, and in response to feedback from previous consultations, finding out what the impact of changes might be on consumers would be part of the process we use for evaluating those devices where it is relevant.

Question:

- How do you think PHARMAC could effectively engage with the appropriate patients or consumers as new devices, or changes to devices, are considered?
- What kinds of devices or situations do you think it would be important for us to seek a patient or consumer view?

Economic assessment

Economic assessment is the process where the costs and benefits of a funding option are calculated and considered.

There are three fundamental economic concepts that summarise the issues PHARMAC faces each time a funding decision is to be made:

- Scarcity – funding resources will always be insufficient to support all possible treatment options we might have for both medicines and devices;
- Choices - as our funding resources are limited, decisions must be made regarding how best to use them; and
- Opportunity cost - by choosing to use resources one way, we lose opportunities to use the same resources for other options.

Every decision that PHARMAC makes has to balance these three issues in a way that enables good decisions to be made.

The assessments that PHARMAC would undertake for devices would be fit for purpose; that is they would only be as detailed as they need to be to enable us to be confident that the device can be prioritised appropriately. Assessments would use the evidence available which would include any clinical trials that may have been done. We would also seek expert opinions from a range of clinical advisors through our clinical advisory committees and any other relevant experts as necessary.

A number of people raised concerns in submissions that the assessment approaches PHARMAC applies to medicines won't be appropriate for medical devices, as there are many differences between medicines and devices. As all medicine interventions are different, all current assessments of medicines are also slightly different. The methods that we currently use we consider would be flexible enough for us to assess a wide variety of interventions and their benefits and costs. However, PHARMAC is tasked to secure the best health outcomes and so our analyses will focus on the decision's effect on the health of New Zealanders.

Cost-Utility Analysis (CUA)

CUA is a type of analysis where the benefits of a particular treatment are estimated using 'quality-adjusted life years' (QALYs). QALYs are a measurement that can be used to compare – in a consistent and standardised way – benefits of different treatments. In measuring QALYs, we look at the combination of two major things: a treatment's effects on how much longer we live, and also on how much better we live.

(For more details on CUA see <http://www.pharmac.health.nz/assets/economic-assessment-guide.pdf>. This guide discusses CUA in regards to medicines but is still relevant to the work that will be done for devices)

Using CUA would allow us to compare all forms of health technologies (medicines and medical devices) against each other using the same scale.

PHARMAC intends to use cost-utility analysis (CUA) for the economic assessment of medical devices; CUA would be mostly used when considering the possible benefits, both clinical and financial, of new technology, particularly where the reported health benefits are at a higher cost than currently used pharmaceuticals. CUA contributes to our prioritisation process in that it enables us to identify how to get the most health benefits for the New Zealand population by spending the available budget.

We appreciated the significant amount of stakeholder feedback on the types of costs we would need to take into account for devices that may be different to what we take into account when assessing medicines. The types of costs that may be considered in a CUA for a medical device include, but are not limited to:

- Start-up costs
- Capital
- Disposal costs
- Operating costs
- Costs for maintenance and repair
- Cost of hiring additional staff, or additional work for current staff
- Cost of need for supporting technology (including software compatibility)
- Overhead costs
- Cost of implementation
 - > Cost of training
 - > Cost of switching out devices that are already in use

The devices assessments that we undertake will take into account savings and costs that might impact the health sector, including health professionals' time, hospital facilities and capacity. Direct costs to patients are considered when applying the current decision criteria.

(Note: We have recently undertaken a review of our decision criteria so we are not seeking any further feedback on the criteria themselves in this discussion document. The review asked for feedback on how the criteria would be applied to devices. Once the submissions have been considered a final decision will be made by the PHARMAC Board on the decision criteria and their use in our decision making processes. The public consultation ended on 21 April 2014.)

Some submitters suggested that PHARMAC should consider wider social impacts, such as those to the environment, when undertaking its assessment. If there are environmental costs faced by the health sector these should be included, such as the cost of disposal. We acknowledge that these comments have also been raised in PHARMAC's consultation of changes to its decision criteria. Under the current decision criteria and decision-making processes, we would not be taking other, wider potential costs into account at this time. Possible impacts to other government agencies or other wider social costs may only be considered if they have an effect on the cost-effectiveness of the device being considered.

PHARMAC does not have a cost-effectiveness threshold for making decisions. Instead, what can be funded is determined by the budget available at any one time. PHARMAC aims to fund the products that will deliver the most health gain within the given budget. What is considered to be "cost-effective" changes from year to year, depending on the current budget, and what other options are available for investment. Also, because the PHARMAC decision criteria are much broader than just value for money, products may be funded even if their cost-effectiveness is relatively low (for example when there is a high health need but only one treatment option available).

The Prescription for Pharmacoeconomic Analysis (PFPA) sets out our standards for analysis for pharmaceuticals. (This document is available at <http://www.pharmac.health.nz/assets/pfpa-final.pdf>).

PHARMAC is due to review this document and update it to reflect the differences in the approach we will take to medical devices. At that time we will be seeking your feedback on any proposed changes.

Question:

- What issues, if any, do you see with PHARMAC using CUA as part of our assessment of medical devices?
- Are there any other costs or benefits that we should consider when making funding decisions that have not been mentioned

Prioritisation

At the heart of PHARMAC's decision making process for funding new health technology, or expanding access for already-funded technology, is the prioritisation process. This is where PHARMAC ranks all the potential proposals for funding and determines which proposals can be funded within the capped budget. The aim of this process is to make sure we get the maximum health benefits from the funding we have available. No matter the size of the budget PHARMAC will eventually hold, we won't be able to fund all new technologies, so difficult choices will have to be made.

A product's ranking on the prioritisation list reflects all of PHARMAC's decision criteria, and aims to balance all the different perspectives and sources of information about a product compared to its possible alternatives. Objective clinical advice is provided by the Pharmacology and Therapeutics Advisory Committee (PTAC). PHARMAC staff provides estimates of the value for money and of the budget impact of a proposal based on information from suppliers and other sources. They also negotiate with suppliers over potential conditions for funding, such as clinical guidelines, targeting to patient groups with greater ability to benefit, commercial risk-sharing arrangements, and price. The prioritisation list is dynamic and is updated regularly. Changes such as new evidence, new alternatives, or an alteration in price can impact on the prioritisation of a product.

We are proposing, eventually, to prioritise all our investment options against each other. This means that when we get to full budget management, we will have a list that includes community pharmaceuticals, hospital medicines and hospital medical devices. Including all options on one list will enable us to compare health benefits from all possible investment options. However budget arrangements have yet to be decided and full budget management is some way off.

Commercial approaches

When we consider what kind of commercial approach to take for a particular proposal, our focus is always on ensuring that we get the maximum health benefit we can from our decision. This means we will not always take the cheapest option if another offers greater health gain or savings elsewhere in the sector.

In contracting with suppliers, PHARMAC operates on a 'willing buyer, willing seller' basis. We are also required to act consistently with the Government Rules of Sourcing maintained by the Ministry of Business, Innovation and Employment (MBIE). PHARMAC's commercial approach for medical devices will be aimed at increasing competition for funding for medical devices.

Competition exists at a number of levels including the following:

- Competition between highly interchangeable products
- Competition for market share between similar but different treatments
- Competition for a limited pool of funding between different treatment areas

Depending on the circumstances, PHARMAC is likely to use a mixture of open competitive process such as 'Requests for Proposals', and 'Request for Information', as well as direct contracting processes as appropriate to the circumstances. For example, where there is competition between highly interchangeable products, we would be much more likely to use an open competitive process. As you move down the list there are likely to be more circumstances where the market need (including service requirements) lends itself more to a direct contracting approach. Any direct contracting activity would need to meet the requirements of the Government Rules of Sourcing.

Contract types

PHARMAC is open to discussing different contracting terms that are appropriate to the circumstances, and create value for DHBs. In general contracts would be for a listing on the Pharmaceutical Schedule, making the product available to DHB Hospitals. We intend to list pricing publicly due to the importance of transparency as we do now for medicines. However we would consider rebates or other discounting arrangements where the arrangement creates value that would otherwise not be available to DHBs.

PHARMAC is not proposing that there will be only one brand of each type of medical device that DHBs have to provide. We recognise that one size does not fit all and that clinical choice is important. However, we do expect that there will be situations where a particular medical device will be able to be used most of the time.

We anticipate that there will be some medical devices where, for a period of time, a single supplier can bring added value to DHBs. We expect there will be many where this is not appropriate. PHARMAC would tailor its approach to the category area and different devices within that category, based on advice it receives from the sector.

We are intending to follow a Category Management approach, where a Category Manager develops and implements a group strategy, taking account of appropriate clinical advice, and other relevant market and sector information.

Consultation – seeking feedback

On top of our specific clinical and user advice that we might seek during our decision making process, before a final decision is made regarding a schedule changes we also seek wider feedback on our proposal as we do now for medicines. This allows us the opportunity to consider anything that we had not considered during our decision making process.

When the decision is made to list a product

If a proposal is successful and approval is given for it to be funded, the device would then be listed in the Schedule and would be available for DHBs to purchase. We anticipate that DHBs would still have some discretion as to whether or not they make the device available to all their services. Once a

device is listed on the Schedule our contract managers would then take over the day-to-day issues associated with managing a contract.

Contract management

PHARMAC is already managing a number of contracts for medical devices. In these agreements, PHARMAC has been trialling a number of new key performance indicators (KPIs) for medical device contracts. Feedback from a number of submitters suggested that PHARMAC should have a role monitoring contract performance, the quality of products and associated services (training/maintenance) and ensuring there is continuity of supply. We will continue to monitor how contracts we are managing are working at a DHB level as we do now for hospital medicines

It is envisaged that PHARMAC contract managers would have relationships with specific suppliers rather than a category of products as they do now for medicines. This enables long term professional relationships to be maintained and also means that any issues are dealt with in a consistent way. A number of submitters commented on how important these relationships are and we intend to continue managing our supplier relationships to the high level we have done in the past.

Several submitters posed a number of questions to PHARMAC relating to continuity of supply, product safety and in particular product recalls. PHARMAC would work with the supplier, Health Alliance, the logistics provider, the DHBs and Medsafe (in the event of a product recall or alert as we do now for medicines), to ensure that if a problem has arisen it is managed appropriately by the relevant agencies. PHARMAC contracts already have clauses outlining responsibilities should an issue arise.

As PHARMAC negotiates new contracts within different categories, any contracts held by either the DHB or Health Alliance will remain in place and continue to be managed by those agents until such time as a PHARMAC contract supersedes it.



Question:

- What suggestions do you have on which existing cross-DHB groups might be able to provide feedback on how PHARMAC contracts are working?

Introducing new or different devices into DHBs

Feedback from our previous consultations made it very clear that an important part of considering changes to devices in a DHB was recognising the possible impact the changes might have on the various users and the wider DHB itself. We know that if we want to gain the best outcomes from any decisions made, we need to support DHBs as they ensure the devices are used by the correct person, at the right time and in the right way.

PHARMAC's management of this important activity will involve close engagement and co-operation between suppliers, DHB and PHARMAC staff. PHARMAC's role is to ensure this is coordinated in a nationally-consistent way. We will ensure that any changes are managed smoothly and that we monitor how

effective the change has been and deal with any issues that may arise. DHBs and suppliers currently play an important role in ensuring smooth transitions, and they will continue to do so.

Activities

Feedback we have received has highlighted that there are a range of activities and support tools that DHBs currently use to support changes in products being used, their introduction and their use. These include:

- Training programmes and resources for clinical staff – vary depending on the number of potential end users and the degree of complexity of the new device. It could be as simple as an information sheet, to an intensive course held off-site, running over several days. Suppliers often provide this activity, as do DHBs.
- Information/training for patients/whanau- depending on the level of a change this could be as simple as an information sheet from a supplier or as complex as several days on a course with a clinical specialist from the DHB or supplier.
- Training for DHB support systems e.g. sterilisation services, clinical engineering. This may be as simple as identifying the new device and the supplier explaining the specific requirements or as complex as requiring an off-site intensive training course over several days organised by the DHB or supplier
- Equipment maintenance and servicing – for the device to work correctly, regular maintenance and/or calibration is needed. There may also be specific infection control processes to be followed.
- Large scale change management programme- for some large and/or highly specialised, complex devices that need substantial changes to support their integration into the DHB e.g. significant building alterations, large scale staffing changes/training requirements or other impacts to the DHB workforce. This may require DHB management and significant staff involvement to support the programme
- Post implementation evaluation – once a device has been introduced and is being used by DHBs there is usually an evaluation of how the implementation process went.

Many of these activities will continue to be required as we move to greater management of medical devices. PHARMAC's role will be to ensure that, particularly for more significant changes or the introduction of a new product, that appropriate support to enable DHBs to manage the change is included in the planning before a decision is finalised.

In order to achieve this, PHARMAC will work to make sure the possible impacts of any changes are considered as part of our assessment process. Where the impacts are more significant, an implementation plan would be developed with the assistance of DHBs and suppliers. We may ask suppliers to provide information on their proposed implementation activities, we would make contact with key DHB staff to understand the impact of a change on them, and ask what support may be required to implement the change. Any costs associated with making a change would, when appropriate, be considered within the economic assessment, and the overall costs of the proposal. (See section on economic assessments)

When considering which changes are more significant, we have identified the following factors that we consider are likely to be relevant. We are open to your feedback on any other

factors you think we should include in our thinking:

- Risk classification of the device as set by Medsafe
- What other systems does the device need to be connected to (e.g. IT, medical gases, power, water)?
- Will there need to be changes made to buildings or other facilities for installation or permanently?
- Who are the people likely to be using the device
- Other issues such as whether it will need regular checks by engineers or other technical staff

For example, devices that are classed as high risk, with highly complex inter-related system requirements and a wide range of end users, are more likely to need a comprehensive package of implementation support that includes many of the tools.

For low risk consumables with minimal impact to the end user, simple resources may be all that is needed.

For devices managed by PHARMAC, we will make sure the required support tools are planned for and put in place. The actual 'tools' may be provided in the DHB by a range of parties including device suppliers or DHB staff. The degree of direct PHARMAC involvement will depend on the specific device and may range from just ensuring contract clauses are present to actively engaging with DHB staff to support an implementation programme. PHARMAC's role is to ensure that implementation is planned for and coordinated in a nationally consistent way and that all changes are managed smoothly.

Question:

- What other characteristics, if any, do you think PHARMAC should take account of when determining how much, and the type of support that is required to implement a new device?
- What challenges, if any, do you see with PHARMAC taking this approach? How might these be overcome?
- What challenges, if any, do you see for DHBs with this overall approach? How might these be overcome?

8. Submission process

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

Deadline:

Submissions may be made until **5pm, 20th June 2014**

How to make a submission:

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 we seek your input into our discussion document. The following outlines where and when we will be holding these meetings:

Palmerston North

Friday 16 May
Medical Lecture Theatre
Palmerston North Hospital
12pm – 2pm

Hamilton

Tuesday 20 May
Bryant Education Centre
Waikato Hospital
12pm – 2pm

Dunedin

Thursday 22 May
Octagonal Room
Dunedin Hospital
11am – 1pm

Christchurch

Friday 23 May
Oncology Lecture Theatre
Christchurch Public Hospital
12pm – 2pm

Auckland

Monday 26 May
Auditorium, Clinical
Education Centre,
Auckland City Hospital
12pm – 2pm

Auckland

Friday 30 May
Main Lecture Theatre,
Ko Awatea Centre,
Middlemore Hospital
12pm – 2pm

Wellington

Tuesday 3 June
Small lecture theatre,
School of Medicine,
University of Otago
Wellington
12pm – 2pm

Invercargill

Wednesday 11 June
CBS Room Kew Hospital
12pm – 1.30pm

Please contact Raylene Bateman on (04) 901 3232 if you would like to arrange a time to meet with PHARMAC.

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.

9. Appendix 1

The list of the questions asked through the document:

Section 5: What is the Pharmaceutical Schedule?

- What challenges, if any, do you see with us developing the Schedule in this way? If so, how might we overcome these challenges?

Section 6: Our intended approach

- How do you think our overall intended approach will work for managing hospital medical devices?
- What, if any, issues do you see with PHARMAC applying the different parts of our process to medical devices?

Section 7a: Funding applications

- Can you name any medical devices that you think we would not be able to use our range of tools (i.e. risk assessment, clinical input, economic assessment etc.) on if we were considering an application?
- What factors do you think should influence how the various 'tools' are applied to medical device applications?
- What 'tools' not listed here do you think should be applied when we are considering a particular device?

Section 7c: How will we manage risk assessment?

- Do you think there is anything we have not considered in the proposed requirement for risk assessment?
- Are there any elements that you particularly support /do not support?
- Can you identify any gaps in the proposed approach, and how would you address these?

Section 7e: Patient/consumer input

- How do you think PHARMAC could effectively engage with the appropriate patients or consumers as new devices, or changes to devices, are considered?
- What kinds of devices or situations do you think it would be important for us to seek a patient or consumer view?

Section 7f: Economic assessment

- What issues, if any, do you see with PHARMAC using CUA for the economic assessment of medical devices?
- Are there any other costs or benefits that we should consider when making funding decisions that have not been mentioned?

Section 7i: Contract management

- What suggestions do you have on which existing cross-DHB groups might be able to provide feedback on how PHARMAC contracts are working?

Section 7j: Introducing new or different devices into DHBs

- What other characteristics, if any, do you think PHARMAC should take account of when determining how much, and the type of support that is required to implement a new device?
- What challenges, if any, do you see with PHARMAC taking this approach? How might these be overcome?
- What challenges, if any, do you see for DHBs with this overall approach? How might these be overcome?

10. Appendix 2

Summary of responses to submissions we have received

Submission content	PHARMAC response and proposed action
General questions/issues	
<p>A number of submitters commented on the need to have a range of approaches to managing devices due to the large variability between the different types. A one size fits all approach will not work.</p>	<p>We agree that this needs to be reflected in our approach. To address this we are recommending that a flexible approach is used across all aspects of the PHARMAC model. What steps are applied and to what extent, will depend on the characteristics of the device under consideration.</p> <p>(For more details see section 'PHARMAC's intended approach to managing medical devices')</p>
<p>Discussion as to the inclusion of devices within the pharmaceutical schedule was raised a number of times by various submitters. The main issue was that term 'pharmaceutical' would be confusing if it referred to devices and medicines.</p>	<p>We agree using the term pharmaceutical to describe devices is confusing. However, the following legal definition (NZPHD Act) of pharmaceuticals captures devices also:</p> <p>Pharmaceutical means a medicine, therapeutic medical device, or related product or related thing.</p> <p>(For more details see 'How will we define a medical device?')</p>
<p>In defining the scope of a funded medical device some submitters suggested applying definitions of a device used by other agencies. Some submitters suggested that some devices be excluded from PHARMAC review</p>	<p>We agree it is useful to use an existing definition as the basis for ours and are proposing to use the Medicines Amendment Act 2013 definition of medical device (which would also apply to Medsafe) which is similar to or based on WHO and other international definitions. This states that :</p> <p>"Medical device means any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold, or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose."</p> <p>(For more details see section 'How will we define a medical device?')</p>
<p>Other submitters commented on the increasing use of hospital devices in the community</p>	<p>We acknowledge this is a key issue; The Pharmaceutical Schedule already includes a Rule in relation to the community use of medical devices provided to patients in hospitals (e.g., insulin pumps); as our role increases we intend to keep the hospital-community interface in mind.</p> <p>Although PHARMAC has a mandate to also manage community devices, and does manage a small number of them, Cabinet has at this time asked PHARMAC to focus on expanding its role with hospital devices.</p>
<p>Defining what constitutes a 'new' device produced a range of responses but a common theme was 'where there had been a change in functionality or something that delivers a new therapeutic benefit'. Other submitters recommended that changes to software applications should not render a device 'new' nor should a next generation product. It was agreed by a number of submitters that a range of clinical advice should be sought when considering a new device.</p>	<p>For PHARMAC's purposes a new device is anything that is not listed in the Pharmaceutical Schedule. This may be a device that has not been used within the health sector before or an existing device that PHARMAC has not yet considered. Any changes to the Schedule would only be made after seeking the appropriate advice.</p>
<p>Determining if one device was interchangeable with another raised a number of responses. A large range of factors were suggested that need to be considered when making such decisions.</p>	<p>All funding decisions of this nature would need to be informed by appropriate clinical input. If the suitability of a product needs to be considered this would be done with the appropriate clinicians or consumers.</p> <p>(For more details see sections 'Clinical input' and 'User input')</p>

Submission content	PHARMAC response and proposed action
General questions/issues	
<p>A risk that was frequently repeated was that clinicians would lose the ability to provide appropriate treatment options as there would be no choice which would lead to loss of positive health outcomes</p>	<p>Where variation is necessary to ensure a health benefit this would be maintained. PHARMAC recognises the importance of making decisions informed by clinical advice and would seek clinical input on all decisions.</p> <p>Should a situation arise that we had not considered when deciding what would be listed on the Schedule, an application would be able to be made through the exceptions process.</p>
<p>A number of submitters raised concerns regarding the confusion surrounding role clarity within the sector due to the number of possible different agencies involved with implementing new devices, with PHARMAC starting work, the possible duplication of processes</p>	<p>For devices that PHARMAC is managing we will have the lead on identifying any implementation activity needed to support that device. This may mean that a number of other agencies could be involved in providing the actual support activity.</p> <p>We will continue to work with hA and HBL (and any other relevant agencies) to ensure the sector is clear about who has what responsibility.</p> <p>(For more details see section Introducing devices into DHBs) and general section Introducing the end state)</p>
Listing on the pharmaceutical schedule (For more details on the Schedule see section 'What is the Pharmaceutical Schedule?')	
<p>A number of submitters noted that there is a need to maintain the current variation between DHBs' purchasing of devices. Particularly mentioned were the different needs of specialties and the specific needs of some patients</p>	<p>We recognise that there would often need to be a range of devices available to cater for the range of patients and clinicians. This would be an important consideration in determining the range of devices on the Schedule. There would be a range of commercial approaches used as well as an exceptions pathway for devices similar to that for medicines to meet the needs of both clinician and patient.</p> <p>(For more details see section 'Exceptions applications' and 'Commercial approaches'.)</p>
<p>A number of submissions commented on the need to support local technology development. The loss of support for industry within New Zealand was seen as a possible risk of PHARMAC's work.</p>	<p>The PHARMAC model is dependent on having a competitive market available to us. It is therefore important to us to have a wide range of suppliers in the market as well as new technologies available for future investment and to improve health outcomes. Primary support of the local technology industry is not within the remit for PHARMAC.</p>
<p>A small number of submitters commented on who should be involved with limit setting on device use. A number felt that such decisions should be made by clinical staff with DHB local budget managers being involved.</p>	<p>PHARMAC decisions would be made with a range of clinical advice and input.</p> <p>Where there is a range of options on the schedule individual DHBs would be able to decide which products they wish to purchase.</p> <p>(For more details see section 'What is the Pharmaceutical Schedule?')</p>
<p>A number of comments were made regarding the involvement of DHB management in funding decisions. Concerns were raised over capital expenditure decisions and how the impacts of possibly major change would be assessed and managed.</p>	<p>PHARMAC will be expected to have some role in relation to items included within capital expenditure I. The extent of this role will depend on funding arrangements with DHBs and will likely evolve over time..</p> <p>(For more details see section 'Introducing devices into DHBs')</p>

Submission content	PHARMAC response and proposed action
Application for new medical device to be listed on schedule (For more details on applications see section 'Funding applications')	
<p>The key issues commented on regarding the application process were that the process be clearly articulated and be rapid.</p>	<p>The application process would need to reflect the variety of possible devices and so would not have a 'one-size-fits-all' approach. As PHARMAC has the responsibility to robustly assess and prioritise its decisions within managing a capped budget, timeframes for a funding decision would vary. It should also be noted that application does not guarantee a schedule listing. All funding decisions are made to meet our statutory objective to get the best health outcomes reasonably achievable from the funding available.</p>
<p>Substantial clinical input into decision making was recommended by a range of submitters</p>	<p>We recognise that for devices the range of clinical advice would need to reflect the range of users associated with that device and so would vary accordingly. Our approach will ensure that all the appropriate clinical input is gained would be established.</p> <p>(For more details see section 'Clinical input')</p>
<p>A number of comments were made on the need for the system to be able to accommodate variations. The suggestion was made that custom made devices be exempt from listing in the schedule.</p>	<p>PHARMAC would account for the need for appropriate variation in setting up the Schedule, and we are proposing that there would be an exceptions process which would include an urgent consideration pathway for special circumstances. At this stage we have not decided to exempt any particular medical devices from our consideration.</p> <p>(For more details see section on 'Commercial approaches')</p>
<p>A range of information was submitted that was felt needed to be collected during the application process. (e.g. the material composition of the device, how the device differs, pre and post market support)</p>	<p>We recognise that there would need to be slightly different application processes for different devices and also variations depending on what kind of Schedule change is being considered. This means that there would be a process that would reflect the aspects that need to be considered for the type of device or schedule changes being considered. There would however be application guidelines developed to help with the application process.</p> <p>(For more details see section 'Funding applications')</p>
<p>A number of submitters commented on the need for an urgent application process with one suggesting that the National Health Committee or Medsafe could take on this role.</p>	<p>We are proposing an exceptions process that would include a pathway for urgent decisions. We also recognise that the circumstances for exceptions would be wider than that currently used for medicines.</p> <p>Neither the NHC nor Medsafe have responsibility for making devices funding decisions on behalf of the DHB's.</p>
Clinical risk assessment of medical devices (For more details see section 'How will we manage risk assessment')	
<p>It was stated by a number of submitters that regulation of devices was not PHARMAC's role</p>	<p>We agree. Medsafe has the responsibility to ensure that any device used in New Zealand is registered. However where it is considered appropriate, PHARMAC would gather enough information to be sure that any risks are outweighed by the benefits.</p>
<p>There was concern expressed that should PHARMAC require changes to the regulatory process this would unnecessarily lengthen and complicate the application process</p>	<p>As noted above regulatory requirements will continue to rest with Medsafe. Any extra activities around risk assessment PHARMAC considers are required to inform its decisions would be based on a case-by-case approach.</p>

Submission content	PHARMAC response and proposed action
Risk assessment of medical devices (For more details see section 'How will we manage risk assessment')	
<p>A number of submitters highlighted some of their concerns regarding the current low bar set for registration of devices when compared to medicines. Many devices have limited research available demonstrating long term safety, with heavy reliance on post-marketing reviews to raise any safety issues.</p>	<p>For new devices entering the market PHARMAC's approach would ensure as far as possible that a robust and appropriate risk assessment would be undertaken, appropriate for the device under consideration. The introduction of ANZTPA would also increase the rigour of product assessments. Until then PHARMAC will ensure any decision to fund a device is made using the most rigorous assessment that is possible and appropriate for the device under consideration.</p>
<p>A range of submitters suggested alternative methods for approval of devices utilising overseas jurisdictions and processes, reflecting these approval processes within the current WAND database</p>	<p>As part of PHARMAC's proposed approach, consideration of other approval processes would be included. The level of rigour would depend on the specific device under consideration.</p> <p>PHARMAC will be liaising with Medsafe on their work with the WAND database</p>
<p>Comments were also made regarding long term monitoring of certain devices, in particular implantable devices, and the need for PHARMAC to take an active role in ensuring patient safety</p>	<p>Post-marketing surveillance is the responsibility of the regulator, Medsafe. However we are aware of some concerns around this issue and so would monitor it moving forward.</p>
<p>Questions were raised about the challenges associated with managing ongoing technology upgrades particularly in relation to IT developments</p>	<p>PHARMAC recognises the substantial changes happening across the sector and will be working with all relevant parties to ensure any decisions made by us would be in alignment with other sector directions. We recognise that the wider impact of any changes need to be considered as part of the decision making process.</p>
<p>Several comments were made regarding recalls/alerts and other performance issues and how these were going to be managed in the future</p>	<p>Medsafe will continue to have the overall responsibility for managing recalls and alert issues. PHARMAC contract managers would support the management of any issues related to funded devices as per contractual agreements ensuring supply issues are managed as smoothly as possible.</p>
Clinical input (For more details see section 'Clinical input')	
<p>While a previous consultation document specifically addressed clinical input, many submitters commented on the importance of gaining clinical input across the various sections of the PHARMAC process.</p>	<p>We recognise the need for clinical input across our processes and are developing an approach that would ensure we get the best, appropriate advice we can for each decision. We also recognise that we would need a wider range of clinical expertise than we currently have for medicines, acknowledging that devices have a much wider range of end users (e.g. Nurses) and other support requirements (e.g. clinical engineering).</p> <p>We also acknowledge that there would be occasions when we would need to seek user input into a decision where a product's suitability is in question. At that time we would seek the appropriate users (both clinical and non-clinical) to ensure we have all the information we need to make a decision.</p>

Submission content	PHARMAC response and proposed action
Economic assessment (For more details see section 'Economic assessment')	
<p>Many submitters stated that effectiveness and safety should be the primary concerns when considering a new application. Comparisons should only occur once this information was received.</p>	<p>We agree that efficacy and safety are important aspects of any application and would always be considered as part of an assessment. Clinical advice on the quality of the available evidence would be the key to deciding if an application is progressed to full assessment or not. Depending on the device being considered a clinical risk assessment would also be undertaken to provide information on the benefits and harms that may be associated with the product.</p> <p>(For more details see section on 'How will we manage risk assessment')</p>
<p>A number of factors were submitted that many felt needed to be taken into account when making any assessment. These included:</p> <ul style="list-style-type: none"> • Clinicians preferences (gaining consensus on devices was seen as being unlikely) • Clinical requirements • Training requirements • Assurance of continuity of supply • Associated consumables • The need for ongoing device support. 	<p>When assessing any new application a range of variables would be considered. In response to the particular factors that were suggested:</p> <p>Clinician preference would not be considered separate from consideration of the health benefits that the device would achieve (where there is a particular reason for a specific request an application under the exceptions process can be made)</p> <p>Any application must demonstrate health benefits to the consumer.</p> <p>Compatibility to current systems would be considered</p> <p>Training requirements would be assessed and provisions made (frequently this would be within supplier contracts where appropriate)</p> <p>Supplier history would be considered as part of the assessment</p> <p>The cost of the provision of associated consumables would be included</p> <p>Service and monitoring requirements would be factored into the assessment and managed predominantly through the contract</p> <p>(For more details see section 'Economic assessment')</p>
<p>One submitter requested that selected groups of devices be excluded from PHARMAC's review</p>	<p>PHARMAC has been asked by Cabinet to apply the PHARMAC model of assessment and prioritisation to all current medical devices and all new technology</p>
<p>When considering what other costs should be considered a number of submissions asked that impact on whole of society be taken into account</p>	<p>We do not consider wider costs to society in general. There is a risk of acting inconsistently with our statutory objective if such broader considerations are substantially taken into account when PHARMAC makes decisions. Factoring in the impact of PHARMAC's decisions on non-health objectives also raises a number of theoretical and practical issues including:</p> <ul style="list-style-type: none"> • ethical and legal considerations – e.g. should the needs of paid workers be valued more highly than children/elderly people? To do so may well be considered discriminatory under the Human Rights Act 1993; • differences in assumptions used by other government agencies resulting in inconsistent analyses; and • the difficulty and cost of PHARMAC accurately estimating the impacts of potential decisions to areas outside the health sector <p>However costs to the health sector would be taken into account. These include such items as doctor/nurse time, use of hospital facilities and hospital capacity.</p>

Submission content	PHARMAC response and proposed action
Economic assessment (For more details see section 'Economic assessment')	
Inclusion of overseas data was seen as being important	Information and reviews from other jurisdictions, both national and international, would be included where appropriate
A number of questions were asked as to the degree that the assessment process would be applied to any one application	We would be taking a 'tool box' approach, applying the appropriate assessment tools at any one time depending on what the application is for, and the type of schedule change being considered. Every assessment would be tailored to the circumstances so our approach would be flexible enough to incorporate a wide variety of both costs and benefits.
When considering what should be taken into account in relation to costs and savings a number of items were discussed. These included whole of life costs, services provided by suppliers, IT compatibility and systems integration, costs to the environment, and the relative merits of reusable verses disposable.	<p>When considering an individual application the range of associated issues would be reviewed and assessed appropriately. We recognise that this will be highly variable depending on the device under consideration.</p> <p>Environmental costs are at this time not considered. However environmental impacts can result in health benefits, costs and / or risks. In instances where this is the case, the health outcomes can and should be considered as part of PHARMAC's decision making framework, to the extent that this is possible.</p>
When considering sources of information for assessment a number of suggestions were made ranging from local DHB staff to national agencies, to international evidence reviews.	<p>Clinical input from a range of professions would be an essential part of the assessment process. We recognise the need to ensure the right range of people is consulted for any individual application. This would include considering any relevant information from international jurisdictions.</p> <p>We also recognise that in some instances the input of patients/consumers may be required to enable the best decision to be made</p>
Some comments were made on the possibility of local evaluations being undertaken with evidence being built up from local use.	There may be some instances where a product is evaluated within a DHB as part of the assessment process to enable real-life assessment within a New Zealand setting.
A number of submitters made comments regarding options such as PHARMAC taking on a broader role within the health sector such as managing a range of budgets; covering regulatory costs, and providing micro cost analyses to suppliers.	These issues are all outside the scope of the PHARMAC model. Cabinet has requested PHARMAC to only apply its assessment and prioritisation model to medical device management within a capped budget. Any data collated as part of a review and/or assessment would be available.
Purchasing strategies and contract management (For more details see section on 'Commercial approaches')	
A number of submitters reflected concerns that taking a standard approach to contracts will not reflect the variety of devices that will be under consideration	Contracts would reflect the type of device that is under consideration. Key performance indicators would be included and conditions would reflect the specifics of that device e.g. training or on-going support.
Leasing of equipment was raised as a potential issue	The application process would consider leasing as part of the assessment for a particular device
Several submitters commented on a range of procurement approaches that might be used as well as different contractual arrangements.	<p>All PHARMAC procurement activity would be consistent with the Government Procurement Guidelines.</p> <p>A range of approaches would be used dependent on the particulars of the device under consideration.</p>

Submission content	PHARMAC response and proposed action
Purchasing strategies and contract management (For more details see section on 'Commercial approaches')	
A number of submissions were made in regards to the use of rebate pricing strategies. Comments were both in favour and some concerned that rebates may become perverse incentives for inappropriate use of some items. DHBs also raised the possibility that rebates could be returned to the department that the savings were made from.	Rebates are one tool that can be used as part of the PHARMAC management approach but would only be used when deemed appropriate to the specific application under consideration. Funding arrangements, including how rebates are dispersed to DHBs would be agreed between PHARMAC and DHBs.
Current DHB purchasing processes have many favourable characteristics that submitters from both DHBs and industry presented as desirable long term	The current range of features would be considered as we develop our approach to a particular area of medical devices.
Industry submitters also recommended a number of improvements to the current system (e.g. improve consistency of process for procurement, standardise basic terms and conditions with customised agreements with DHBs, longer contract terms)	These have been reflected in the development of our approach particularly in recognising that no one approach would be appropriate for all devices. Develop an approach to provide greater national consistency is what PHARMAC has been requested to do but at the same time, we recognise that where clinical practise requires a degree of flexibility this would need to be retained.
A question was asked about current contracts held by DHBs and whether these would be taken over by PHARMAC.	Contracts already in place would remain in place until a PHARMAC negotiated contract supersedes the DHB/hA negotiated contract.
Integrating new devices into hospital processes (For more details see section 'Introducing new devices into DHBs')	
A range of submitters commented on the strengths of the current system which ranged from clinical autonomy to close working relationships with DHB staff and suppliers that ensures smooth and rapid integration of new products	The PHARMAC approach acknowledges the importance of a range of clinical input into the decision making process as well as the importance of supplier relationships and their role in supporting the introduction of new products into a DHB.
A number of weaknesses with the current system were identified by a range of submitters particularly variability in the processes and available resources in different DHBs.	National consistency is a key aim of PHARMAC's role in the management of devices. Implementation planning would consider the available resources and current support systems within DHB's as part of assessing the requirements for implementation support.
Suggested improvements on the current system came from a number of submitters and ranged from the introduction of standard processes to dedicated project managers for implementation	PHARMAC recognises that integration of new devices would vary according to the type of device under consideration. Planning would involve assessing what would be needed for support and then ensuring the various activities are in place. The provider and intensity of the support would vary depending on the device under consideration but may range from, for example, a simple information sheet produced by a supplier to a full multimedia communications plan, or from a simple training demonstration to an off-site training course over several days, all dependent on the particular device under consideration.
Communication processes were raised as a possible issue by a number of submitters with concern that the appropriate DHB staff need to be involved in discussions	As part of our clinical and non-clinical input we would ensure that the appropriate people are involved. We would also be seeking advice as we look at the possible implementation impacts of decisions and how best to manage these. We would also be ensuring that when key decisions are made they are communicated to the sector as clearly as possible.
Risk management post implementation was raised by several submitters with questions asked as to how issues with PHARMAC managed devices would be dealt with	PHARMAC would work closely with Medsafe to monitor any issues that arise as well as ongoing management of supplier contracts to ensure any issues are dealt with promptly. Safety of both patients and staff would always be paramount.

11. Appendix 3

Our relationship with other agencies

Health Benefits Limited (HBL)

Cabinet acknowledged that, in order for PHARMAC to gain the maximum benefits from managing medical devices on behalf of DHBs, it would need comprehensive and consistent data regarding the use of hospital medical devices from all 20 DHBs. We also need the means to manage compliance with the Pharmaceutical Schedule and how new technologies are introduced into a DHB.

HBL is currently working with DHBs to build a National Catalogue of all the things DHBs currently use, and a single financial management information system across all DHBs.

The financial management system and the Catalogue will, amongst other things, provide PHARMAC with the data and tools to create the most effect from our role.

Shared Services (including healthAlliance)

HBL is establishing new processes for DHBs' shared services – including procurement. These operating systems are outlined in HBL's Finance Procurement and Supply Chain shared services operating model. The changes will apply to medical device procurement in areas that PHARMAC isn't yet managing, as well as some we are managing. healthAlliance has been chosen by HBL as the organisation that will manage procurement activity for DHBs until PHARMAC has applied its management approach to the range of medical devices.

PHARMAC's activity will be carried out incrementally, on a category by category basis and will take time, so healthAlliance will continue to have a medical device procurement role for some time. Once PHARMAC is managing all medical devices, some procurement activity for medical devices – such as purchasing – will remain within the scope of the shared services and will not be undertaken by PHARMAC.

Medsafe

PHARMAC does not decide which pharmaceuticals are safe for use in New Zealand: this is the role of Medsafe. Medsafe is the Medicines and Medical Devices Safety Authority. Medsafe is responsible for the regulation of medicines and medical devices in New Zealand to ensure these products are acceptably safe for use. PHARMAC works closely with Medsafe and will continue to do so.

National Health Committee (NHC)

NHC has a mandate to provide the Minister with advice on which services and procedures should be publicly funded, including new technologies. We have a MOU that describes our joint working relationship.

12. Appendix 4

Other resources

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

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

Our previous medical device consultation documents can be found at: www.pharmac.health.nz/medicines/hospital-devices/consultations/

Information on the consultation on our decision criteria can be found at: www.pharmac.health.nz/about/operating-policies-and-procedures/decision-criteria-consultation

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

PHARMAC

Pharmaceutical Management Agency

Pharmaceutical Management Agency

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