Consultation on applying the PHARMAC model for hospital medical devices management

MTANZ workshop 6 November 2013

Key points raised by attendees

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

It's essential that PHARMAC's hospital medical devices work is informed by the views of the people from across the health sector and the approach to these forums was to outline that PHARMAC is in an information gathering phase and 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 shape how the PHARMAC model will applied to managing hospital medical devices.

As part PHARMAC's consultation, a workshop was held for members of the Medical Technology Association of New Zealand (MTANZ). The workshop consisted of two sessions, each based around three questions. The below is a summary of responses to those question.

General Questions and Comments:

> Questions would be easier to answer if more context was provided – ie, why does PHARMAC need to know if something is new, the same as something else, or similar but significantly different?

> There are different ways to asking and answering these questions across different categories of medical devices.

> Characteristics of each category might be different

> Get the experts to answer the questions.

> Costs and benefits of a medical device go far beyond the device itself.

> What are the costs and benefits of the clinician or patient using or having this device used on them?

> There are a lot of grey areas to consider in these questions.

> There was a case in Australia where a blood transfusion device was not classified as a medical device which ended up having an effect on the cost of licencing and therefore the overall cost.

> Grey areas therefore need more clarification and transparency.

> International movements, decisions and assessments need to be considered and developments need to be taken into consideration.

> Devices and their ICT requirements need to be looked at as one service

> Packs or bundles of a device and the consumables that come with it already exist.

> How will these be split if one is funded but the other isn't? And do you bother splitting them in the first place?

> Custom-made devices: They most likely won't be registered on the Schedule or be on the National Catalogue, so how will this work in terms of funding?

Session 1:

What makes a new medical device a new medical device?

> A new, different or better answer, outcome or process.

> Any improvement made to a device means it should be considered as a new device.

> If it's got a new GMDN code then it should be considered as a new device.

> Do the procedures differ? Is significant user (re-)training needed?

> Does the device need to undergo WAND registration? If so, then it's new.

What should PHARMAC consider when assessing if one medical device is the "same as" or "similar" to another?

> Is the outcome, material, disposal, classification, quality the same or different?

> A different material may need to be disposed differently.

> If one device can be substituted for another without compromising outcomes and/or without re-training users in its use and/or without recalibrating/reconfiguring associated devices; need to consider differences in longevity of otherwise similar devices.

> Is the cost to register different?

> GMDN codes – ie, similar products have similar codes.

> Are there differences in training and education aspects?

> New Zealand and overseas markets should be assessed to determine differences and whether there is a difference in support as well.

> Purpose helps with the definition of what is the same as or similar to another product.

> Are there differences in compatibility with other devices/consumables/sytems?

> Total cost of ownership, i.e. the consumable that are associated with a device.

> What are the intended clinical and therapeutic outcomes?

> When selling consumables for medical devices there can be an overlap with the same consumables being part of a capital expenditure. This grey area and others like it need to be considered and where the boundaries lie.

> There should be a warranty to show that the calibration between the device and the consumable is in fact warranted and that the device still fulfils its function. The example of a printer and the different colour cartridges was used to illustrate.

> The warranties around consumables should come with the device.

> Safety and quality of products supplied from overseas.

In what circumstances might variation in DHBs' purchasing and use of medical devices be needed and/or reasonable?

> "One size does not fit all": The size of a patient needs to be considered to ensure everyone is catered for; not just about size either (patients have many characteristics); also applies to clinicians' and hospitals' characteristics (ie, what might be suitable for one clinician or hospital or service may not be suitable for another).

> To trial new devices and/or as part of research– sites should be established, available and accessible

> A DHB may have the expertise and other necessary devices/equipment to use one device, but maybe not another.

> When does a new product become new and how is this simplified to ensure that all DHBs could use it if needed?

> DHBs purchase devices at different times – when one needs a new/replacement device, others probably won't. Are there disposal issues?

> Access and connectivity to other devices, systems and the people who supply them.

> Clinical knowledge of a medical device and the cost and time associated with any changes that would come with introducing a new or different product.

> The higher the risk classification of a medical device, the more variance needed.

> The interconnectivity between different devices needs to be considered.

> Variations to existing contracts: Transfer in treatment that occurs when contracts change.

> Clinicians should be able to request which device needs to be used for treatment to minimise the occurrence of these transfers and the time and cost associated.

> Medical emergencies: clinicians should have access to the medical devices they need and the services that sometimes come with these devices from suppliers.

> Demographics and geography may call for variation

> Research/teaching hospitals vs. provincial and/or regional hospitals.

Session 2:

What are the strengths and weaknesses of how DHB hospitals currently assess the safety and quality of medical devices?

Weaknesses:

> Safety and Quality: Currently there is more of a focus on price and cost rather than safety and quality

> Lack of expertise in clinical evaluation when considering the wide groups of people that end up using the device or having it used on them.

> There is variable professionalism and a lack of transparency

> Lack of feedback on applications and assessment processes

> The timelines for tender submissions are sometimes too short which results in a lack of tender submissions.

> Time taken to get a new product through clinical review processes.

Strengths of DHBs:

> FDA, CE and TGA certification is considered

> User evaluations should continue to be run.

> Clinical advisors are specific to their areas.

> Current regulations meet international standards

What is done to ensure smooth implementation and support the optimal use of newly introduced medical devices?

> Servicing, training, education on inventory needs to be provided – and may require doctors to travel overseas

> On-site presence of suppliers – including during procedures; this is crucial to supporting the safe and best use of those devices.

What could be done better?

> A broader scope needs to be introduced:

> Sometimes it isn't possible to gather all the information needed to properly assess a medical device.

> A standardised process should be introduced

> Published and firm tender/RFX timelines of appropriate length

> Greater access to clinicians to ensure the proper services can be provided as access to clinicians is not easy to obtain currently

> Less waste of products with a wider range of devices

> Education should be included in the cost of a device

> Timelines:

> Sometimes the given response time is between 1-2 weeks for tender submissions, but then decisions aren't made or don't get published until a year later.

> Timelines are important for suppliers to be able to accommodate.

> There needs to be a better understanding of quality assurance for on-going plans.

> DHBs should show stronger endorsement of products that are there to minimise cost of supply.

> Recognition (rather than duplication) of robust international quality assurance processes

> The cost for reps to go into DHBs for training and ensure safety and quality is up-kept needs to be considered.

> There should be a greater reliance on reps to help and ensure the device is being used as intended

> On-going education and the associated costs, such as occurs with simulators need to be included along with the cost of the person conducting the training.

> This will ensure the quality of the implementation

> DHBs should honour their contracts.

General Questions and Comments:

> 3PL:

> Where will the products be going? This needs to be communicated for support purposes – concern at potential loss of visibility of where stock is sitting and being used (implications for suppliers' ability to assist recall processes)

> What delivery costs are associated for suppliers?

> Distribution of cost should come under implementation of the device.

> Ownership of the stock – When is it out of the supplier's control and no longer their responsibility? There is a risk associated with this if it is not clearly communicated

> Also risks if people unfamiliar with products are doing logistics (ie, many devices are specialised and fragile)

> One tender with a two year RFP period and five year contract duration equals seven years of a fixed price.

> This will have an effect on competition.

> What are the TGA registration timeframes associated with the processes PHARMAC, HBL/hA are looking at implementing?
  > Are similar issues expected to be had once ANZTPA are introduced to the process?
> Q&A within the different DHBs currently is inconsistent.
  > hA is expected to bring the consistency needed and the quality assurance expected.
> Through this standardisation process that is happening will supplier reps still be required to ensure that usability is optimal for surgeons?
> If New Zealand opens its doors for international competition, will there be a registration process of suppliers be introduced to ensure that all the suppliers in the market are accredited?
  > In Australia there was a process like this where other suppliers voted and could give input as well.
> Free-trade agreements:
  > Will there be a preference to use local or international suppliers?
  > What is the competitive advantage for New Zealand suppliers over international suppliers?