CONSULTATION

PHARMAC
Pharmaceutical Management Agency

17 May 2013

Request for Feedback on PHARMAC'S Initial Medical Device Activity

PHARMAC is in the process of expanding its role to include procurement and management of medical devices. As part of this work, PHARMAC intends to pick up some specific procurement activities to help develop its systems and generate benefits for the DHBs over the next 12-18 months. We would now like to seek your views on the areas we propose to undertake activity in, and invite comment on key issues to consider in those areas.

We are aware that feedback requests have been made in the past for various reasons, and you may have provided information you think relevant to this request previously either to PHARMAC, or to another agency such as HBL. In this case you only need to refer to your past feedback, and we will locate it.

This document sets out some background, and while there may be numerous approaches we might consider, we need to determine what will be appropriate in each context. By obtaining your feedback we anticipate it will assist us in building our processes going forward.

We have also attached an outline of the areas we are proposing to undertake activity in and some specific questions about each. We appreciate your time is valuable and hope the detail in this document provides you with an adequate overview of PHARMAC's current thinking. We do not expect every respondent to answer all the questions, just those that are relevant or of interest to you.

Once we have received feedback from stakeholders, the submissions will be collated and considered. We will use this information to inform which areas to focus on, and help inform the activity in each of these areas. We expect there will be a need for ongoing discussion with stakeholders over the following months as we develop our specific approaches in different areas.

There will be further opportunity to input into this work and we look forward to hearing from you and working with your organisation to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into the health sector.

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Providing Your Views

You can provide your responses to this Request for Feedback in one of the following ways:

1. Email: devices@pharmac.govt.nz

2. Fax: (04) 460 4995

3. Post: Medical Devices Procurement Team
   PHARMAC
   PO Box 10-254
   Wellington 6143

4. We also invite you to meet with us to discuss your views or feedback. Please email devices@pharmac.govt.nz if you are interested in meeting with PHARMAC staff to discuss this request.

We would like to start collating the feedback in June, therefore would appreciate your responses by **Friday, 14th June 2013.**

Information requested under the Official Information Act

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

If there is any other part of your response or correspondence that you consider could properly be withheld under the OIA, please include comment to this effect along with reasons why you want the information withheld.

Categories

PHARMAC's preliminary work, including that with Health Benefits Limited and National Health Committee, has identified the following categories of devices as possible projects for PHARMAC to commence with (a background summary of these categories is attached at the end of this communication):

Anti-Embolism Stockings
Disposable Sterile Instruments
Hand Hygiene
Interventional Cardiology
Mechanical Compression Devices and Consumables
Orthopaedic Implants – maximisation of suite of contracts
Sterile Surgical Gloves
Sterilisation Wrap, Tray Liners and Associated Consumables
Sutures
Thermometers
Wound care

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Questions

PHARMAC is happy to receive any feedback you have on any of the category areas, and the relevant processes or issues that you think we should be aware of. We understand some responders may wish to focus their feedback to particular areas. In order to help focus submissions we have set out some questions relevant to DHBs (a separate document with the same content but Supplier relevant questions is available on our website):

1. What do you think about the categories proposed for PHARMAC to undertake activity in? (i.e. do you think there could be value in these areas?, are some categories more important than others in your view?)

2. What issues are you aware of that PHARMAC need to consider if it undergoes work in these areas?

3. Do you think there are other areas that PHARMAC should focus on? If you suggest a further category, do you consider this to be higher priority than a listed category and why?

4. Do you want to be kept informed about PHARMACs work in one or more of these areas? (please specify any area of particular interest).

5. Are the national terms and conditions templates provided to DHBs by the National Procurement Taskforce in 2010 still appropriate?

6. Are you able to specify a key contact at your DHB for PHARMAC to engage with generally around medical device procurement? This person would not be expected to provide detailed feedback on every area but, for example, might help us reach the right people in the DHB for different product areas. To that end, PHARMAC requests that each District Health Board provide details for a key contact as set out below. If you have a preferred method of communication please indicate this also.

Contact Name:	
District Health Board:	
Position/Role:	
Telephone Number:	
Email Address:	

Please email this person's contact details to devices@pharmac.govt.nz.

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Background

In 2010 Cabinet decided that PHARMAC should take a more active role in the management of medical devices used in DHB Hospitals. PHARMAC and the Ministry of Health were asked to develop a plan to give effect to this decision. The plan, which was approved by Cabinet last year, involved the establishment of a common system for procurement of medical devices across DHBs, followed by budget management to be implemented by 2017.

In parallel Health Benefits Limited has been working to deliver on the Finance, Procurement and Supply Chain (FPSC) business case that will see a range of shared services for the 20 DHBs delivering national savings. In 2012/13 PHARMAC has been working to support the FPSC programme and we have a key role to play in delivering the benefits relating to procurement of medical devices.

Building and implementing such systems takes considerable time. There is some benefit in PHARMAC taking on some specific procurement activity while these systems are established. This will both assist with developing the long term systems, and build PHARMAC's experience in the area of medical devices in a manageable way.

Since the Cabinet decision PHARMAC has been working through a process with other agencies such as Health Benefits Limited and the National Health Committee to understand what areas need initial attention.

This document outlines the kind of approaches we consider we might follow, and the areas we consider we might focus on. The purpose of this is to seek your views on these areas and approaches. We welcome any and all comments. We have endeavoured to send this request widely, but please feel free to circulate this request to anyone you think would be interested.

Approaches

There are many factors to be considered in defining market approaches, including market complexity, size, and variability of clinical needs. We are broadly thinking about two basic approaches at this stage that we will choose between, based on market factors.

Straightforward Market Approach

- PHARMAC will be open to entering into national agreements that are aimed at simplifying the commercial arrangements for clinical products. Typically this approach would not involve review of the range of products available, and is unlikely to impact on availability of products in that range.

- While it is unlikely these arrangements would significantly impact on clinical practice, we would still want to have appropriate input from clinical stakeholders to ensure there is confidence in the processes and arrangements.

- Negotiated pricing will be published on the Pharmaceutical Schedule, and all DHBs will be able to access it. We will be working with DHBs to ensure this pricing is attractive and any terms and conditions are appropriate. The outcome of this process may be discretionary or binding agreements for DHBs. We would consult on any arrangement that had a binding effect.

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Product Range Review

- In some areas it may be appropriate to take a closer look at the category to determine if there is efficiency to be obtained from standardisation, or rationalisation of the product range. It will be important to ensure this activity does not adversely impact on clinical practice, and we would be seeking significant clinical input on any recommendations to come out of such reviews.

- We consider clinical input is important, but is not limited to; determine the requirements and scope, to develop generic descriptors, to obtain feedback for consideration and make recommendations on an appropriate range. Evaluation of responses, including evaluation of products or recommending a process for their evaluation, may also be required.

- This approach may take around 12 months to complete up to implementation stage and the outcome of this process may be discretionary or binding agreements for DHBs. We would consult on any arrangement that had a binding effect.

PHARMAC will be working towards the implementation of national contracts over selected categories or subcategories using the procurement approaches as detailed above. We may also consider the strategies contained in PHARMAC's Operating Policies and Procedures and act on any of those options which could provide a better outcome in gaining benefits for the DHBs. Some of these strategies could be bundling arrangements, or entering into arrangements which involve the sharing of financial or other risks between PHARMAC and the supplier. If you wish to view PHARMAC's Operating Policies and Procedures document, it is available on our website – www.pharmac.govt.nz.

Ongoing Procurement Activity

While we are building our processes and clinical engagement models, PHARMAC recognise that sector procurement activity will need to continue. PHARMAC is keen to work with DHBs and others in the sector to understand procurement activity that is planned. There may be some activities that we can undertake that could have the potential for wider national application and reduce duplication.

We understand DHBs currently include clauses in agreements allowing them to exit if a national agreement is put in place. If you think it is helpful PHARMAC is prepared to provide an updated standard clause to DHBs.

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Background Information on Categories

Anti-Embolism Stockings

This category covers a distinct range of products. It is limited to hospital surgical and medical use and there are a number of suppliers and range/sizes of products. A process could be undertaken to assist in developing national clinical guidelines/standards as well as work towards investigating opportunities that will lead to greater efficiencies.

There are a number of regional and DHB contracts currently in place, however, a number of DHBs have identified this category on their procurement plans for 2013/14 financial year. The current spend for the DHBs is estimated to be $2 million per annum.

Questions

1. What specialty areas and clinical situations is this product used in within your DHB?
2. Do you see this as an area of growth or decline in usage?

Disposable Sterile Instruments

This is a category that has been identified due to the increasing usage of single use disposable instruments in preference to reusable/reprocessed instrumentation in a clinical situation.

The annual spend as identified from DHB spend data is approximately $14 million per annum, and the majority of this is on sharp blunt scissors and basic disposable wound care equipment. There are a large number of distributors and varying levels of quality and price. Very little work has been done on comparative models between disposable and re-useable instruments and despite this it has become a commodity that is used in many parts of a DHB's daily work. PHARMAC would see this area as a good opportunity to review the real cost/savings of funding disposable sterile instruments. It may be appropriate to limit our focus to the most basic products initially with processes being developed that would enable a broader application if appropriate.

Various supply arrangements are in place and recycling/medical waste costs may or may not be included in those contracts. This may be an opportunity to test the cost issues and obtain significant savings for the sector through a standardised approach.

Questions

1. What is your DHB's current practice in the use of disposable instruments relative to reusable alternatives?
2. If you are using disposable instruments, is the use widespread or limited to areas/specialties? If limited, what are the areas/specialties using them?
3. If you are using disposable instruments, what range of products are you using?

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Hand Hygiene
This has been identified as an opportunity due to the 5 moments of hand hygiene programme that has been promoted throughout DHBs. This is viewed as one of the key drivers to prevent hospital acquired infections, which are both costly and avoidable.

This is a fairly easily defined category and is seen as a good area to develop our procedures. Spend is estimated to be $2-3 million per annum and although the range of the products is not especially large, the cost implications of not having appropriate products in DHBs are high due to associated infections that can lead to longer hospital stays, long term disabilities, extra time off work and can cause considerable distress to patients and their families. There are a large number of providers over various ranges and with varying formulations. This category requires a large amount of input from Infection Control and Occupational Health Specialists to ensure product range selection is appropriate for use both in the health sector and by the end users.

There are some contracts in place, to varying degrees, and most include brackets/dispenser systems which has significant impact in relation to hospital facilities.

Questions

1. What range of products do you currently use? e.g. moisturisers, varying chlorhexidine strengths etc.
2. How widely distributed are antibacterial hand rubs in your DHB? i.e. at every bedside, 1 per room, etc.
3. What challenges and opportunities do you see in this category?

Interventional Cardiology
The National Health Committee has identified 'interventional cardiology' as a category they would like PHARMAC to explore due the increased use of this technology, emerging international trends and the high costs associated with it.

Through our discussions to date, it has been identified that interventional cardiology is a recognised clinical category that covers a distinct group of specialist products. There are also electrophysiology and imaging areas of cardiology that may have been considered to come under the umbrella term of interventional cardiology in this context. We would appreciate your feedback on how these areas should be addressed and as a collective what they could be called.

The cardiology category is highly specialised and the use of medical devices in this area requires a high level of clinical training. There are a large number of suppliers in this market internationally, with a mixture of direct supply and distributor arrangements in place in New Zealand. The current spend in this area has not been fully identified at this stage.

Some areas within this category are under contract, primarily by region and/or collaborations of groups of DHBs providing this service. Many contracts are panel arrangements allowing choice to remain with the clinicians and the opportunity to access new innovative products.

Questions

1. Would PHARMAC's use of the term 'interventional cardiology', to cover all cardiology services that use devices, confuse the industry?
2. How would the areas of cardiology best be considered as distinct categories?
3. What are the challenges and opportunities you see in this category?

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Mechanical Compression Devices and Consumables
Mechanical Compression Devices and consumables have been identified as a possible category as it covers a distinct range of products to be used alongside a hardware device. Use is limited to hospital surgical areas and there is only a limited number of suppliers and range of products.

The current spend for all DHBs is unknown at this stage, however, it has been identified that the spend from five DHBs is $500,000 per annum, extrapolated out to 20 DHBs this spend could possibly be more than $2 million assuming reasonable usage.

Questions

1. What is your DHB's current practice in the use of this product range?
2. Is this seen as a growth area in your DHB?

Orthopaedic Implants
This category is currently under contract until mid-2014, and PHARMAC has identified it as an area where further cost efficiencies may be able to be achieved through good engagement with clinicians.

The Hips, Knees, and Orthopaedic Spine and Trauma categories have been through commercial processes with Health Benefits Limited. The Hips and Knees spend is approximately $45 million per annum and PHARMAC are looking to work closely with NZOA and Orthopaedic Specialists to ascertain where further efficiencies can be achieved to maximise the return on these contracts. This could be through standardised banding structures for national adoption, hybrid construct costing's or many other processes that would; enable further efficiencies, remove costs from the supply chain, and retain choice for clinicians.

Questions

1. What are the challenges and opportunities you see in this category?
2. How have the National contracts affected your purchasing practices?

Sterile Surgical Gloves
As the Health Benefits Limited Personal Protective Equipment and Examination Glove contracts are now in place for patient and/or staff protection, it would be appropriate that Sterile Surgical Gloves be considered.

This is seen as a very specific category area that can be clearly defined, however, clinician usability needs to be considered, and there are specialty products within this category. There are several strong brands in the market and they are all preferred to varying degrees by the DHB's using them.

Various contracts are in place with DHB's and regions but it would appear pricing and terms are variable.

Questions

1. What challenges and opportunities do you see in this category?

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Sterilisation Wrap, Tray Liners and Associated Consumables

Sterilisation wrap, tray liners and associated consumables have been identified as a potential category as there are emerging changes in practice and associated costs/savings with those changes. There are now a number of suppliers that offer a range of products in this category. Products are generally used by Sterile Services, Theatre, Outpatient Clinics and Endoscopy units, and in some areas laundry's that provide a theatre linen wrapping service.

The various DHB sterile services processes, and the wrapping methods used, will need to be fully considered. Machine revalidation costs also need to be taken into account if changes are to be implemented. A process could be undertaken to assist in developing national clinical guidelines/standards as well as work towards investigating opportunities that will lead to greater efficiencies. Various contracts are in place with DHB's, and in some cases regionally, but it would appear pricing and terms are variable.

The current spend for all DHBs is unknown at this stage, however, sterilisation wrap has been identified from five DHBs to be $350,000 per annum, estimated for 20 DHBs could be approximately $2 million.

Questions

1. What is the current procedure for wrapping instruments in your Sterile Services Department?
2. Are there any other issues you think are important to consider when looking at this category?

Sutures

This is a complex category with spend of approximately $12 million per annum. There is a strong clinical requirement for dependable, quality product and this category has a high level of training, support and supply chain management associated with it, that all needs careful consideration in any process that may be undertaken.

There are some DHB contracts in place with some regional work in this area, but terms and costs vary.

Questions

1. Do you see any distinct sub-categories within this product area?
2. What challenges and opportunities do you see in this category?

Thermometers

Thermometers for taking body temperatures could be a complex category as clinical engagement will need to be extensive as the range of products are used extensively throughout the DHBs.

The hardware can be a capital device with a significant consumable component, and equipment is required to be accurate. Some DHBs may have more than one type of system for taking body temperatures and more than one supplier supplying the same products. There are a large number of suppliers.

A process could be undertaken to assist in developing national clinical guidelines/standards as well as work towards investigating opportunities that will lead to greater efficiencies. The current

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spend for all DHBs is unknown at this stage, however, usage of consumables is high volume in this category.

Questions

1. What types of thermometers are used in your DHB?
2. What challenges and opportunities do you see in this category?
3. Has your DHB undertaken procurement activity in this category, and if so what lessons have been learned?

Wound Care

Wound care is a complex category that has a high spend over a wide range of products/choices available to clinicians, there are a large number of established suppliers and brand preference is also prevalent. As the category is so large, it may be desirable to undertake activity on a sub-category basis. Clinical engagement will need to be comprehensive due to the large stakeholder group and the vast range of products being used extensively throughout hospitals and the District Nursing Service.

This category has been through two previous national processes and there are current national contracts in place that are due to expire in August 2013, with a majority of the suppliers providing a comprehensive schedule of products. A formal national rationalisation/standardisation process has not been undertaken. If this sort of rationalisation activity were to be undertaken, it would likely require the establishment of a Clinical Advisory Group to provide advice on options that ensure any result meets the needs of clinicians and does not affect patient outcomes.

The current spend for the DHBs is estimated to be $40 million per annum.

Questions

1. In your view is it better to undertake activity in wound care in sub-categories or more comprehensively?
2. What product areas within wound care do you think form intuitive sub-categories?
3. Do you think there is scope for a national standardisation review in wound care, or in particular sub-categories of wound care?
4. What challenges or opportunities do you see in this category?

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