Consultation on applying the PHARMAC model for hospital medical devices management

Wellington Forum 4 November 2013

Key points raised by attendees

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

It's essential that PHARMAC's work is informed by the views of the people who work with devices. The approach to these forums was to outline that PHARMAC is in an information gathering phase and that we wanted to hear from the sector. PHARMAC was not there to provide all the answers, but to hear what the issues were for those working in this space so they can help develop the proposed approach to management.

General question discussed:

What are the key considerations PHARMAC needs to take into account when developing its policies and processes for hospital medical devices management?

Differences & compatibility of systems and devices

> There are significant differences in the nature of the different products

> ICT compatibility of the medical device?

> Units of measure + calibration ease

> Sensitivity/specifically with compatible groups

'Whole of life' costs; Associated costs

> Training for staff using the devices?

> Will the consumables and spare parts associated throughout the lifecycle of a medical device be considered?

> The difference to medicines is the on-going support needed for medical devices and the costs associated with this

> Repairs, maintenance & training

> Cost of attached consumables

> Cost of change

Assessment, clinical input, funding decisions and implementation

> Clinical Input

> Will usability aspects be considered in assessment?

> Recognising the need for clinical advice and advisory groups

> Take note of the well-trained surgeons and try to retain them

> Clinical engagement/ relationship liaison at each DHB that is possibly employed by PHARMAC during the implementation period of a devices and its services, once these have been decided through the PHARMAC process

> This could possibly be a previous clinical person, who is aware of DHB processes and devices, eg. Nurse, O.T; Physiotherapist

> Assessment

> Will the safety of a medical device be considered?

> Who is responsible for providing support around training and maintenance?

> Bundling of services

> Not splitting the servicing and maintenance components from the medical device.

> DHBs should have the mandate to get the support they need (onsite)

> What kind of economic evaluation will devices undergo?

> Economic evaluations can be expensive

> Is the evaluation fit for purpose?

> The longevity aspects of a medical device, how will this be assessed?

> There are known "metal on metal" issues relating to orthopaedics. Is Medsafe likely to have any part in assessment of such issues?

> In consideration of each competitive product/ medical device; these should be evaluated with independent evidence based research. May not necessarily be the most cost effective initially, but will ensure decreased costs long term. E.g. Anti-embolism stockings that work effectively might be costly at first but will ensure less cost long term.

> Consideration given to:

> Direct patient care

> Indirect patient care (clinical monitoring)

> User acceptability (noise, storage, size etc – e.g. CPAP machines)

> Sensitivity, specificity

> Robustness

> Clinical relevance

> Business reputation/ security (due (word unclear)

> Integration issues / potential business planning

> Capacity / operation model

> Processes

> It is important to recognise the differences between medicines and medical devices;

> Recognising the need for selection

> Category management: The structure needs to be thought about

> Process for RFI: Clear instructions and or easy communication so suppliers can liaise directly and explain the product.

> Possibly arrange meetings to give a full explanation at the second stage of RFIs

> For application process, need to include clinicians, IT specialists

> Process for urgent decisions

> Recalls

> In case of "catastrophic" product failure, will there be a Plan B?

> Product recalls need to be allowed for

> FDA approval should be sought

> Decisions

> Fit for purpose criteria?

> How will excellence in the field be factored in?

> When reviewing and making decisions on which devices will be funded?

> Schedule

> Will the Schedule for Medical Devices be publicly available?

Supply of devices

> Reliability, security of supply (back up plans)

Flexibility to meet local/patient need; retaining choice

> There is importance in providing choice:
  > Tailoring treatments
  > Training
  > Recalls have led to a decrease in choice
> The national database needs to be good (in terms of choice)
> Circumstances for variation in DHBs:
  > Transition costs – staff training etc
  > Security of supply
  > Purchasing power, consistency across settings (patient transfer / movement)
  > Technology growth
  > Single supplier
  > Cost of change – impact on patients / failures – NPT

Asset management

> Has PHARMAC given any thought to tracking and tracing products throughout the different sites?

Definitions & scope

> What is a medical device?
  > There is a very wide range to be considered
  > How will they be compared against each other?
> Will PHARMAC look at becoming a "sourcing body" for medical devices?
  > 'Therapeutic' or 'Clinical'? (Metabolic? Endocrine?)
  > International definitions? e.g. MDA, UK
  > All devices that improve quality of life / health outcomes / therapeutic / clinical
> NPT only or wider? Renal dialysis? Pump therapies?

Data capture

> Databases throughout all DHBs should be nationalised, using the same system and should also be using common coding

Relationships with other providers/entities

> Will there be on-going support and servicing from suppliers?
  > Will suppliers still have the ability to be able to offer this?
> What are the different roles of PHARMAC, HBL, hA and Medsafe?
  > How will it work?

Advances/changes in technology

> How will PHARMAC deal with the growth in technology?
> What about research and development? Trials?
> A 'new device' needs to show improved therapeutic and clinical outcomes

Interim Procurement

> Where are we at with our current procurement work?

Communication with/consulting the sector

> Who will be the contact person "on the ground" from PHARMAC when it comes to leasing with DHBs and the different areas within the DHBs in terms of Clinical Engagement and giving feedback on devices?
> Clarity will to be provided about who to contact and where to find them in future in terms of positions that used to lie within the DHB and won't be in future.
> Simple and effective communications between PHARMAC and DHBs via IT communications, e.g. Meeting Room IT system that enables easier access of shared documents for approval and sign off for a decision making process, instead of waiting until all DHB clinicians/ PHARMAC/ procurement are able to attend meetings.
  > Saves time in the process for decision making on devices.