Combined executive summary of

Key themes from PHARMAC'S hospital medical device consultations

PHARMAC
Pharmaceutical Management Agency

This summary presents the key themes relating to four of PHARMAC's consultations, specifically those that included discussion and submissions that relate to hospital medical device management. It also includes points raised by submitters in response to questions relating to PHARMAC, posed in Health Benefits Limited's consultation on the Finance, Procurement and Supply Chain business case implementation*[1]. The overall summary provided here is necessarily brief – links to the individual consultation summaries which provide more detail are included below.

Obtaining clinical input **– November 2012 to March 2013**

This consultation was aimed at obtaining feedback from those working in clinical settings about the sorts of information PHARMAC needs to consider to ensure sensible funding decisions are made for medical devices (including consumables), and how PHARMAC can best work with those in clinical settings (clinicians and non-clinicians). Eighty one submissions were received from industry groups, clinicians and allied health practitioners, professional groups, medical unions and others. The summary of submissions is available at: http://www.pharmac.health.nz/assets/devices-establishment-clinical-input-submissions-analysis-2013-07.pdf

PHARMAC's initial medical device activity **– May to June 2013**

This consultation sought responses from suppliers of medical devices, DHBs and associated health and other groups about PHARMAC beginning interim procurement activity in a range of medical device categories.

PHARMAC's preliminary work in this project, including discussions with sector stakeholders, had identified 11 categories of devices as a starting point for PHARMAC's procurement activity. The consultation sought views on whether these categories were appropriate, issues around categorising products, considerations when putting in place national contracts for items in these categories, and suggestions for other categories of products where activity could be undertaken in the short term.

There were 46 responses from industry groups, clinicians and other health practitioners and organisations. The summary of submissions is available at: http://www.pharmac.health.nz/medicines/hospital-devices/consultations/#initialactivity

Decision criteria **- June to August 2013**

This consultation was aimed at obtaining feedback from the health sector and the wider community on PHARMAC's current decision criteria. The criteria, which form part of PHARMAC's wider Operational Policies and Procedures, are used for making decisions. The consultation sought the community's views on whether the criteria are still fit for purpose and if there are any changes, additions or deletions people think should be made to them.

[1] * Feedback received as part of HBL's consultation was considered by PHARMAC alongside other information provided by submitters during PHARMAC's own consultation *Applying the PHARMAC model to hospital medical devices management.* This is reflected in the summary of submissions on this consultation.

Within the consultation were a number of questions about how the criteria are (and could be) used for medical devices. Feedback relating specifically to these questions is what has been included in this summary.

A total of 139 submissions were received, with feedback also from 12 regional community forums around New Zealand (over 300 people attending), and five meetings held with industry and government sector groups. The summary of submissions is available at: http://www.pharmac.health.nz/about/operating-policies-and-procedures/decision-criteria-consultation

***Applying the PHARMAC model to hospital medical devices management* - October to November 2013**

This consultation sought to gain a greater understanding from the health sector of how medical devices are obtained and used, what considerations DHBs take into account when deciding which ones to use, what the implications are for managing these on a nationally consistent basis and any other issues relevant to PHARMAC taking on the management role. The aim was to ensure PHARMAC knew what it needed to consider when applying the PHARMAC model to this area.

A total of 50 submissions were received. Feedback was also taken into account from regional meetings, Deloitte's white paper *Hospital medical device decision criteria* commissioned by the Medical Technology Association of New Zealand (MTANZ), and the Finance, Procurement and Supply Chain Consultation carried out by Health Benefits Ltd (HBL).*

Key themes

Essential in a medical device management system

PHARMAC's medical device management system must focus on patient safety and high quality healthcare services. It should take a multidisciplinary approach that includes clinicians, allied health professionals, consumers and the medical device industry. The process must allow clinical choice, support multiple suppliers, take a long term view and consider the total cost of products and the total care pathway.

Defining products within PHARMAC's scope

With input from the sector, PHARMAC must clearly define medical devices. Categories of devices should be distinguished by the complexity and technology they involve. Definitions should include an extensive list of related services such as training, consumables and servicing.
Defining what constitutes a new device is complex; but may be characterised by developmental changes or changes in use. Different classes of products may need different definitions.
Interchangeability is dependent on the complexity of the device, and affected by a wide range of factors. Simple low-risk devices are easily interchangeable; more complex products are not.

Having greater national consistency

It is crucial to maintain some variation in District Health Boards' (DHBs) purchasing options because clinically defined need must drive access to devices. Additionally, sole supply may pose critical clinical and other risks.

Greater national consistency may achieve economies of scale. Health benefits may arise from consistency of practice, national management of product recall, and growing expertise in health technology assessment. There are health risks if clinicians cannot choose from a range of products. There are also risks if the quality of products supplied and the long-term viability of suppliers in New Zealand is insufficiently considered.

The use of devices might be limited in cases of regulatory approval indications, indicated patients where the technology would not be cost-effective or an issue requiring a recall. Decisions to limit use must be based on expertise, clinical risk and patient outcomes and made by expert staff. DHB management may also need to be involved.

Application processes must be clear, transparent, rapid and with avenues for appeal. Clinical and industry stakeholders must be involved in the design. A robust review process is required to ensure flexibility for exceptional or urgent cases.

There are complications relating to capital equipment, which would require significant work on first creating standards, and then time lag for differing procurement cycles in DHBs before a level of national standardisation is achieved.

Quality assurance

Strengths & weaknesses of the way safety and quality of devices are assessed

New Zealand currently benefits from the regulatory assessment processes of major economies at little cost. The current process is straightforward, allows for local innovation and enables earlier access to devices. DHBs have flexibility and it can be low cost to conduct assessment. However, the process is ad hoc; hospital conducted assessments can be inconsistent, and efforts may be duplicated. There is heavy reliance on post market reviews and limited research relating to long-term device function.

Approaches for a nationally consistent quality assurance process prior to ANZTPA

Devices could be approved by an International Medical Device Regulators Forum (IMDRF) regulator prior to being supplied in New Zealand; however, consumer advocacy groups have concerns about relying on the approval of overseas jurisdictions. Robust post-marketing surveillance may be necessary – including registries.

Assessment

Evidence

Numerous sources of evidence are available for devices, but standards are not as robust as those for pharmaceuticals. It may be impossible to independently assess the value of a device prior to its use. Any assessment framework needs to include international and local evidence, input from affected stakeholders (including clinicians and other health professionals, and the medical devices industry), and lessons learned.

Best sources of information

Information from a variety of sources (e.g. evidence-based research, clinical advisory groups, consumers, product sponsors) is required to carry out assessments; this information may need to be

linked. PHARMAC should keep working with national agencies in this area, and with clinicians, other DHB staff, suppliers and consumers. In some cases, it may be necessary to provide the device and then collect evidence from usage.

Economic assessment

Effectiveness and safety should be primary concerns. Other factors to consider include: clinicians' preferences, clinical requirements, consumer views, training required and supplied, continuity of supply, consumables, maintenance and servicing of devices and ongoing device support. PHARMAC must also consider the costs associated with the IT components in many devices. The whole of life costs and benefits of devices over a long-term timeframe must be considered, as should the indirect social and community costs, including environmental costs.

There must be long term and comparative assessment of the costs and benefits of both the new device and the existing alternative. However, the degree of analysis should depend on the actual or potential impact of the device.

Purchasing strategies & contract management

The more complex a device is, the less suited it is to simplistic purchasing mechanisms, therefore different assessment tools should be determined by the nature and degree of risk. Tools and processes should be effective and transparent. Purchasing strategies and contract management need to account for the total cost of ownership including the direct and indirect costs and benefits of a device. There may be advantages in some circumstances to confidential rebate arrangements; however DHB and professional groups described difficulties with these.

The way medical devices contracts are managed now

DHB and other clinical submitters support being able to purchase medical devices on direct clinician request. Relationship development and trust are also favourable characteristics of the current process. Suggested improvements include more careful evaluation of medical devices at a national level, having strict requirements relating to DHBs purchasing off contract, and having a centralised ordering and distribution system. Industry submitters suggested improving the consistency and quality of contracting processes.

Integrating new devices into hospital processes

Product evaluation committees with a multidisciplinary approach work well with a generally satisfactory level of clinical input. The recognition of clinical autonomy and the minimally restrictive pathway for approval and purchase are also strengths of the current process. Current processes are largely well defined within DHBs and suppliers generally work with DHB stakeholders transparently. There are mixed views about the current system related to the length of time the process takes and communication with stakeholders. The variability in the process between or within DHBs is a major weakness. Similarly, there are issues around the insufficient number of clinical product co-ordinators in DHBs, and the lack of close scrutiny of all information available before a decision is made to purchase.

There could be more flexibility with accessing new technology, improvements to device trials, and a more integrated approach to assessing and procuring devices.

Submitters to the HBL *Finance, Procurement and Supply Chain* business case implementation consultation questioned procurement capacity at PHARMAC and other organisations, and how this would change when PHARMAC was managing devices. These comments will be taken into account when PHARMAC looks at organisational design relating to device management.

PHARMAC's role in ensuring that a newly listed hospital medical device can be used

PHARMAC should provide clarity around definitions, its intentions, and the processes that will be used in device management. In particular, PHARMAC must be clear about which agencies will be doing what, and ensuring processes are not duplicated. There is a need for inclusive stakeholder engagement.

PHARMAC has a role in contract management, device implementation, reviewing Schedule listings when new technology becomes available and managing risk. There were mixed views of PHARMAC's role in providing final approval of any medical device used in hospitals.

Applying PHARMAC's existing decision criteria to medical devices

Views are divided as to whether the existing decision criteria are appropriate for medical devices. The criteria are seen as appropriate by some largely because many of the basic principles required to prioritise investment in medical devices are in the current criteria. The criteria are seen as inappropriate by some because devices are fundamentally different to pharmaceuticals, and generating sufficient evidence to inform decision making will be a major challenge. It is questionable whether the decision making process can keep up with the rate of change in medical devices. More clarity is needed on criteria 5 (cost effectiveness), criteria 8 (Government's priorities for health funding) and criteria 9 (other criteria as PHARMAC thinks fit) in relation to devices.

Other criteria that might be needed when considering medical devices

Criteria must be able to take in to account the clinical safety of medical devices (noting the current lack of pre-market regulatory approval), rapidly changing technology and highly complex integrated devices, as well as low-tech devices, and the support and services offered by device suppliers.

Advantages & disadvantages of using the same set of criteria

The primary advantage of a common set of criteria is that it best provides for the comparative allocation of resources for the best health outcomes within the funding available. A common decision criteria is possible if the scope and interpretation of the criteria accommodate differences – analysis need not be identical. However, the current criteria may not be able to address the comparative complexity of medical devices, and the different evaluative methods required. PHARMAC may need to consider other models where decision criteria sets are very broad based. Further, decision criteria must be set within a robust operating procedure.

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