Summary of consultation feedback

Applying the PHARMAC model to hospital medical devices management

December 2013

PHARMAC
Pharmaceutical Management Agency

SUMMARY OF KEY THEMES

The key themes from PHARMAC's October 2013 consultation *Applying the PHARMAC model to hospital medical devices management* are presented here. PHARMAC received 50 submissions. In addition, feedback from regional meetings, Deloitte's white paper *Hospital medical device decision criteria* commissioned by the Medical Technology Association of New Zealand (MTANZ), and comments about PHARMAC in response to the *Finance, Procurement and Supply Chain Consultation* carried out by Health Benefits Ltd (HBL) have also been included in this summary.

Key themes

Defining products within PHARMAC's scope

Devices could be defined by established definitions (eg, World Health Organisation). However, with clinical input PHARMAC needs to clearly define 'medical device,' and differentiate between categories of devices based on the complexity and technology involved. Any definition must include an extensive list of related products and services.

Defining a new device is complex and will require further stakeholder input. Suggested characteristics centre on developmental changes, or changes in use. Different approaches could be used according to the different classes of products.

Interchangeability is highly dependent on the complexity of the device, and affected by many factors. Simple low-risk devices can be easily interchanged; more complex products can not.

Listing on the Schedule

It is crucial to maintain a degree of variation in DHBs' purchasing options because clinically defined need must drive access to devices. Additionally, sole supply can present serious risk in some instances.

Benefits & risks of greater national consistency

Greater national consistency provides an opportunity to achieve economies of scale, avoid duplication of effort and consistency of access to devices for patients, no matter where they live. There may be health benefits from consistency of practice, national management of product recall, and development of expertise in health technology assessment.

There are risks to health outcomes if clinicians cannot choose from an appropriate range of products. There are also risks if the quality and safety of products and the long-term viability of suppliers in New Zealand are not considered.

Limiting the use of devices

The use of devices might be limited because of regulatory approval indications, high-risk applications in cases of indicated patients, or when there is an issue requiring a recall. Decisions to limit use need to be based on product expertise and knowledge of its use, clinical risk and patient outcomes, and made by experts. DHB management may also need to be involved.

The application process

Any application process must be clear, transparent, rapid and with avenues for appeal. Clinical and industry stakeholders must have the opportunity to input into the design. A robust review process is required to ensure flexibility for exceptional use and/or urgent cases.

Quality assurance of medical devices

Strengths & weaknesses of the current system

Currently New Zealand gets the benefits of rigorous international regulatory assessment processes for new devices. New Zealand is able to play a role in the development of new devices and can get earlier access to devices. Hospitals have flexibility to use a product if they wish and assessment can be low cost.

However the current process is ad hoc; hospital conducted assessments can be inconsistent, and efforts may be duplicated. There is a reliance on post-market reviews and limited research about long-term device function and efficacy. The failure of current processes to protect consumers was noted, with surgical mesh cited as an example.

Approaches for a nationally consistent quality assurance process prior to ANZTPA

It could be a requirement for medical devices to be approved by an IMDRF[1] regulator prior to being supplied in New Zealand. However, consumer advocacy groups were concerned about relying on the approval of overseas jurisdictions. Other approaches are: piloting quality assurance processes for specific devices within a variety of categories, and taking a risk-based management approach. Post-marketing surveillance may be necessary – including registries.

Factors to consider when assessing whether a medical device is safe for use & effective

Clinical teams need to decide on the criteria that define safety and effectiveness relating to particular devices. Factors to consider include: urgency of need, intended purpose, available alternatives, risk classification, and any clinical or equivalent evidence.

Economic assessment

What to consider when assessing the benefit of using a new device

Effectiveness and safety should be primary concerns. Other factors 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 be able to deal with the IT component in many medical devices, and consider the whole of life costs, benefits of devices over the long-term, and the indirect social and community costs, including environmental impact.

What to take into account when working out costs & savings

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 reflect the actual or potential impact of the device. Transparency in decision-making was stressed.

Information from a variety of sources (e.g., evidence based research, clinical advisory groups, consumers, product sponsors) is required to carry out assessments. PHARMAC should keep working with national agencies that hold knowledge in this area, and with clinicians, other DHB staff and consumers. In some cases, it may be necessary to provide coverage and then collect evidence from real life usage.

Purchasing strategies & contract management

The more complex a device is the less suited it is too simplistic purchasing mechanisms. Thus PHARMAC should use different assessment tools determined by the nature and degree of identified risk, device complexity and inter-connectability with other devices/products. Processes and tools should be effective and transparent and have procedural fairness. Purchasing strategies and contract management need to account for the total cost of ownership and the direct and indirect benefits of a device. Completion of the design of the tools envisaged would help with further comment.

[1] International Medical Device Regulators Forum

Industry submitters considered that there may be advantages in some circumstances to rebate arrangements. DHB and professional groups described difficulties with confidential rebates.

The way medical devices contracts are managed now

DHB and other clinical submitters support being able to purchase medical devices on direct clinician request. Submitters across interest groups cited relationship development and trust as favourable characteristics of the current process.

There could be more careful evaluation of medical devices at a national level, strict requirements relating to DHBs purchasing off contract, a centralised ordering and distribution system, and improvements to the consistency and quality of contracting processes.

Integrating new devices into hospital processes

The strengths of the current process for approving devices for use are the recognition of clinical autonomy, the minimally restrictive pathway for approval and purchase, and the short timelines. Processes are generally well defined within DHBs and suppliers largely work with DHB stakeholders transparently. Submitters commented favourably on the role of clinical product co-ordinators and the level of engagement and communication achieved.

The variability in the process between or within DHBs is a major weakness. There may be an insufficient number of clinical product co-ordinators, and/or a lack of close scrutiny of all information available before a decision is made to purchase. Industry and DHB submitters variously suggested a wide range of improvements to the device purchase approval process.

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

PHARMAC should provide clarity around its intentions, and the processes that will be used. In particular, PHARMAC must be clear about which agencies will be doing what, and ensure processes are not duplicated. PHARMAC must maintain inclusive stakeholder engagement.

Submitters variously considered PHARMAC had 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.

Submitters to the HBL *Finance, Procurement and Supply Chain* business case implementation consultation questioned the capacity of PHARMAC to be able to manage devices on behalf of DHBs. These comments will be taken into account when PHARMAC looks at its organisational design relating to device management.

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INTRODUCTION

1. This report presents a summary of submissions received by PHARMAC in response to its 2013 consultation *Applying the PHARMAC model to hospital medical devices management*.

Background to the consultation

2. The Government has determined that PHARMAC will manage vaccines and hospital medicines within a fixed budget on behalf of District Health Boards (DHBs). In 2012, the Government also agreed to a phased plan for PHARMAC to progressively take on management of hospital medical devices, while also undertaking some immediate interim procurement activity. This builds on PHARMAC's previous involvement in managing some medical devices used in the community.

3. PHARMAC's management of hospital medical devices will increase over time, as the organisation picks up activity that has previously been managed by other organisations in the sector. PHARMAC has started development of its processes and policies to support this expanded role. The consultation reported on here – *Applying the PHARMAC model to hospital medical devices management* – gathered further information from the health sector (and other interested stakeholders) about how to best apply the PHARMAC model to take on management of hospital medical devices.

4. The aim is to have a functional framework for medical devices management in place by mid-2015, with management activity taking place on an incremental, category by category basis. This will be working towards full budget management, with a capped budget agreed by the Minister of Health and DHBs sometime in the future.

5. The key purpose of the consultation summarised here was to seek information from interested stakeholders to inform PHARMAC's thinking on any issues submitters considered relevant to PHARMAC taking on the management role. The consultation was open from 16 October 2013 to 29 November 2013.

6. PHARMAC will use the information from the feedback summarised here, and from other consultations, to help form a proposal for how it might apply the PHARMAC model for management of medical devices. Consultation on that proposal will be held in May-June 2014.

Preparation of this summary

Fifty one formal submissions were received by PHARMAC for this specific consultation. However, PHARMAC also received verbal and written feedback from regional meetings, , a white paper, *Hospital medical device decision criteria*, commissioned by the Medical Technology Association of New Zealand (MTANZ) and written by Deloitte, , and the *Finance, Procurement and Supply Chain* business case implementation consultation carried out by Health Benefits Ltd (HBL) have also been included in this summary.

Table 1 Feedback received

Meeting notes	*15*
Medical specialty representative group	1
Medical device supplier	1
Medical device industry	2
Regional meetings in the sector	11
Reports & other sources	*2*
Medical device industry association	1
PHARMAC-related responses to HBL's consultation: Finance, Procurement and Supply Chain business case implementation	1
Submissions	*51*
DHB clinical & other healthcare providers	7
DHB non clinical staff	5
Health sector professional organisations	11
Healthcare provider association	1
Government agency	1
Suppliers (Industry)	11
Industry association	2
Individuals	7
Consumer groups	6
Total	**68**

1. In the analysis, emphasis has been placed on the range of views presented, rather than on the numbers of respondents expressing a particular view. Counting was more difficult because some of the responses represented a single voice, while others represented several or many people. An indication of the level of support for various positions has been given in places to show how widely held particular views were. For ease of expression, the term 'submitters' has been used in places to refer to feedback received from various sources.
2. Many of those providing feedback to the current consultation had provided input to PHARMAC's previous medical devices consultations. Submitters were advised it was not necessary to repeat information already given as all feedback provided in any of the consultations will be considered together. An overall executive summary, of all information received from various consultations and sources, is provided in a separate document, which is available alongside this document.

ANALYSIS OF FEEDBACK

1. The analysis of feedback is structured around the guiding questions for submitters included in the consultation document.

General questions

2. The consultation document noted that the Medicines Act 1981 provides a definition of a medical device. This definition focuses on medical devices having a therapeutic purpose.

Defining the products within PHARMAC's scope of hospital medical devices

3. For the most part, feedback on how to define products within PHARMAC's scope was general rather than specific. Several submitters suggested using established definitions such as those provided by the World Health Organisation or Medsafe.

4. Several submitters noted that many newer products combine biological products with biomechanical devices, and employ converging technologies. Due to this, an industry submitter suggested using the definition of the Global Harmonization Task Force[2] (possibly with the addition that these are devices intended for use in a hospital setting). Additionally, several industry submitters suggested that Global Medical Devices Nomenclature (GMDN) categorisation of products may provide a starting point for how PHARMAC determines the scope of hospital medical devices it will manage.

Community use of devices

5. A number of submitters commented on the increasing use of DHB medical equipment in the community, and the interaction between the primary, secondary and tertiary sectors. It was recommended by one submitter that consideration be given to PHARMAC's management of medical devices being extended to cover DHB provided devices which are used in the community.

6. Several industry and DHB submitters suggested that the whole of health technology and all products that are used by a DHB should be within PHARMAC's remit in order to properly consider substitutable or competing technologies.

Management of procurement processes may differ

7. Both industry representatives and a DHB submitter considered that the management of procurement processes may differ according to the type of device. They believed that management of procurement processes for consumable products and medical capital equipment may follow similar broad principles; however, other medical devices, for

[2] The Global Harmonization Task Force on Medical Devices (GHTF) carried out the foundational work for the International Medical Device Regulators Forum (IMDRF). This is a voluntary group of international medical device regulators working to accelerate international medical device regulatory harmonization and convergence.

example, those in the clinical engineering portfolio, would require a more comprehensive process.

8. It was suggested PHARMAC differentiate between categories of devices based on the complexity and technology involved because how an item is managed should relate to the complexity of the device and risk to the patient. Industry and professional groups suggested that the current PHARMAC procurement model could best be applied to low complexity/low risk devices, or those products which have little functional differentiation and for which there are true generic options. An industry submitter recommended PHARMAC classify products based on internationally recognised classes of risk. Further, it was suggested by several submitters that devices in Medsafe's Risk Classification of Medical Devices Class 2a, and above, should come within the scope of PHARMAC's management, and by one industry submitter that Class 1 medical devices could be managed by DHBs.

9. Several submitters commented on areas of particular clinical interest. For example, a medical professional representative group stated that from a diabetes perspective, devices would include: blood glucose monitoring equipment, insulin pump therapy and continuous glucose monitoring devices. One industry submitter considered point of care ultrasound as a category in its own right that should be separate to the category of traditional diagnostic ultrasound performed in radiology and cardiology departments. A medical professional group recommended that PHARMAC consider inclusion of selected neuropsychological and psychological assessment tools.

10. Overall, submitters wanted PHARMAC, with clinical input, to provide a very clear definition of 'medical device.' Submitters also wanted PHARMAC to clearly distinguish which categories of device would be managed by PHARMAC.

Questions about defining products

11. Submitters and those attending regional meetings put a number of questions to PHARMAC:

- Is it PHARMAC's intention to include core laboratory services as part of its remit (e.g. clinical chemistry, immunology and haematology tests that are run on large analysers)?
- How will PHARMAC manage devices where there is very rapid innovation?
- If a DHB takes an innovative technology from another DHB, will this be considered for funding?
- Are there going to be any rules in place nationally for how DHBs handle donated products?
- How will PHARMAC manage trial devices?
- How will PHARMAC manage any costs associated with devices implanted in other countries?
- If community-use devices are included within the definition of medical devices managed by PHARMAC, what will be DHB funded and what will be patient purchased?

Related services that should be included

12. Submitters agreed that an extensive list of related services should be included in the definition of a medical device. It was noted that many medical devices have an element of maintenance, training, support and/or consumable components: these must be considered as part of the scope of that particular medical device.

13. Device related services were generally agreed by submitters to include:

- physician and other healthcare provider training
- regular in-services and education for clinical teams
- in-theatre support
- monitoring, repairs and maintenance of equipment including routine maintenance carried out by users (with guidance from the manufacturer)
- device tracking and safety, and adverse event monitoring.

14. One professional group submitted that funding medical devices should be a holistic contract where implantation assistance, supply and logistics are all included in the contract price – 'the Full Service model is best.' However, an industry submitter noted that as the variety of products and delivery settings in the proposed PHARMAC model is so extensive, the question of whether services, repair, maintenance and training should be included in the PHARMAC purchasing model or whether they should be separately sourced at the service delivery level may need to be determined on a case-by-case basis.

What falls outside the scope of a funded medical device?

15. Defining what was outside the scope of a medical device was difficult for some submitters given the uncertainty of how PHARMAC will define a medical device. However, several submitters suggested product categories or items that should fall outside PHARMAC's scope included:

- ACC and insurance funded devices
- stationery, furniture, and building materials
- major equipment which is specific to the area it will be used in (eg, MRI scanners, operating tables)
- low volume patient specific products
- laboratory developed test (LDTs) equipment, when an approved in vitro diagnostic (IVD) test is available in the New Zealand market (because LDTs, which are developed in laboratories, are not subject to the same quality and safety standards as IVD manufacturers, to ensure safe and effective use of test equipment).

16. A DHB submitter asked that allowance should be made for the development of products within DHBs (eg, a cardiac surgeon designing a heart valve) to ensure expert staff are not lost overseas, for the benefits these developments can bring to health outcomes, and the value they offer to the New Zealand economy. Feedback from regional meetings queried how PHARMAC would maintain such local innovation.

What makes a medical device a 'new' medical device?

17. Submitters took various approaches to the question of what constitutes a new medical device. Suggested characteristics centred on change to a device or in the use of a device, including:

    - any material difference in structure, composition, form, or function from those previously considered
    - any incremental development or change in functionality
    - a fundamental shift in technology, treatment or procedure
    - if a device provides a new answer outcome or process
    - anything that has not been used in an area before
    - if a Medsafe application/notification is required
    - anything new to market and offering better patient outcomes than devices currently on the market
    - something that delivers a new therapeutic benefit or achieves a similar therapeutic benefit to an existing medical device but in a different way that has a convenience or price advantage.

18. It was considered by an industry submitter that new health technology needs to be considered based on the proposed change in health outcomes. Thus it may be a combination of existing products and services offering a different clinical or cost approach; or it may be a combination of device/pharmaceutical targeting a different clinical indication and hence outcome.

19. Another industry submitter suggested that PHARMAC may wish to consider medical technology which is delivered outside of hospital and prevents patients going to hospital or allows a therapy to be delivered in a non-hospital setting as a substitute for an existing in-hospital service.

20. Submitters suggested a device was not new if it treats the same population and:

    - uses the same clinical approach and mode of action to function
    - is iterative or the 'next generation' of an existing medical device.

21. Software changes to a medical device should not render a device 'new.' Similarly, in relation to in vitro diagnostics (IVD), next version assays using the same technology and comparable performance characteristics should not be considered 'new'. On a wider scale, though, emerging technology would be considered a 'new' device.

22. It was noted that changing technology means the introduction of new products will be continuous across the industry and there may need to be different approaches according to the different classes of the products. An industry submitter suggested that PHARMAC may be able to use GMDN to select categories of devices because, in the future, a new medical device will require a Unique Device Identifier and this may create the framework to determine if a product is a 'new device' or not.

23. Another industry submitter also considered that if a device has a new GMDN code it should be considered a new device. This submitter also noted that a different Global Trade Item Number (GTIN)[3] is not 'an appropriate surrogate for a new medical device as different GTINs are required for multiple reasons including different carton sizes, different product sizes and minor variations.'

24. Industry, professional groups and DHB submitters noted that defining a new device could be complex. For example, is a replacement oxygen regulator that is from an alternate supplier a new medical device? The device itself is not, however the product and the associated distributor is a new device. What about a new test on a core laboratory instrument? Submitters also questioned how PHARMAC would incorporate very new products, and DHB designed or customised products into the PHARMAC model. Several submitters suggested that PHARMAC would require the advice of various medical advisory committees to advise when a device is just a new model or when it is a new device.

Determining if one medical device is interchangeable with another

25. Devices were generally considered by submitters to be substantially clinically equivalent if they have:

- the same intended use
- the same patient population
- comparable risk profiles
- the same safety and effectiveness outcomes
- substantially equivalent patient outcomes
- the same clinical utility
- a basically similar method of treatment, including time to treat and ease of use
- the same design, function and technological characteristics
- the same clinician skill levels required for use
- no additional training required for use.

26. Submitters also commented on a range of factors to take into account when considering interchangeability:

- how devices are used and who uses them – clinicians are 'notoriously innovative' in using a medical device for something other than what it was originally designed for.
- alternatives staff will switch to if they do not like the new device
- techniques and other devices used during the procedure
- individual patient differences – and opportunities for the patient's voice to be heard
- environmental costs
- interchangeability of components which need to interface with other products and systems and which may be needed for future revisions.
- compatibility with software.

[3] Global Trade Item Number (GTIN) is an identifier for trade items developed by GS1.

27. With respect to all of these factors, PHARMAC must take into account variation between DHBs and where devices will be used (e.g. tertiary or regional healthcare facilities). The appropriateness of devices will be driven by the clinical care provided in each locality.

28. Additional factors to consider are:

- consignment values, access and volumes
- logistics and supply chain
- inventory management and support
- the cost and risks of change
- loan set requirements, instrument set requirements
- historical data on quality, failure rates, infection
- supplier quality – local staff, clinical abilities, range of products, availability of support services
- quality assurance systems and processes including cleaning and disinfection standards for all facilities.

29. Overall submitters considered that interchangeability is highly dependent on the complexity of the device. Simple low-risk devices such as tongue depressors are easily interchangeable; more complex products may not be. Where technologies have the same functionality, comparative clinical and cost analysis should be possible.

30. One industry submitter considered that medical devices are rarely 'interchangeable' the way many pharmaceutical products are, even though they may be in the same class, performing similar functions and produce similar outcomes. With the absence of clinical trial data evidence in relation to medical devices, 'substantially similar' becomes a subjective measure.

Listing on the Pharmaceutical Schedule

31. The consultation document noted that the Pharmaceutical Schedule will list medical devices available for use in public hospitals. The Schedule will provide a nationally consistent list of medical devices that DHBs can procure.

32. Several industry and DHB submitters asked that the segment of the Schedule covering all medical devices should be renamed *the Medical Devices Schedule*, as having devices listed under the Pharmaceutical Schedule was misleading. It was also considered by one industry submitter to send an inappropriate message about the interchangeability of all aspects of regulation and health technology assessment between pharmaceuticals and devices. This was problematic as there are very different considerations and methodologies required.

Reasonable variation in DHBs' purchasing and use of medical devices

33. Submitters agreed that it would be crucial to maintain a degree of variation in DHBs' purchasing options, although it was not clear to submitters what this would mean in practise. However, several submitters stated that in many cases more than one option must be available for a specific therapy or procedure area.

34. Health outcomes related clinical preference was the reason most commonly cited by submitters for having variation in DHBs' purchasing of devices.

35. Many submitters related the need for variation to considerations of clinical expertise with devices amongst clinicians, and the need to consider patients that do not fit the standard criteria for the use of some devices (including cases of orphan technologies[4] or under rule of rescue.[5]) Certain medical emergencies may also require variation in DHBs' purchasing. These considerations may result in variation requirements for medical devices even within one DHB. Variation in uses may also be dictated by the types of medical diseases and surgical specialties that are treated within an institution.

36. An industry submitter considered that maintaining variation in DHBs' purchasing options was particularly crucial for specialty products in specialised tertiary centres. It was noted too that variation may be necessary because DHBs are very different in structure, staffing and the data systems they use.

37. The need to maintain a viable medical technology industry in New Zealand was also stressed. Submitters considered there was a need to have a range of companies in the New Zealand market for the purposes of competition, as well as having alternative suppliers available in the case of supply interruptions from tendered suppliers. Also, existing products may require the ongoing support of supplier companies – who will not be able to viably maintain a presence in the small New Zealand market if they are locked out of ongoing supply contracts.

38. Related to the above point, many submitters commented on the risks relating to sole supply. These submitters stressed that PHARMAC needs to ensure that small suppliers are on an equal playing field and do not leave the New Zealand market. There was also a risk of multinational companies not entering the New Zealand market.

39. Further, submitters commented on the need to maintain local innovation, and support local industry and job growth. It was noted that the locally based industry could be seriously disadvantaged by global market strategies.

40. One clinical group submitted that if PHARMAC did not incorporate health-related environmental indicators into its devices criteria, DHBs should retain the right to receive subsidies on the purchase of devices that are demonstrably more sustainable than the devices listed on the PHARMAC schedule. This would prevent DHBs having to breach their statutory responsibility to the environment (under the Public Health and Disability Act 2000).

[4] 'Orphan technologies represent treatment for niche indications with such small patient populations that significant levels of evidence will never be available to support a comprehensive assessment.'

[5] 'A Rule of Rescue should apply when a technology is associated with residual clinical or financial uncertainty, but offers the last treatment option for a relatively small and clearly defined patient group who face considerable morbidity or mortality.'

Benefits and risks associated with greater national consistency of DHBs' purchasing and use of medical devices

Benefits

41. The primary benefit of greater national consistency in the purchasing of medical devices, cited by industry and DHB submitters, is the opportunity to achieve some economies of scale.

42. Submitters also considered that there may be health benefits to New Zealanders. These would come from:

- consistency of practise no matter where in New Zealand people seek treatment
- extending proven DHB models of care that work for particular patient groups
- staff and patients moving between hospitals having access to products that they will be reasonably familiar with – creating a safer treatment environment
- in relation to product recall, incidents will be managed nationally.

43. Further possible benefits suggested by a range of submitters included:

- the development of corporate expertise in health technology assessment
- innovation through health technology horizon scanning and risk sharing options
- transparency of processes
- avoiding duplication of effort
- clarity in pricing models.

44. One DHB group submitted that national consistency provides an opportunity to reduce the impact the sector has on the environment. This submitter noted that it would be better to adopt such principles at the time of establishing PHARMAC management rather than 'overhaul the entire process in five years' time when carbon reduction becomes an international necessity.'

Risks

45. Industry and DHB submitters identified a similar range of risks associated with greater national consistency of DHBs' purchasing and use of medical devices.

46. Primarily, submitters considered that there are risks to health outcomes if clinicians are not able to choose from an appropriate range of products to cater to the inherent differences in patients and conditions. There are also safety risks if appropriate consideration is not given to the quality of products supplied and the long-term viability of the suppliers chosen. In addition there is a learning curve effect involved in surgeons changing to new products and procedures which can have impacts on outcomes. Similarly there can be patient usability and compliance risks when changing technologies with which patients are familiar.

47. It was also suggested there may be a tendency to simplify and rationalise the diverse range of products needed by particular patient groups. There is the risk of a technology poor health system depending on the approval processes.

48. Additionally, if clinicians refuse to use a poorly chosen device there may be a failure in the delivery of services. A reduction in choice could also frustrate clinical staff, leading to a loss of experts because they are not able to obtain the latest technology.

49. Supply defragmentation may mean a lower level of customised support to DHBs. There may be a transfer of unfunded costs to DHBs, for example, costs associated with education around medical devices. The geographical variation in access to support must be taken into account.

50. Greater national consistency could reduce competition leading to suppliers leaving the New Zealand market. Submitters considered it critical to avoid sole supplier situations to maintain a competitive, innovative market, continuity of supply and strong service support. A monopoly could result in complacency on the part of a supplier, uncontested price increases and risk to patient care (where there is any failure in the supply chain or a device is found to be inadequate on long-term follow-up).

51. Further, a mass purchasing programme for devices, for example, anaesthetic machines, must take into account that the entire fleet for the whole country may fail at about the same time. For example, modem machines are designed to function for 5 to 10 years. At the 10-year mark, compatibility issues mean that it may not be possible to fix the machine, there may be a new supplier, and 'there is a very real risk of surgery across the country grinding to a halt with the previous supplier having left the New Zealand market entirely.'

52. Damage to the long-term viability of the New Zealand market in medical technology would mean increased costs as hospitals and DHBs 'pick up the slack' left by departing companies that had provided a support service, and remaining companies – without competition – also withdraw this support. Consideration must be given to spreading risk and due diligence regarding the viability of suppliers chosen.

Limiting the use of some medical devices

53. Industry groups suggested a range of circumstances in which the use of devices might be limited:

- regulatory approval indications
- high-risk applications such as:
  - situations where the device could lead to serious injury or death if it malfunctioned
  - where a high degree of skill was required to correctly implant or use the device
  - where clinical outcomes had demonstrated an otherwise unexpected concern with a specific technology or design
- if an assessment of a new medical technology by PHARMAC identifies a sub-group of indicated patients where the technology would not be cost-effective
- when a manufacturer determines that there is an issue which requires a recall.

54. DHB submitters and medical professional groups also considered that the use of some medical devices might be restricted to certain practitioners where there are limited

indications for their use or where the devices are used infrequently. Thus a smaller group of users would gain and retain sufficient experience in the use of a device to ensure its appropriate usage, correct technical application and optimal clinical outcomes.

55. It was noted by a medical professional group that high cost medical devices within the surgical sector, (eg, harmonic scalpels) are largely limited to those used by consultants, or by residents under direct consultant supervision. This submitter saw no reason to change this. There would be an issue if this process was formalised and required prior approval, thereby creating delays in procurement.

56. A DHB submitter suggested that examples of IVD medical devices, where special authority might be applicable, are point of care devices, and any IVD medical device tests that are low volume (suited for single national testing laboratory) and highly complex.

57. One clinical group considered that devices should not be allowed that are detrimental to the environment because of hazardous manufacture, excessive travel emissions, poor in-use energy efficiency, short lifecycle or hazards associated with disposal (or excessive costs associated with responsible disposal).

58. An industry submitter noted that limitations based on budgets should be avoided. However, several DHB submitters suggested that there may be situations where the use of veryexpensive products are limited.

Who should be involved in setting those limits

59. The small number of submitters who commented on who should be involved in setting limits agreed that decisions to limit use of devices need to be made by staff who are expert in the area, including physician associations and health professional bodies. These decisions should be based on expertise, clinical risk and patient outcomes. A few submitters noted that budget holders also need to be involved.

60. It was noted by a healthcare provider association that there will always be circumstances where 'inappropriate for general use' items need to be made available for treatment. However, these situations should not be permitted to occur on a large scale in individual DHBs when there is a national contract in place.

When DHB management should be involved

61. Feedback from several submitters and those attending meetings suggested that there was insufficient information about PHARMAC's intended device management processes to comment on when DHB management should be involved. One submitter noted they needed to understand how capital expenditure would function in DHBs. For example, who will have control of asset management funding in DHBs?

62. A clinical submitter commented that management does need to be involved because many DHBs have a huge store of knowledge about devices and their deployment and it makes sense to use this; it would also contribute to developing goodwill between PHARMAC and

end users of listed devices. One industry group noted that DHBs need to own health technology decisions equally with PHARMAC to ensure quality outcomes are achieved.

63. Submitters described various circumstances where DHB management should be involved – noting that decisions about what type of device is to be used must be clinical decisions:

- at a local level managing DHB budgets – because each DHB has a different mix of medical device requirements
- in determining the provision of a service where the need is frequent and the associated costs are high
- in cases of capital expenditure purchases, suite layouts, DHB-wide changes of products, releasing staff to be involved in processes off site, large expense products, and products that require in-depth education and training
- through a clinical assessment team (e.g. when a surgeon makes a case to go outside of the implant banding requirements) .

Creating an application process for medical devices

64. In the consultation document PHARMAC noted there needs to be an application process to list medical devices on the Pharmaceutical Schedule. This process will set out who can make an application and what information PHARMAC needs to consider in the application. In accordance with its governing legislation, PHARMAC will also operate a scheme for DHBs to access medical devices not listed on the Pharmaceutical Schedule in exceptional circumstances. Respondents were asked what needs to be considered when creating an application process for medical devices.

65. The main considerations put forward by submitters for creating any application process were that the criteria are clear and the process rapid. It was noted that many medical devices are required urgently and any delay in availability may compromise patient outcomes. Professional groups, DHB and industry submitters stressed the importance of consulting with clinicians.

The information required

66. Clinicians and other DHB submitters noted that the application process should collect information on:

- the proposed medical condition or situation where the device would offer improved quality of life
- the material composition of the device
- how the proposed device differs from existing medical devices
- any specific associated benefits and risks
- compliance with national safety and efficacy standards
- pre- and post-market support and service (which may differ according to location) and the impact of any reduction in existing suppliers on this
- ongoing education require
- comparative clinical and cost outcomes evidence (noting difficulties with evidence)

- engagement and endorsement of all components of the care pathway affected, including device integration with electronic medical records, and interconnections with other systems and information exchange.

67. One DHB group considered that carbon costs, environmental degradation, costs of manufacture and the full life cycle of the product should also be considered in the application process. This submitter referred to methodologies for carbon pricing of both pharmaceuticals and medical devices.

Evidence

68. Several submitters commented on studies of the device being considered in the application process. Studies should encompass the performance of the device in laboratory development studies, animal testing and human studies; and independently funded and conducted clinical studies of the device. These should demonstrate satisfactory outcomes with an acceptable risk profile. The studies should cover a sufficient duration to ensure that the device does not show significant deterioration in its performance for the clinical outcomes achieved over time. There should also be an investigation into local assessment that has been undertaken.

69. An industry submitter noted that the application process should avoid unnecessary cost and delay or duplicating processes or studies that already exist. For example, in order to claim IVD status under FDA or CE regulations, manufacturers are required to verify performance claims through a number of robust verification studies and in some cases, clinical validation studies. It is common practice in New Zealand for individual laboratories and hospitals to repeat verification studies on a smaller scale, thus delaying time to adoption. The value and efficiency of conducting these local studies is questionable.

The process

70. DHB and industry submitters wanted an application process which:
    - is transparent for all stakeholders
    - has contestability of process
    - has clearly defined requirements
    - indicates timelines
    - is designed in conjunction with clinical and industry stakeholders
    - is efficient and minimises delays to the device being available to clinicians
    - minimises duplication of work
    - does not burden any part of the healthcare system and industry with additional costs
    - has an avenue for appeal.

71. Several submitters also recommended that PHARMAC consider the following in the application process:

    - the speed at which technology changes
    - how many clinicians will be using the device
    - whether the device would replace another item.

72. Submitters also suggested that applications need to be easy to complete, and to have enough of the required detail upfront so that there is no 'to and fro' with clarifying information and providing more information

73. A supplier asked that Requests for Information be characterised by clear instructions and easy communication so suppliers can liaise directly and explain the product.

74. One industry submitter recommended a rapid triage process that could route any device assessment through fit-for-purpose evaluation pathways, based on potential financial exposure and degree of change required to implement.

75. Relating to designing a process, a health professional group recommended PHARMAC should use the FDA guidelines and consult with the relevant clinical societies and Medsafe. This submission stressed that the approval of new implants should not be PHARMAC's role.

Local sign off

76. One healthcare provider association noted that a decision needs to be made as to whether a central process will be applied so anyone can place a request with PHARMAC, or whether there is a local sign off requirement.

77. Another submitter asked whether applications will need to have agreement from specialist groups nationally (in order to encourage standardisation). PHARMAC must also consider what level of decision making about products lies with specialist doctors as opposed to nurses or procurement only.

Exceptional circumstances

78. Industry submitters noted there must be a robust review process for 'named' patients, thus ensuring flexibility for exceptional cases. A defined process removes the need for case-by-case judgement. However, there should be sufficient flexibility in any process to consider orphan devices.

79. One submitter questioned how PHARMAC would assess and prioritise custom-made products for individual patients. It was suggested that custom-made devices be exempt from the Pharmaceutical Schedule listing. Submitters requested further consultation by PHARMAC around what constitutes exceptional circumstances in relation to medical devices.

Situations where urgent decisions might be needed

80. Overall, submitters considered that the provision of medical devices should be driven by patient need, based on clinicians' determination of requirements. Submitters suggested that the following situations may require urgent decisions:

- the provision of acute care
- constraints around expensive but very specific devices used in emergency procedures (e.g. radiological catheters)

- emergency situations such as natural disasters or epidemics
- a major recall with no immediately available alternative
- supply shortages and logistics issues
- revision procedures.

81. Other situations warranting urgent decisions were compelling new evidence either about a new technology or one which calls into question an existing alternative technology; or a breakthrough technology which may not have significant evidence of long term cost efficiency and outcomes but which shows strong promise of these.

82. One industry submitter considered that urgent decisions should be limited to circumstances where there is no comparator product and access to the medical device will result in avoiding an adverse clinical event. This submitter considered that PHARMAC's current criteria for urgent assessment described in the named patient pharmaceutical assessment process would also apply to devices.

83. A health professional group suggested the National Health Committee (NHC) and Medsafe should have a subcommittee which makes urgent decisions, with PHARMAC arranging the purchase price. This submitter noted that urgent decisions on implants can cause unintended consequences later.

Quality assurance of medical devices

84. The consultation document noted that PHARMAC must consider how to gain a reasonable level of confidence about the quality and safety of the medical devices listed for use, especially before it is intended the Australia New Zealand Therapeutic Products Agency (ANZTPA) take on pre-market approvals for medical devices in July 2016.

85. Submitters were asked about the strengths and weaknesses in the current assessment of the safety and quality of medical devices used in public hospitals.

86. It was stated by several submitters that the quality and safety of medical devices is not one of PHARMAC's responsibilities. However, a patient interest group noted that PHARMAC does have a current role in 'clinical assessment of pharmaceuticals', 'maintaining patient safety and balancing access with evidence of health gain and cost-effectiveness.'

Strengths and weaknesses in the way safety and quality of medical devices are assessed

Strengths

87. Industry and clinical submitters stated that although New Zealand is an unregulated environment, DHBs make it a condition of supply that products have current regulatory approval in another major regulated economy. Products with CE, FDA or TGA approval have already been thoroughly evaluated. Through this system, New Zealand gets the benefits of the regulatory assessment processes that provide assurance to the citizens of major economies at little or no cost to New Zealanders.

88. Many submitters considered that the current Medsafe, WAND and PEHNZ process provides suppliers and DHBs with a relatively short and straightforward method for allowing new products to be added to DHBs' systems. The benefit of the current process is its simplicity and acceptance of work done by other jurisdictions. Additionally the current system allows devices to be made available for particular patients or circumstances, in a relatively short timeframe.

89. It was noted that new medical products gain access to the market more easily in New Zealand than in many other countries. Manufacturers and developers of medical devices have taken advantage of this in their product development. This has allowed New Zealand to play a role in the development cycle of new devices. Several submitters noted that the current system promotes innovation, research and development in the New Zealand health system. This has benefits for the whole economy not just the health system.

90. DHB submitters noted that from a hospital's perspective conducting their own safety and quality assessment allows them to be flexible. In hospitals, devices are selected on broader criteria than device features and clinical preference alone. One of the strengths of the current process is that each DHB is able to ensure that the piece of equipment being looked at is compatible with the other pieces of equipment already in the DHB.

Weaknesses

91. One industry submitter considered that Medsafe does not currently have the capability to assess risk-benefit analysis of devices. Additionally, a consumer advocacy group noted the failure of Medsafe processes to protect the public from harm. Surgical mesh was cited as an example of this by several individual submitters and advocacy groups.

92. Submissions from individuals and consumer advocacy groups stated that medical devices are not sufficiently tested before being used on patients. An industry submitter noted that the lack of pre-market assessment to verify the quality and safety of devices meant there was heavy reliance on post market reviews for detecting problems – potentially too late for patient safety. Further, consumer advocacy groups considered that monitoring the negative effects on health of certain devices has been 'less than robust' in New Zealand.

93. A professional group noted that many devices have a long life expectancy but only limited research is available about long-term function. There is a lack of tracking and reporting systems for implant devices designed to become a permanent part of the body.

94. Several DHB submitters stated that the current process was ad hoc: any product can be used in a public hospital as there is no robust system for approving products. Hospital conducted assessments can be inconsistent if not using a standardised protocol, if there is poorly defined acceptance criteria, variable evaluator skill sets or a lack of clinical input.

95. Additionally, there is a reliance on clinical product co-ordinators (CPCs) to ensure the relevant TGA, CE or FDA certificates are available; however there has been no training

available as to what to look for in the certificates or how to identify a fake certificate. Not all teams within a hospital may be diligent with checking products against recognised standards. Some devices may not follow normal processes, such as donated equipment or devices 'free' from suppliers if consumables are used. Consequently strengths and weaknesses vary by hospital.

96. In relation to IVD devices, manufacturer's quality assessments may not be considered by DHBs, resulting in duplicated efforts at potentially every DHB, adding to cost and unnecessary delay. Further, the manufacturer's assessment is not always independently reviewed by an objective expert, nor is there a national guideline on validation criteria in New Zealand. Even if assessed and approved, off-label uses are not always reported to clinicians: this may result in improper use of the test.

A nationally consistent quality assurance process until ANZTPA starts operations

97. Many DHB, health professional group and industry submitters suggested the requirement for medical devices to be approved by an International Medical Device Regulators Forum (IMDRF) regulator (e.g. TGA, Health Canada, EU, FDA) prior to being supplied in New Zealand. This would provide a high level of assurance at low cost. This requirement could be administered at PHARMAC or within DHBs, as is currently the case.

98. Similarly, the current system of Medsafe WAND notification could be amended to restrict WAND listing – and consequently supply in New Zealand – to medical devices which currently hold one of these certifications. This would remove the administrative requirement from DHBs and PHARMAC; it would also widen the requirement to all medical devices – whether they are supplied on tender or not. It was noted by one submitter that WAND processes are adequate in relation to the safety and efficacy of devices if the request for compliance to CE mark is maintained as a minimum.

99. In relation to the current operation of the WAND database, a health professional group suggested that the status quo is probably adequate for low-risk devices such as gloves.

100. One submitter suggested maintaining existing regulatory documentation (and reviewing it with knowledge), and ensuring products all have sign-off by Clinical Engineers, Infection Prevention and Control staff, and other relevant services. Using this approach, PHARMAC will need to consider what processes should be applied to DHBs without CPC roles in place currently and what impact that might have on consultations and implementation.

101. A professional group noted that being used elsewhere is not a warrantee for use in New Zealand. Products should be used either in an appropriate level DHB or in quantifiable numbers in Australia. References should be obtained in both cases.

102. One industry submitter noted that health providers should use reputable global companies as such companies not only have a robust quality system in place, but a reputation that depends upon it.

103. Another industry submitter suggested taking a risk-based management approach, designed to ensure public health and safety. Review should be directed toward a select few higher risk devices.

104. Any process should not introduce excessive cost and delay and should be fair. For example, laboratory developed tests or in-house developed tests should be held to the same standards as regulated IVD tests. If local assessments are required, these should be performed by independent national assessment centres and should include vendor quality assessment.

105. A professional group suggested piloting quality assurance processes for specific devices within a variety of categories. This should include some high value/low volume and some low value/high volume examples. The process should continue only when the pilot shows that PHARMAC has a robust approach which is widely accepted by all the key participants.

Monitoring & reporting

106. Consumer advocacy groups asked that PHARMAC identify what systems will be in place for reporting adverse events in relation to use of medical devices; and how the public, as well as clinicians, can report specific concerns that are addressed in a timely manner. There must be robust reporting pathways that link data from various sources, (such as reports to ACC, hospital incident reports, sentinel event reports, reports to and from the manufacturer) and these should be collected in a single, independent New Zealand clearinghouse repository. The dismantling of the Intensive Medicines Monitoring Programme was noted, giving one submitter no confidence that safety and quality are a priority.

107. Advocacy groups considered it essential that PHARMAC put in place a robust and publicly accessible system (without waiting until ANZTPA starts operations) that obtains the following information:

- the approval process the medical device has gone through – if any
- the number and size of the clinical trials that have been undertaken
- whether all the data from the clinical trials was published and is available to health agencies and authorities
- any financial ties that the researchers have to the company that manufactures the medical device.

108. Industry and patient interest groups suggested that PHARMAC consider the establishment of a central registry to record implanted devices. Such a central registry would:

- collect product numbers, user information (including surgeon), patient characteristics, etc
- ensure that a reliable record exists of patient treatment (which may be critical in cases of recalls)

- facilitate the systematic accumulation and synthesis of knowledge about product history to inform future decision-making
- help ensure that knowledge held by individual clinicians is not lost to PHARMAC.

109. Patient advocates also suggested that DHBs and clinicians use a robust informed consent process if they are using certain devices, and that doctors be mandated to report all and any complications patients experience after device implantation.

110. More generally, these submitters recommended:
- better evaluation of new and some current technologies and their applicability in the New Zealand healthcare system
- improved accountability
- consulting with key stakeholders, including patients.

111. A health professional group suggested a specific work stream should be established on management of device recalls, to address patients' and health practitioners' expectations, and appropriate communications regarding replacements and alternatives.

The proposed ANZTPA

112. In relation to the proposed ANZTPA, it was suggested by an industry group that the ANZTPA adopt Global Harmonization Task Force (GHTF) Essential Principles of safety and performance and the ISO 13485 standards, rather than developing local unique principles and requirements. Products that can show CE certification or FDA clearance should not be expected to repeat the process under ANZTPA to enter a significantly smaller market.

113. A professional group noted that ANZTPA may slow the process down ('as it has in Australia'). This group considered that if the process is too slow and cautious, New Zealand is unlikely to retain its 'extremely high outcome level' surgeons.

Factors to consider when assessing whether a medical device is safe for use and effective

114. Overall, submitters stated that, firstly, PHARMAC must consider whether evidence exists – appropriate to the perceived risks of the device to support its safe and effective use; and secondly, that an appropriate system is in place for monitoring the ongoing performance and safety of the device. However, clinical teams need to decide on the criteria which define safety and effectiveness relating to particular devices.

115. Submitters suggested the following factors to consider when assessing whether devices are safe for use and effective:
- the urgency of need of the device
- classification of the device (based on risk)
- the intended purpose
- alternatives that are already available
- any clinical evidence or equivalent evidence
- the lifecycle of the product

- the degree to which there will be on-going support and servicing from suppliers.

116. Where applicable, devices must have the ability to have technology upgrades, interoperability and connectivity. Connectivity should allow for wireless use and information storage locally, should the connection terminate. There must be secure two-way messaging of information from and to the medical devices that follows health information exchange standards and security, and robust back up storage systems for information that is suitably encrypted.

117. There should be a robust system for distribution and recall that ensures the quality and safety of devices, in particular considering the disparate geographical distribution of products.

118. One submitter noted the importance of global standards for identification, especially when paired with automatic identification technologies to track individual healthcare products (drugs, devices, biologics and blood products).

119. Several submitters posed questions to PHARMAC relating to product safety:
    - How responsive will PHARMAC be when a device does not perform to standard?
    - What will the incident management system look like?
    - How will PHARMAC manage any constraints in availability of devices (which pose a risk to quality and safety) related to a reduction of suppliers in the market?
    - How will ongoing issues such as recalls, product complaints, and discontinued products be dealt with?
    - Where does the responsibility lie for indemnity?
        - What is PHARMAC's role in taking responsibility for an item placed on the Schedule that turns out to be faulty?
        - What is the role of the industry?
        - What is the role of the clinician?
    - Noting the significant differences in the nature of various products, has PHARMAC given any thought to tracking and tracing products throughout the different sites?
    - How will the 'long-jeopardy' aspects of a medical device be assessed?

Information needed to demonstrate whether a device is safe for use and effective

120. Many submitters stressed that clinical teams need to decide on the criteria which define safety and effectiveness. Beyond this point, submitters suggested a range of information that could demonstrate whether devices are safe and effective.

121. A health professional group and DHB submitters suggested that safety and effectiveness should be confirmed by consideration of available laboratory evidence. ECRI, ASNZ Standards and Joanna Briggs Institute (JBI CONnECT) were suggested as repositories that relevant specialists would reference. This evidence would establish the effectiveness and safety of the device, and the outcome measures of well-conducted independent clinical trials with adequate length of follow-up. Where such information is not available, close

scrutiny of the applicability of the device is needed with a requirement for outcomes monitoring – if a device has sufficient perceived benefit for early introduction.

122. A number of industry and DHB submitters stated that recognition of prior approval from an IMDRF regulator was sufficient. This condition would essentially be met if accepting third country certifications. Several submitters considered there should be no requirement to assess whether the medical device is safe for use if it has already been approved by one of the IMDRF (previously GHTF) founding member countries who have well established regulatory frameworks. Further review in New Zealand would be an unnecessary duplication of efforts.

123. However, one DHB submitter noted that a device may be CE registered but not meet criteria for safe and effective use. Further, an industry group noted that while it could be a requirement that suppliers provide third country certifications, these can be complex to cross check and interpret. A simpler solution may be to have suppliers self-certify that they hold one of these approvals and provide for significant penalties for deliberate false declarations. Additionally, the reputation of the supplier and associated systems and processes mitigate any possible risks.

124. A patient advocacy group noted their concern with the increasing trend in New Zealand to rely on overseas jurisdictions' approval of various medicines or devices. This submitter noted that while this may appear to be an efficient use of resources there have been multiple cases where FDA approvals have been shown to be influenced in a biased way by the sponsor, with subsequent unsafe outcomes for patients.

125. Several submitters suggested that products be coded using GMDN and marked with a GTIN for ease of distribution and recall. Further, databases throughout all DHBs should be nationalised, using the same system and common coding.

126. It was suggested that coding and selection based on expected clinical impacts should adopt international clinical risk modelling. A stratifying process based on clinical risk to the patient and therefore strength of evidence should have similar coding standards as proposed for ANZTPA, to minimise additional administrative costs to all stakeholders.

127. It was also suggested by several submitters that robust post-marketing surveillance was necessary (including registries). It was noted that PHARMAC will need to resource this (pre and post marketing) knowledge.

128. A professional group considered that information relating to safety and efficacy should be obtained by working through the National Health Committee, clinical groups and Medsafe: PHARMAC should not be required to operate in this field.

Economic assessment

129. The consultation document noted PHARMAC's use of cost-utility analysis (CUA) in deciding whether funding a new medicine or medical device will make the best contribution to New

Zealand's health. It was also noted that PHARMAC understands that medical devices differ from medicines in a range of ways.

Considerations when assessing the benefits of using a new device

130. Many submitters stated that effectiveness and safety should be primary concerns. Only after these have been taken into account, should the relative merits of a new device compared to an existing device be considered.

131. One industry submitter noted that there are currently complex funding and stakeholder relationships which support New Zealand health outcomes; if PHARMAC dissembles these extended service/product structures, the full impact of such actions must be properly analysed.

132. Noting these general points in relation to making any assessments, submitters suggested a number of factors be taken into consideration:

- clinicians' preferences – feedback from DHBs suggested it would be difficult to get consensus with regard to which devices individual clinicians prefer
- clinical requirements – how an item is used, does it fit with other items needed for the same procedure?
- training required
- assurance of continuity of supply
- associated consumables
- the need for ongoing device support.

133. Submitters commented extensively on maintenance and servicing of medical devices. PHARMAC must consider:

- the service specifications
- specialised testing requirements of the equipment
- manuals and service operator training
- servicing in-house compared to servicing externally (by a supplier) – in-house servicing is faster, does not have expensive hourly rates and other costs and may not result in clinics and theatre operations being cancelled
- appropriate differences in service contracts between a small healthcare facility and a tertiary centre.

Data & assessment

134. Submitters asked that the indirect social and community costs arising because of a health condition, as well as direct healthcare costs, be considered. Further, the whole of life costs and benefits of devices over the long term should be taken into account.

135. Patient advocacy groups asked for consumer involvement in decisions. It was noted that where patient groups are small the evidence base for best clinical practice will generally be anecdotal. Patient groups need to be able to trial products and assess for themselves if they are suitable for their needs. A consumer advisory group also noted that consumers need to

be able to provide input into PHARMAC's analysis of a product's effect on a patient – particularly for devices where patients are expected to use or manage these themselves.

136. Cost analysis and health economics should not only be done in New Zealand: international information and evidence should also be considered.

137. One industry submitter, who endorsed the use of CUA, noted that many confounding factors may influence patient outcomes. Although unrelated to the medical technology (e.g., hospital infection control), these factors may be attributed to the intervention. This adds to the complexity of evaluation.

138. In relation to the evidence base, the capital spend may be relatively easily obtained but the costs of accessories and consumables will be somewhat harder to collect.

139. Considering all of these aspects of data collection and assessment, some submitters doubted that the infrastructure to adequately capture this data currently existed.

Approaches

140. One professional group requested that PHARMAC exclude orthopaedic implants from any new assessment process. 'There are already established best practice international processes for assessment and PHARMAC should use these when a new device is needed.' Similarly a healthcare provider association suggested PHARMAC use clinical advisory groups with a CPC and the appropriate representative input and 'leave it to them.'

141. It was suggested by an industry group that the level of assessment should match clinical and fiscal risk – products with strong clinical evidence and/or limited financial impact should require a less detailed assessment and therefore be progressed more quickly. Noting the specialised expertise required and the resources associated with making these assessments, one industry submitter considered it important that the role of health technology assessment is detached from any procurement responsibility. This submitter proposed a tiered evaluation process whereby:

- Selected therapies are evaluated by the NHC, which will conduct an evidence-based, generic health technology assessment and consider the available evidence from all sources (not just randomised controlled trials).
- The NHC's report should identify which specific products have adequate clinical and economic evidence to warrant inclusion on a list of 'approved products.' It would then be PHARMAC's responsibility to negotiate with the sponsors of products on the approved list.

142. Further benefits may be gained by PHARMAC monitoring the efforts of international assessment agencies such as NICE, and selectively adopting medical technologies that have been identified as cost effective in other places. Adaptation of the findings using New Zealand inputs (costs, epidemiology, etc.) may be enough to inform decision makers as to whether the device should be adopted.

143. The need for transparency in decision-making was stressed by DHB and industry submitters.

Questions put to PHARMAC by submitters

144. Submitters commenting on the assessment of benefits put a number of questions to PHARMAC:

- Given the very wide range of medical devices, how will they be compared against each other?
- How will PHARMAC take cost savings and efficiencies into account?
- Will DHBs benefit from savings? If so, how? (A patient advocacy group noted their expectation that any savings would be reinvested so that availability of high quality devices is both enhanced overall and consistent across DHBs.)
- What will happen when a new technology is introduced – how responsive will PHARMAC be?

Working out the costs and savings from initial and ongoing use of a medical device

145. The consultation document asked submitters what should be taken into account when working out the costs and savings from initial and ongoing use of a medical device.

146. Submitters commenting on this question strongly suggested a broad approach should be taken. There must be long term and comparative assessment of the costs and benefits of both the new device and the existing alternative. The assessment should include all disease related events, resource use (hospitalisations, specialist consultations, diagnostic services), quality of life (independence, mobility, self-care, etc) and societal impacts (productivity, community care requirements, etc). Whole of life costs must also be taken into account – this includes the costs associated with revision, removal, replacement and disposal in the event of failure.

147. This approach will require input from clinicians and other staff, for example, information technology, biomedical engineers, infection prevention control and health and safety staff. It was noted that each hospital is likely to differ in their preference for in-house or outsourcing of equipment maintenance (some for reasons of proximity to suppliers).

148. DHB and industry submitters stressed the significant services provided by sponsors that must be factored into assessment. These services include technical support, stock management, supply chain capabilities and efficiencies, education and training. PHARMAC must also be aware that many medical devices are held on consignment in hospitals and payment is made only following their use. In this situation the supplier carries the cost of making available the requisite range of devices and the risk of stock going out of date.

149. Several submitters recommended that PHARMAC must be able to deal with the IT component in many medical devices. Two key results from the increasing trend for complex devices to come with operating and/or integration software are:

- Systems integration – a number of software packages are not developed using standard operating systems, which can mean they require large amounts of IT resource to integrate into hospital systems.
- Cost – most software packages not only include purchase costs but also additional licences, annual support charges, systems support etc. In a Total Cost of Operation model these costs are significant.

150. One DHB group noted that PHARMAC should prefer products that are repairable and recommissionable, have good reliability ratings, and repair/maintenance services easily accessible across New Zealand. This submitter asked that energy efficiency and consumables be factored in, as should the power source components (eg, avoid disposable batteries), responsible disposal and recycling of devices.

151. Similarly, PHARMAC will need to consider the relative merits and cost implications of funding single use disposable versus reusable medical devices – not only the relative technical merits

of the medical device, but also all associated costs related to the environment through disposal or reuse, employment, etc.

152. PHARMAC must also recognise the (unusual) situation where device manufacture must be customised to meet the needs of the patient. It was noted that this service is not available through all device manufacturers and distributors and there must be provision within the negotiating process to recognise the value of such services.

153. An industry submitter asked that PHARMAC include the cost of achieving regulatory approval when ANZTPA starts operating in 2016.

The best sources of information for assessment

154. Submitters considered that a variety of sources of information would be required to carry out assessments. Evidence from various sources may need to be linked 'using a logical and defensible methodology.' These sources included:

- independent evidence based research, trials of new/improved products
- appropriately configured clinical advisory groups
- independent technical panels of respected clinicians and scientists
- published data with a high level of clinical evidence from Statistics New Zealand and the Ministry of Health, including:
    - Diagnosis Related Groups (DRG) cost data
    - the National Minimum Dataset (hospital events)
- information from the sponsor of the product.

155. A clinical group provided an extensive list of sources of environmental and carbon accounting information.[6]

156. Submitters recommended that PHARMAC should continue to work with the national agencies that hold knowledge in this area, and with DHB staff such as clinical product co-ordinators (CPCs), specialist clinical staff, infection control, medical waste, clinical engineering, etc.

157. An industry submitter noted that DHB resource is limited and academic input may be a cost-effective solution – 'however this needs interpretation to sensible commercial realities.'

158. Patient advocacy and DHB submitters asked that consumers be involved in assessment (as noted under point 135 in this paper).

159. PHARMAC was advised to retain specialists who can collect and analyse micro costing at the DHB level for the purposes of assessment, and to provide to suppliers in order to construct economic value cases for consideration by PHARMAC.

160. A submitter to HBL's *Finance, Procurement and Supply Chain* consultation recommended investment in quality price benchmarking information, so that contract negotiations rather

[6] See submission from Ora Taiao NZ Climate & Health Council in collaboration with the Green Hospitals Group Aotearoa New Zealand, Appendix A – Guidelines for sustainable procurement and healthcare.

than standardising products could be the focus of device management. 'Virtual teams' (with 'clinical credentials, fluency in business issues and superior interpersonal skills') should work with DHBs analysing the hospital's business, including margins, historical purchasing trends and existing physician/clinician relationships with vendors.

161. Operational cost modelling must be taken into account and as such data must be able to be collected from product introduction. The lack of common device descriptors and disparate enterprise asset management systems will create challenges for capital based devices.

162. An industry submitter suggested not setting minimum standards of evidence, but allowing evidence from all sources to be considered (not just data from clinical trials). Evaluation should aim to assess the complete body of evidence to determine overall benefits and harms associated with the proposed new device. The assessment methodology and the type of evidence considered should therefore reflect this aim and all of the evidence obtained from a range of study designs (registries, observational trials, adaptive trial design, etc.) should be identified and appropriately weighted in an overall evaluation. The degree of analysis should depend on the actual or potential impact of the health technology.

163. It was noted that in some cases where new technology is being introduced it may be necessary to provide coverage and then collect evidence from real life usage in the clinical setting. Additionally, exceptional circumstances need to take into account different users of items.

164. One submitter outlined a framework for prioritising health technologies based explicitly on value for money. The proposed prioritisation framework involves comparing four main variables for each technology:

- incremental benefits to the population
- incremental total cost to the health system
- quality of evidence
- any additional factors not elsewhere included, such as strategic or legal factors.[7]

165. It was suggested by one industry submitter that PHARMAC's move into device management gives it an opportunity to view the overall healthcare system and avoid a 'silo' approach to healthcare budgets.

Purchasing strategies and contract management

Whether some medical devices are more suited to certain commercial tools

166. The consultation document asked whether some medical devices are more suited to certain commercial tools, and if so, what the attributes of these devices are.

[7] Golan O and Hansen P (2012) Which health technologies should be funded? A prioritization framework based explicitly on value for money. *Israel Journal of Health Policy Research*, 1:44. http://www.ijhpr.org/content/1/1/44

167. Submitters noted that devices vary greatly in their complexity and requirements for maintenance and continuing support. Generally, submitters considered that the more complex a device is, the less suited it is to simplistic purchasing mechanisms. More complex medical devices, such as magnetic imaging scanners, may be more appropriately procured through direct negotiation with suppliers. High volume medical devices with predictable usage patterns and lower levels of service, professional education and post-sales support are more appropriate for tender based procurement. Submitters considered that PHARMAC should employ different assessment tools, determined by the nature and degree of identified risk.

168. Several industry submitters commented on the required characteristics of commercial tools that might be used to achieve better pricing. These submitters supported effective and transparent processes and tools that have procedural fairness. Purchasing strategies and contract management need to account for the total cost of ownership including the direct and indirect benefits of a device. A health professional group also suggested that if the tools used are transparent, equitable and use appropriate consultation, then the tools will work.

169. One industry submitter noted that particular commercial tools may be a competitive advantage for some but there will be smaller companies who find these tools an anti-competitive barrier.

170. Another industry submitter suggested that the application of price per treatment (PPT) models, common in leasing of equipment, need special consideration. PPT models are attractive to DHBs to avoid capital outlay, however they rely on the ability to individualise pricing to a DHB's specific requirements. One overarching model may disadvantage certain DHBs.

171. A DHB and an industry submitter noted that it is important to take into consideration not only price, but the desired outcome from the device –'if patients will not use it, then the desired health result will not be obtained.' Rather than focussing simply on lowest pricing PHARMAC should consider tools which achieve better or the same outcomes more cost effectively.

172. An industry submitter recommended that PHARMAC consult with all stakeholders regarding the specific terms and conditions, stated intent, commercial and clinical applicability and use of the 'certain tools' and seek expert clinical, procurement and industry input regarding the most appropriate 'tools' for specific categories of medical device.

Length of contracts

173. In relation to the length of contracts, an industry association emphasised the need for appropriate contract lengths according to the type of product. Contract terms need to reflect the opportunity for innovative new technology to have access to the market in a timely manner. One industry submitter suggested that supplier agreements should be between 2 and 4 years (including options to extend) to ensure that new technology is accessible in

reasonable time frames, and that the appropriate level of competition and access to markets exists. Further to the length of contracts, other submitters asked:

- Will contracts be long enough to ensure that skills don't have to be re-learnt too often?
- Will contracts be long enough to accommodate to the adjustment in training and the length of time it takes for the training to take effect?

Other questions put to Pharmac

174. A few submitters remarked that clarification of the commercial tools envisaged would help with further comment. Industry and DHB submitters also put a number of questions to PHARMAC:

- How will PHARMAC provide choice relating to how many players are in the market – and also in terms of backup if a supplier fails to deliver?
- Service contracts:
    - Does full management of medical devices include service contracts?
    - How will imposed service contracts be managed?
    - Will there be national agreements for servicing?
    - How will PHARMAC manage services in relation to bundling or splitting services and components of a treatment (e.g. the imaging devices that come with an implant)?
    - Will preferences be taken into consideration, especially with New Zealand companies?
- How will decisions be made to purchase products with no procurement staff at DHBs?
- How will contracts allow for innovation and local practice?
- Pharmaceutical companies work with medical technology companies to deliver companion diagnostics. How will this be managed?

Circumstances in medical devices markets that lend themselves to using confidential rebates rather than transparent pricing

175. The consultation document stated that with medicines there are some market drivers that mean PHARMAC is able to get a better price if it uses confidential rebates. Submitters were asked whether there are circumstances in medical devices markets that would lend themselves to these sorts of arrangements, and what some of the challenges are of rebates compared to transparent pricing.

176. Industry submitters considered that there may be advantages in some circumstances to rebate arrangements. Confidential rebates could be an effective way to partner with suppliers. Also, suppliers may be willing to provide better prices through rebates if volume and market share targets are established and met, and there is an element of risk sharing between supplier and purchaser.

177. One industry submitter stated that a rebate model allows suppliers to eliminate the risk with information sharing around pricing. For example, the reagent pricing model in diagnostics comes from the capital investment required, patient test volumes and other value-added services offered to laboratories. These variables can differ from one laboratory to the next which leads to varying levels of pricing. The inherent risk with this pricing model (and often

with transparent pricing) is information sharing around pricing. This can lead to pricing concerns and attempted negotiations without purchasers fully understanding the underlying details of a given deal.

178. One industry submitter remarked that the challenge in using confidential rebates is the perceived anti-competitive nature of the arrangement.

179. DHB and professional groups described the following difficulties with rebates (with one noting that rebates may be appropriate, but not confidential rebates):

- Relatively small savings at purchase may be greatly exceeded by the longer term costs associated with premature failure of a medical device.
- DHB management may make policies which force the use of inappropriate devices because they want to increase the number of a particular type of implants in order to get the confidential rebate.
- Rebates falter when the bulk of the contract is clinically appropriate for use, but the financial incentive requires minor unapproved (often inappropriate) product(s) to be added to the list and the procurement and supplier staff 'hassle' users to change their current use product.
- If a cheaper item of the same quality is sourced, it is very difficult to change suppliers as it will impact on the rebate.
- A rebate may take a year to realise while price reduction would mean immediate cash benefit – a good tracking system is required for rebate and making sure that the claim is being made, otherwise it will greatly benefit the suppliers (but not DHBs).

180. Additionally, a healthcare provider association noted that money from rebates goes back to the DHB, not specific departments. One DHB submitter suggested that the rebate needs to be divided fairly between the departments who have purchased the products. However, this is difficult as not all departments will have purchased exactly the same products in exactly the same quantity. This submitter asked how the rebates would be managed by PHARMAC. Will they go to each DHB or into a pool of money?

181. Suggestions made by DHB submitters included:

- Negotiating better prices for some large volume single use devices (which have no enduring impact on the quality of health and do not require continuing support, e.g. simple dressings) through linking other products provided by the same manufacturer or distributor.
- Making a confidential price schedule available to DHBs, with appropriate price breaks.

182. Noting the desire to have a wide choice of equipment available to select what is best for patients – one DHB submitter suggested that panel agreements have worked well in the past at DHBs, where a contract or 'maximum price' is set by the framework contract, with the individual agencies free to negotiate additional discounts if willing to commit to preferential status or volumes. These arrangements have been effective because they allow clinicians to make choices that will bring additional savings benefits. This submitter noted that if such a choice is not possible, the contract maximum price is still an attractive 'plan b' option.

183. It was suggested by a professional group that open pricing done in a timely manner would be best for both the industry and clinicians as it allows open competition and transparency around device choice. Similarly, an industry submitter considered that an attempt to be less than transparent with pricing or rebate structures will reduce trust on both sides of the negotiating table.

How medical devices contracts are managed now in public hospitals

184. The consultation document asked submitters to comment on what they liked about the way medical devices contracts are managed now in public hospitals, and what improvements they would like to see.

What submitters like about how contracts are managed

185. Compared to industry submitters, DHB and other clinical submitters made slightly more favourable remarks about the way medical devices contracts are managed now in public hospitals.

186. These favourable comments related to the ability to purchase medical devices on direct clinician request. This was considered to strongly support good decision-making – where requests are based on sound clinical evidence.

187. Other favourable characteristics of the current process that DHB and professional groups cited were:

- the current level of engagement and communication
- relationship development and trust
- multidisciplinary involvement
- visibility and ongoing review of the current system
- clear processes and transparency with suppliers
- evaluation involving price and non-price attributes
- a robust process overall.

188. Some of these same features were also commented on favourably by industry submitters:

- good relationships with current procurement managers who provide sufficient information to assist with establishing a fair price for all parties.
- honest and respectful discussions with an appreciation of both parties' expectations and business models, while focusing on a win-win solution
- straight forward and transparent process
- a free and openly competitive market
- ability for both parties to negotiate terms suitable to that DHB and that supplier
- the consideration of many factors in selection, trialling, negotiation and subsequent contract execution and management.

Improvements to how contracts are managed

189. A professional group suggested there would be benefits from more careful evaluation of medical devices at a national level to better inform purchasing decisions. Improved evaluation combined with a national purchasing strategy would probably mean competitive prices could

be negotiated where larger volumes are sought from selected providers. This submitter suggested PHARMAC consider developing national governance and audit structures for DHBs or regional groups to use in managing medical device contracting – without taking direct control of the process.

190. One healthcare provider association suggested having (and monitoring) strict requirements relating to DHBs purchasing off contract (which erodes economies of scale and is unfair to the suppliers). In the case of panel contracts, this submitter noted that there is danger if all DHBs choose one of the panel and others do not get some business. This creates a single supply market, which is a huge clinical risk for device management in DHBs. An exceptions process for non-compliance should be in place, based on sound clinical input.

191. A patient advocacy submitter considered that a centralised ordering and distribution system would be preferable where products can be ordered in the frequency and volumes suitable for each individual patient. In relevant cases this could include an allowance where the patient is encouraged to keep a buffer in case of an unpredictable supply problem.

192. Industry submitters also suggested a different range of improvements:

- improve the consistency of processes for procurement related to new contracts
- improve the consistency of the contract management relationship (e.g. with shared contracts across several DHBs, a supplier may be required to process changes in products or variations for each DHB)
- account for purchasing and contractual arrangements for support from the company to train clinical specialists
- standardise basic terms and conditions but retain the ability to customise agreements for specific DHB requirements
- improve efficiency to finalise the contract terms and conditions and to get final contract sign-off so that it is in place prior to implementation and commissioning
- put in place longer contract terms and an element of risk-sharing where appropriate
- adhere to the principles of government procurement in New Zealand.

193. One industry submitter also suggested public contracts in the private sector – private entities should have access to the PHARMAC Schedule or National Catalogue for medical devices.

Questions

194. Submitters across interest groups had questions for PHARMAC about how contracts would be managed in future:

- How will PHARMAC manage the contracts already in place?
    - Will decisions be incorporated under one umbrella between PHARMAC and healthAlliance?
    - Is there a pathway to vary contracts?
- In relation to the DHB National Catalogue requiring the inclusion of negotiated contract assay reagent pricing:
    - How will HBL/PHARMAC take into account the large capital investment made by suppliers to place capital equipment in laboratories free of charge?

- How will HBL/PHARMAC take into account the additional value-added investments to contract deals that may extend across different laboratory departments?
- Is HBL still planning to use Wairarapa, Hutt and Capital Coast DHBs as the pilot sites for the DHB National Catalogue implementation?
- It is correct that HBL/PHARMAC is planning to have a central distributor and inventory management through EBOS?
- What assurance can PHARMAC give suppliers that there will be appropriate risk sharing for the placement of core lab instruments?

- In order to make accurate price comparisons between suppliers and share risk, will PHARMAC's model move towards DHBs purchasing instruments and standardising service agreements?
- Will suppliers that have broad product portfolios spanning multiple areas have an advantage negotiating with PHARMAC through their ability to provide a combination offering affecting different healthcare sectors?
- Will PHARMAC fund cost of change?

Integrating new devices into hospital processes

Strengths and weaknesses of how a medical device gets approved for use in a public hospital now

195. The consultation document asked submitters about the strengths and weaknesses of how a medical device gets approved for use in a public hospital now, and what is done to ensure a smooth implementation.

Strengths

196. Across interest groups, submitters considered that the strengths of the current process are the (interrelated) recognition of clinical autonomy, minimally restrictive pathways for approval and purchase, and the short timelines. It was noted that the acceptance of international standards ensures a fast route to market – which may not be the case in the planned ANZTPA processes.

197. Processes are generally well defined within DHBs or groups of DHBs and suppliers generally work with DHB stakeholders transparently. In the current process suppliers have access to clinicians to discuss new devices to determine whether there is a clinical need or clinical support for a new device.

198. Submitters across interest groups also commented favourably on the role of clinical product co-ordinators (CPCs) and the level of engagement and communication achieved. The current process was considered to provide a balance of clinical and economic information allowing a DHB to make informed decisions. An industry submitter noted that implementation processes are greatly improved when the DHB (or healthAlliance) has a dedicated and trained project manager involved in the implementation.

199. An industry submitter also noted that with implanted devices, the current post implantation partnership with clinical teams is essential to device performance.

Weaknesses

200. The major weakness noted across interest groups was the variability in the process between or even within DHBs. In some DHBs processes may be ad hoc.

201. There are too few clinical product co-ordinators. This may lead to delayed access to beneficial medical technologies.

202. A professional group considered that the lack of close scrutiny of all information available before a decision is made to purchase is a major weakness of the current process. For example, replacement costs of major items are seldom appropriately factored into annual DHB budget development.

Improvements

203. Industry and DHB submitters variously suggested a wide range of improvements to the device approval process:

- introducing a standardised process
- recognising rather than duplicating robust international quality assurance processes
- including the costs of ongoing education in contracts to ensure the quality of the implementation
- using supplier representatives to ensure the device is being used as intended – and taking account of the costs of this
- greater access of suppliers to clinicians to ensure the proper services can be provided
- improving timelines
- using dedicated and trained project managers in implementation

204. In relation to devices changing, an industry submitter asked that the current stocks held in New Zealand be considered, as well as the investment that the supplier has made to fulfil their contractual obligations.

205. A healthcare provider association suggested that DHBs should be visited to ensure staff understand the change. Any issues relating to other equipment should be dealt with prior to the implementation taking place. Any new protocols or policies must have been written, approved and communicated to staff before introduction if the new device affects these.

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

Clarity

206. Most submitters responding to this question stated that PHARMAC's role was to provide clarity around its intentions, and the processes that would be used.

Alignment with other parties

207. In particular, submitters asked that PHARMAC provide clarity around who will be doing what, to ensure processes (eg, used by Medsafe, HBL, healthAlliance and the Ministry of Business, Innovation and Employment) are not duplicated.

208. Several submitters considered the current interface between HBL and PHARMAC to be unclear; and questioned how the work of HBL will intersect with PHARMAC's work.

209. Additionally, a few submitters suggested that organisations such as Enable NZ; Access Able, and ACC need to be involved in the listing process.

Communication & engagement

210. Most submitters also commented on the need for inclusive stakeholder engagement by PHARMAC. For example, DHB staff want to know how and when they can have input. Processes used should be transparent, and involve the relevant people at the appropriate time. Communication and sound relationships were considered essential to ensuring the Schedule is current and users are aware of it.

211. It was suggested at one regional meeting that PHARMAC provide 'neutral ground' for concerns to be discussed between suppliers and clinicians – noting that there must be consideration of the resources required by DHBs to deal with processes on a national level.

212. It was suggested that there should be simple and effective IT-based communications between PHARMAC and DHBs, instead of waiting until all DHB clinicians and PHARMAC procurement staff are able to attend meetings.

213. Several DHB submitters remarked on the need for PHARMAC to be clear about who to contact and where to find them – as procurement positions that used to lie within a DHB may not be there in future. One submitter suggested that PHARMAC employ a clinical engagement person at each DHB during the implementation period of a device and its services.

214. PHARMAC also needs to communicate with stakeholders when decisions have been made.

Contract management

215. Submitters considered PHARMAC had a role in contract management. This included:
    - providing suppliers with strong estimates of quantity requirements to ensure sustainability of supply
    - monitoring contract performance
    - implementing a process to ensure committed contracted volumes are adhered to by DHBs.

Implementation

216. In device implementation, submitters considered PHARMAC had a role in ensuring:
    - all clinicians and healthcare providers are fully trained with new devices
    - that there has been appropriate transition to the new devices to ensure clinical outcomes are not compromised

- that there is a complaints process to manage current procurement if no longer suitable for clinical need.

New technology

217. Several submitters suggested that PHARMAC has a role in reviewing Schedule listings when new technology becomes available. An industry submitter suggested that PHARMAC have a point of contact that can give advice on any new technology that comes to the market. Submitters also wanted PHARMAC to ensure the process used can deal with new technology in a timely manner. PHARMAC could also facilitate assessment groups (clinicians, procurement specialists and hospital managers) for potential suppliers.

Managing risk

218. Several submitters considered that PHARMAC needs to be able to adjust rapidly to any mistakes made in funding decisions. PHARMAC also has a role in managing risk in selection criteria for new equipment. For example, PHARMAC could develop a feedback mechanism to capture the success of a device, to allow for monitoring and adaptation as the technology evolves.

Other roles

219. One industry submitter suggested that the most constructive role PHARMAC can provide is clarity relating to the availability of funds for the listed device.

220. A professional group considered that PHARMAC's role is to negotiate the price and whether a full or partial service contract is required.

221. A healthcare provider association submitted that PHARMAC's role is to put the appropriate systems and processes in place to ensure that all product decisions made are characterised by thoroughness, appropriateness and relevance. This includes researching the product (e.g. how much clinical usage has there been since it was released), and checking that all the mandatory paperwork is available, and that it has been adequately assessed by New Zealand clinicians in a reflective range of DHBs.

222. A DHB group suggested that PHARMAC should also ensure device procurement was environmentally sustainable.

223. A professional group submitted that PHARMAC could have an important role in providing final approval of any medical device used in hospitals. (This would occur after the device's clinical performance and utility have been previously considered by a technical review panel.) This would avoid repetition at each DHB (or even within DHBs), and add strength through the engagement of colleagues in this decision-making process.

Questions

224. Submitters across interest groups had questions about PHARMAC's role in device management:

- How will the process be applied to all the different devices?
- How is PHARMAC approaching interim procurement?
- How are panel and national contracts being dealt with?
- How is PHARMAC intending to deal with lobbying and conflicts of interest?
- Will the procurement team within PHARMAC be leveraging on existing resources and how will that look in terms of a national view?
- How will the local evaluation of products be managed when people are being disestablished?
    - Will there be any local expertise available for rural locations?
    - How will DHBs continue to be able to be responsive to the regions?
- When a product gives the same health outcomes but is significantly cheaper, will the process be the same as switching to generic brands in pharmaceuticals?
- What does PHARMAC think about Closer Economic Relations between New Zealand and Australia (a legislative requirement)?

Other comments

Related to medical devices

225. A number of points outside of the consultation questions were raised in submissions and other feedback.

HBL/hA Finance, Procurement and Supply Chain programme

226. There were comments from submitters to the HBL *Finance, Procurement and Supply Chain* business case implementation consultation that related to PHARMAC's organisational structure during the period of interim device procurement. These submitters 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 considers its organisational design relating to device management.

Having separate budgets

227. Several submitters requested that a separate budget be established for medical devices and kept separate from pharmaceuticals as 'there was a risk that hospitals could be overwhelmed by pharmaceutical spending imperatives.'

Particular products

228. In relation to wound care consumables for epidermolysis bullosa patients, a submitter suggested that PHARMAC consider keeping the Canterbury DHB stores department open and for this to be a main hub for the supply of medical consumables.

229. One submitter asked for an improvement in the range of devices for obese people in hospital.

Private versus publicly funded medical devices

230. Several submitters queried whether PHARMAC would be looking at purchasing in both the private and public sector, and how this would fit in with ACC as a public service. Submitters noted there may be differences in the availability of medical devices in the privately and publicly funded sectors.

The process

231. Many submitters, attendees at meetings and contributors to the HBL consultation had questions about PHARMAC's role and intended processes with device management. These questions ranged from the elemental 'Why are PHARMAC, HBL/ healthAlliance taking over the management of medical devices?' to those addressing details such as what steps PHARMAC was taking to reduce carbon emissions. Many of these submitters were unclear about PHARMAC's role and processes. Some of them considered that the process was taking too long, while others thought the timeframes were unrealistic. One of these submitters considered there is a massive risk with PHARMAC taking over medical devices, 'particularly in light of the incompleteness of the proposed structure, and inability of PHARMAC to definitively define the term 'medical devices', or the proposed system for contracting.'

Global standards for product identification

232. An industry submitter described the value of using GS1 product identification standards in terms of business value and improvements in patient safety and quality of care.

The consultation

233. In relation to the current consultation, one submitter noted that the questions posed in the consultation document were not always clear and asked that PHARMAC accept feedback in good faith.

Other

234. Several submitters also made other points relating to PHARMAC's business more generally. These comments related to:

- the absence of an overall vision for the sector
- PHARMAC's responsibility to inform Maori of the best use of quality products from the health system
- PHARMAC's current decision criteria being inadequate for determining whether access to life enhancing and life saving devices is warranted in cases of rare conditions.

LIST OF SUBMITTERS

Submissions

Age Concern
Aotearoa College of Diabetes Nurses, NZNO
Auckland Women's Health Council
Bates, Raueka
Baxter Healthcare
Biotronik
Bay of Plenty DHB
Boston Scientific
Cassidy, Sharon
du Toit, Stephen
Dystrophic Epidermolysis Bullosa Research Association NZ
Enable NZ
Federation of Women's Health Councils
Forrester, Mike
FUJIFILM SonoSite Australasia Pty Ltd
Gaston, Renee
GS1 New Zealand
Hansen, Paul
Health Funds Association of New Zealand
Infection Prevention & Control Nurses College, NZNO
Intermed
Johnson & Johnson (New Zealand) Ltd
Kennedy, Dianne
Korte, Charlotte
Mane, Aron
Medtronic Australasia Pty Ltd
Milnes, Karina
Montgomery, Renee & Blackler, Tony
Mossman, Stuart
Medical Technology Association of New Zealand
Muscular Dystrophy Association
National Health IT Board
Neonatal College of Aotearoa
New Zealand Medical Association
New Zealand National Committee of the Australian & New Zealand College of Anaesthetists
New Zealand Society of Anaesthetists
New Zealand Orthopaedic Association
Nichol, Donna
New Zealand District Health Board Psychology Leadership Council
New Zealand Nurses Organisation (NZNO)
Ong, Karen
OraTaiao in collaboration with the Green Hospitals Group Aotearoa New Zealand
Product Evaluation Health NZ
Roche Diagnostics New Zealand Ltd
Royal Australasian College of Surgeons
Stryker New Zealand
The Royal Australasian College of Physicians
Thornley, Rosser
Wideman, Nonie
Women's Health Action

Meeting notes

Medical Technology Association of New Zealand
Cardiac Society of Australia and New Zealand

Notes from regional meetings

Auckland
Manukau
Hamilton
Palmerston North
Wellington
Canterbury
Dunedin
Invercargill

Report

Deloitte (2013) *Hospital medical device decision criteria. A whitepaper funded by the Medical Technology Association of New Zealand*.

Other

PHARMAC-related responses to HBL's Finance, Procurement and Supply Chain business case implementation Consultation 2013

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