NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

19 December 2014

Feedback on PHARMAC's proposed approach to managing hospital medical devices

PHARMAC is pleased to announce the outcome of its engagement during May and June 2014 on its proposed approach to managing hospital medical devices. The discussion document for this can be found here: http://www.pharmac.health.nz/news/consultation-2014-05-07-devices-discussion/

Overall both the written and verbal submissions reflected general support for the proposed approach. Key themes were similar to those raised during earlier consultations and most people were seeking clarification on specific issues rather than expressing any major disagreement or significant concern about PHARMAC's proposal.

The most commonly raised issue was the need to ensure PHARMAC obtains the right advice (both clinical and non-clinical), from the right people to be able to make robust decisions. PHARMAC understands it will need to work with relevant experts as activity is undertaken in different categories of medical device. Other themes included the need for better quality evidence regarding effectiveness and risk to inform decision making, the importance of considering the features of medical devices that may affect their usability and concerns about the timeframes and implications of budget management of medical devices.

Feedback received has already influenced PHARMAC activity, For example:

- PHARMAC's review of its nine decision criteria. Medical device characteristics have been reflected in the recently announced Factors for Consideration, which we expect to implement in late 2015. The suitability dimension of the Factors is particularly relevant to medical devices. Information about the Factors can be found here: http://www.pharmac.health.nz/medicines/how-medicines-are-funded/factors-for-consideration/
- A Wound Care Advisory Group has been established to provide advice to PHARMAC to inform decision-making in the wound care category.
- PHARMAC has begun to develop a more robust approach to undertaking or commissioning research. This may result in an Operating Policy and Procedure to underpin this activity. PHARMAC expects to engage with stakeholders about research during 2015. The need for a more structured approach to research activity was identified partly in response to feedback from medical device stakeholders who noted the quality of evidence for medical devices was sometimes weak compared with medicines.

During the engagement period and subsequently, stakeholders have sought clarity about the timeframes for when PHARMAC will take on budget management of hospital medical devices.

The diagram below shows the stages PHARMAC expects to move through before reaching a budget management state for hospital medical devices. It also shows the stage of activity particular categories have reached as of December 2014 and how this compares with

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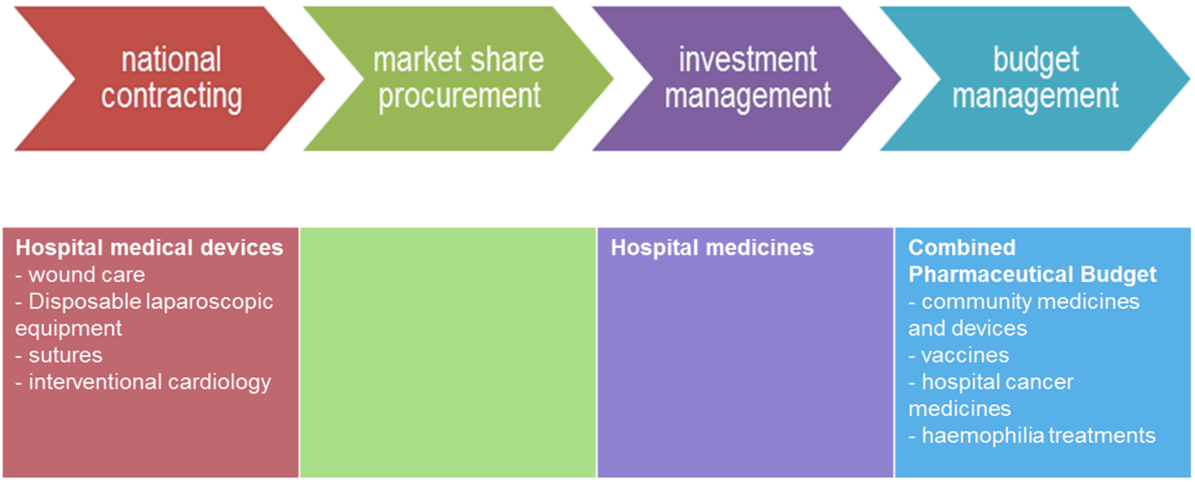
medicines and other treatments. Currently PHARMAC's activity is focused on national contracting within some categories as we build capacity. National contracts for further categories will be established in 2015 and beyond, and some categories will move through the stages towards management faster than others. PHARMAC expects to move towards market share procurement in at least one category during 2015.

However, full budget management of hospital medical devices is many years away and it is not yet known what form this will take. Moving to this stage will not occur without extensive engagement with District Health Boards (DHBs). In the meantime PHARMAC will continue to work closely with DHBs and DHB agents such as healthAlliance and HBL to ensure we have regard to other work happening in this area.



Next steps

PHARMAC will consider the feedback obtained through this process as we undertake our rolling review of our Operating Policies and Procedures (OPP). Further information about our OPP can be found here: http://www.pharmac.health.nz/about/operating-policies-and-procedures

If PHARMAC identifies a need for substantial change to the OPP during the rolling review, we will engage with stakeholders at that time. Hospital medical devices will be explicitly considered as part of the review and information about current OPP activity will continue to be made available on the PHARMAC website.

PHARMAC will also be consulting with the relevant specialty, interest and consumer groups as we undertake activity in more device categories and as the level of activity increases within a category in future years. All the information received to date, and which we will continue to gather over time, will continue to inform PHARMAC's work.

Feedback received

Thank you to all those who responded to the hospital medical devices discussion document released in May 2014 either in writing or through attendance at the many meetings and regional forums that were held around the country. We appreciated the time and effort involved in providing feedback, which has been invaluable as we develop our hospital medical devices role. The feedback received will continue to be used as our medical device activity grows.

Feedback	**response**
Funding applications Submitters indicated ongoing confusion about the use of the term 'pharmaceutical' to refer to both medicines and medical devices. Clarity was also sought as to how devices that also had a medicine component would be classified and managed. It was felt that clarifying the definition would make the application process clearer. Questions were also asked about the timeliness of the application process with some concerns being expressed that delays due to the process would reduce prompt access to new technology.	PHARMAC acknowledges that confusion surrounds the use of the term 'pharmaceutical' in the context of medical devices. However, our use of the term derives from the statutory definition of pharmaceutical in the New Zealand Public Health and Disability Act 2000, which is the legislation that gives us our mandate. Where it is important to differentiate between medicines and medical devices in our communications and activity we will identify each type of therapeutic product separately (ie, medicine or medical device).
Exceptions applications A number of submitters asked for clarity on the proposed timeliness of the exceptions process, with concern being expressed that if there was a considerable time lag this could impact negatively on patient outcomes. Concern was also expressed that for some niche products that have a wide range of uses, but are only occasionally used, there would be a continual need to go through the exceptions pathway assuming they are not listed products; and that this would reduce access.	PHARMAC acknowledges these concerns and will include this feedback in the development of exceptions processes for medical devices. We note that the current process used for medicines does provide a pathway for urgent or rapid assessment depending on clinical circumstances. An exceptions process is not required in the current national contracting phase of medical device management but we will be considering what might be needed as we move towards market share procurement for some categories.
Clinical risk assessment A number of submitters pointed out the current low level of regulatory control and questioned how PHARMAC would ensure patient safety when making decisions to fund a particular device. Many suggested that there should be a greater expectation that suppliers provide better evidence before devices are widely used.	PHARMAC acknowledges that current regulatory controls for medical devices are not as robust as for medicines. At a point when we are making funding decisions, we will consider the clinical risk category of the medical device in question to determine the level of assessment required. This will help inform the types and level of information we need from suppliers to assess the product appropriately.

Feedback	response
Submitters also noted that the high current level of recalls and alerts issued by MedSafe creates a significant workload for staff managing the follow-up actions required. Particularly with reference to implantable devices, the use of national registries to monitor long term safety issues was raised by a number of submitters, with some suggesting that PHARMAC should take an active role in facilitating their establishment and use. Some questioned how and what evidence regarding clinical risk would be sought and considered by PHARMAC when it made decisions.	It is important to be aware that PHARMAC is not a regulator and does not have a mandate to approve or endorse a product for quality and safety. PHARMAC notes recent announcements that the Australia and New Zealand Therapeutic Products Agency (ANZTPA) will not be proceeding. The government will instead develop a new modern regulatory framework for therapeutic products in New Zealand and we intend to engage with the Ministry of Health and Medsafe as this work progresses. The range of stakeholder feedback we have received is valuable for informing discussion with the Ministry.
Clinical input Most submitters said the range of expertise needed to support the decision making process would need to be substantially wider than what PHARMAC currently uses. Many noted that the Pharmacology and Therapeutics Advisory Committee (PTAC) would need medical devices expertise. The importance of considering all potential users and professions integral to the functioning of medical devices and who may present a different perspective to medical clinicians was stressed by a number of groups as being important. This was the most frequently expressed point across all submissions.	PHARMAC agrees that the range of clinical expertise to inform decision-making for medical devices can be wider than that required for medicines. We will continue to develop the clinical input required as we move from category to category, and through the stages of management. As an example, wound care is one of the first categories we are working in comprehensively and we have formed a Wound Care Advisory Group to provide clinical advice.
User and patient / consumer input The usability of any particular device was considered key by many submitters. The appropriate use of clinical evaluations was seen as being an important way of ensuring clinical usability. The inclusion of a patient perspective and the importance of considering consumer usability were seen by many submitters as positive aspects of the proposal. Use of patient and advocacy groups was suggested as a way of accessing this information. Seeking clinicians' recommendations for specific patients was also suggested as a way to ensure the appropriate patients were being consulted.	PHARMAC agrees that medical devices may have features or characteristics that affect the ease with which they are used and this may have an impact on clinical outcomes. Stakeholder feedback on this issue was important for informing the review of PHARMAC's nine decision criteria as part of our rolling review of our Operating Policies and Procedures (OPP). We recently announced the outcome of this review, which can be found here: http://www.pharmac.health.nz/medicines/how-medicines-are-funded/factors-for-consideration/ In late 2015, the new 15 Factors for Consideration will come into effect. A key

Feedback	response
Some patient advocacy groups suggested that ongoing support needed to be given to patients using devices in the community.	feature of the factors is the suitability dimension, which will take into account the sorts of usability features that stakeholders have noted. The long lead in time for implementing the new factors is to ensure both staff and external stakeholders understand how to use the factors to inform PHARMAC's decision-making.
Economic assessment Ongoing sustainability and environmental issues were raised by a couple of submitters. Submitters stated that PHARMAC should consider how it could support current DHB activity in this area as more DHBs were taking steps to manage these issues. Some asked whether costs such as training and servicing and the total cost of ownership would be included in the economic assessment of an application.	PHARMAC will be reviewing the Prescription for Pharmacoeconomic Analysis (PFPA) during 2015 as part of the rolling review of our OPP. We will be considering the approach we take to economic assessment for medical devices as part of the review. The stakeholder feedback received to date will feed into this and there will be further opportunities to engage with on the issue. It is important to note that PHARMAC must work within its statutory objective *"to secure for eligible people in need of pharmaceutical treatment the best health outcomes that are reasonable achievable from pharmaceutical treatment and from within the amount of funding provided*." This means we cannot consider broader issues such as the environment at the expense of achieving best health outcomes. Nevertheless we acknowledge there may be times where such broader considerations like the environment may have an impact on health outcomes. Our new Factors for Consideration have been framed as "health-related", to enable us to use our judgement in cases where broader issues such as the environment are relevant to health outcomes.
Commercial approaches Some clinical and many supplier submitters were concerned that a loss of market share (which it was assumed would follow from the implementation of the PHARMAC approach) would impact negatively on the commercial viability of some companies, especially smaller ones. These submitters suggested fewer suppliers would then lead to reduced access to innovative technology and an absence of competition. Some submitters questioned if there would be a loss of ongoing training and support – currently provided by some suppliers – if those companies withdrew from the New	PHARMAC notes stakeholder concerns regarding commercial viability of some companies. Our decision making is underpinned by our statutory objective to achieve best health outcomes within the available funding (noted in full under economic assessment above). PHARMAC relies on having a robust competitive market to enable the savings and improved health outcomes we are aiming for. PHARMAC is aware that training and support is important for the use of some medical devices. We understand that suppliers often deliver this training. We would consider any need for ongoing provision of service when making decisions and seek to ensure that

Feedback	response
Zealand market.	required support continues
Contract management The general expectation from submitters was that all PHARMAC contracts would adhere to government rules for procurement and that there would be a transparent contracting process. Submitters noted that contracts would need to be flexible and well supported by PHARMAC contract managers.	PHARMAC will comply with the Government Rules of Sourcing. We agree that it is important to have robust contracting processes with strong contract management support.
Implementation ('introducing new or different devices into DHBs') Some submitters said there was a need to provide some form of long-term monitoring of the impact of new devices, particularly where the device had little evidence associated with its use, or the potential impact of a negative outcome on patient health was significant. It was suggested that PHARMAC could have an ongoing evaluation/monitoring role.	PHARMAC acknowledges that introducing new or different devices will require support. This could range from change support during implementation through to monitoring and feedback over time. Support needs will differ depending on the type of medical device and the stage of medical device management the category is in. We recognise there may be little evidence for the use of some medical devices and will be considering the sort of research or evaluation mechanisms that might be required to address gaps. We anticipate engaging with stakeholders during 2015 about research, including any research needs for medical device. It is likely that an OPP will be developed to support any research activity.
General A few submitters questioned how the movement between private and public hospitals for both patients and clinicians would be managed. Submitters noted that for clinicians working across both, there was likely to be an impact on device use and possible poorer outcomes if surgeons were using fundamentally different products in private and public settings.	PHARMAC notes that our mandate is to manage hospital medical devices in public hospitals. However, we acknowledge that there is cross-over between public and private hospitals (eg, workforce or private facilities being contracted to deliver public funded services). We expect that the clinical advice we receive will be a key input to help us consider the impact such cross-over might have. The Factors for Consideration will

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A concern was expressed that any activity undertaken by PHARMAC in relation to diagnostic laboratory services would be difficult and potentially highly disruptive. A couple of submitters from some clinical specialties believed that the devices used in their areas of expertise should sit outside PHARMAC's management due to the degree of complexity/specialisation and that they considered the current arrangements were satisfactory. Other specialties also wondered if their specific requirements, particularly in regards to ability to have a wide range of devices available, would be adequately addressed. A question was also raised about how PHARMAC proposed to manage capital expenditure items. A number of submitters felt there was a lack of clarity regarding the roles of Health Benefits Ltd, healthAlliance and the National Health Committee in the sector. There was a perception that there was duplication of work occurring across these agencies and PHARMAC's work. A number of submitters asked for timelines as to when the various aspects of PHARMAC's approach would be implemented. Questions were also asked about which categories PHARMAC would be looking at next.	enable us to consider the consequences for the health system for a particular funding proposal. The Factors also allow us to consider the features of a medical device that may impact on use by the health workforce. PHARMAC notes stakeholder concerns about specific categories of medical devices. We are initially working in the 12 categories of medical devices we consulted on and will ensure stakeholders are regularly updated on progress including any proposals we are considering. PHARMAC is working closely with DHBs, HBL and healthAlliance on areas of mutual interest. We will continue to do so to strengthen understanding of each organisation's respective roles and responsibilities. PHARMAC also meets regularly with the National Health Committee (NHC) with a view to sharing information and identifying where there might be cross-over in activity. We have an established Memorandum of Understanding with the NHC and will continue to work with it to increase sector confidence that work is aligned. We will consider capital expenditure as we work towards full budget management of medical devices, which is still many years away. We anticipate this will not be fully implemented for at least 10 years. It is likely that different categories of medical device will move through progressively more sophisticated stages of management at a different pace. We will keep stakeholders informed and engage as appropriate throughout.

More information

If you have any further questions, you can email us at devices@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.